As confidentially submitted to the Securities and Exchange Commission on May 21, 2021 as Amendment No. 2 to the draft registration statement submitted on April 19, 2021. This Amendment No. 2 to the draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains confidential.

Registration No. 333–

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

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Monte Rosa Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2836	84-3766197
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

Monte Rosa Therapeutics, Inc.
645 Summer Street, Suite 102
Boston, MA 02210
(617) 949-2643
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Markus Warmuth, M.D.
President and Chief Executive Officer
Monte Rosa Therapeutics, Inc.
645 Summer Street, Suite 102
Boston, MA 02210
(617) 949-2643
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Robert E. Puopolo
Marishka DeToy
Goodwin Procter LLP
100 Northern Avenue
Boston, Massachusetts 02210
(617) 570-1000

Nathan Ajiashvili
Alison Haggerty
Latham & Watkins LLP
885 Third Avenue
New York, New York 10022
(212) 906-1200

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Securities Exchange Act of 1934.

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)	Amount of registration fee
Common stock, $0.0001 par value per share	$	$

(1) Estimated solely for the purpose of computing the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the aggregate offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant files a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the Securities and Exchange Commission declares our registration statement effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated , 2021

Preliminary prospectus

Shares

Monte Rosa THERAPEUTICS

Common stock

This is an initial public offering of shares of common stock by Monte Rosa Therapeutics, Inc. We are offering shares of common stock. We expect that the initial public offering price will be between $ and $ per share.

Prior to this offering, there has been no public market for our shares. We intend to apply to list our common stock on The Nasdaq Global Market under the symbol "GLUE."

We are an "emerging growth company" and a "smaller reporting 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.

	Per share	Total
Initial public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to Monte Rosa Therapeutics, Inc.	$	$

(1) See "Underwriting" beginning on page 197 of this prospectus for additional information regarding underwriting compensation.

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

Investing in our common stock involves a high degree of risk. Before buying any shares, you should read carefully 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 has 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.

The underwriters expect to deliver the shares of common stock to the purchasers on or about , 2021.

J.P. Morgan **Cowen** **Piper Sandler** **Guggenheim Securities**

, 2021

Table of contents

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representation other than those contained in this prospectus, any amendment or supplement to this prospectus or any free writing prospectuses prepared by or on behalf of us or to which we have referred 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. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any amendment or supplement to this prospectus or any applicable free writing prospectus is current only as of its date, regardless of its time of delivery 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.

Market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. 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. We are responsible for all of the disclosure contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled “Risk factors” and elsewhere in this prospectus. Some data are also based on our good faith estimates.

We have applied for various trademarks that we use in connection with the operation of our business. This prospectus may also contain trademarks, service marks and trade names of third parties, which are the property of their respective owners. Our use or display of third parties’ trademarks, service marks, trade names or products in this prospectus is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks and trade names referred to in this prospectus may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the right of the applicable owner of these trademarks, service marks and trade names.

Through and including , 2021 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Prospectus summary

This summary highlights information contained in greater detail elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto included elsewhere in this prospectus. You should also consider, among other things, the information set forth under the sections entitled "Risk factors," "Special note regarding forward-looking statements," and "Management's discussion and analysis of financial condition and results of operations," in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, we use the terms "Monte Rosa," the "Company," "we," "us," "our," and similar designations in this prospectus to refer to Monte Rosa Therapeutics, Inc. and, where appropriate, our subsidiaries.

Overview

We are a biopharmaceutical company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. We have developed a proprietary protein degradation platform, called QuEEN, that enables us to rapidly identify protein targets and molecular glue degrader, or MGD, product candidates that are designed to eliminate therapeutically-relevant proteins in a highly selective manner. We believe our small molecule MGDs may give us significant advantages over existing therapeutic modalities, including other protein degradation approaches, by allowing us to target proteins that have been considered undruggable or inadequately drugged. We focus on therapeutic targets backed by strong biological and genetic rationale with the goal of discovering and developing novel precision medicines.

We have utilized our Quantitative and Engineered Elimination of Neosubstrates, or QuEEN, platform to design novel MGDs focused on delivering therapies to targets that have been considered undruggable or inadequately drugged in well-characterized biological pathways across clinical indications in oncology and non-oncology, including immunology, inflammation, neurological and genetic diseases. Our lead program is a series of potent, selective and orally bioavailable GSPT1-directed MGD molecules, one of which we plan to evaluate in molecularly-defined subsets of Myc-driven cancers. We expect to select a development candidate in , and submit an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or the FDA, in . Beyond our lead program, we have a number of discovery programs in our pipeline and intend to nominate at least two for lead optimization in 2021.

Our approach

A new and promising approach to modulating protein function using small molecules in cells was recently elucidated: protein degradation. Protein degradation is one of the body's natural processes by which proteins are eliminated from human cells through the attachment of a molecular tag, called ubiquitin, to a protein by any of the approximately 600 human E3 ligases, marking the protein for degradation by the proteasome in the cell. Protein degradation can be induced by small molecule-based degraders, including both proteolysis targeting chimeras, or PROTACs, and MGDs. It was found that lenalidomide, now an approved best-selling drug in multiple indications with 2020 global sales of $12.1 billion, functioned as a small molecule-based degrader, or as an MGD more specifically. In one of these indications, multiple myeloma, lenalidomide acts by causing two disease-driving transcription factors, IKZF1 and IKZF3, that lack druggable pockets, to bind to cereblon, an E3 ligase protein, resulting in their degradation.

Our approach to protein degradation involves rationally designing and developing small molecule-based MGDs to precisely edit the human proteome. Molecular glues are small molecules that induce protein-protein interactions, but not all known and characterized molecular glues lead to degradation of proteins. Lenalidomide and pomalidomide are two approved drugs that were subsequently found to function as MGDs by causing the degradation of therapeutically-relevant proteins through the induced interaction with a component of the E3 ligase cereblon. They provide clinical validation of the MGD approach.

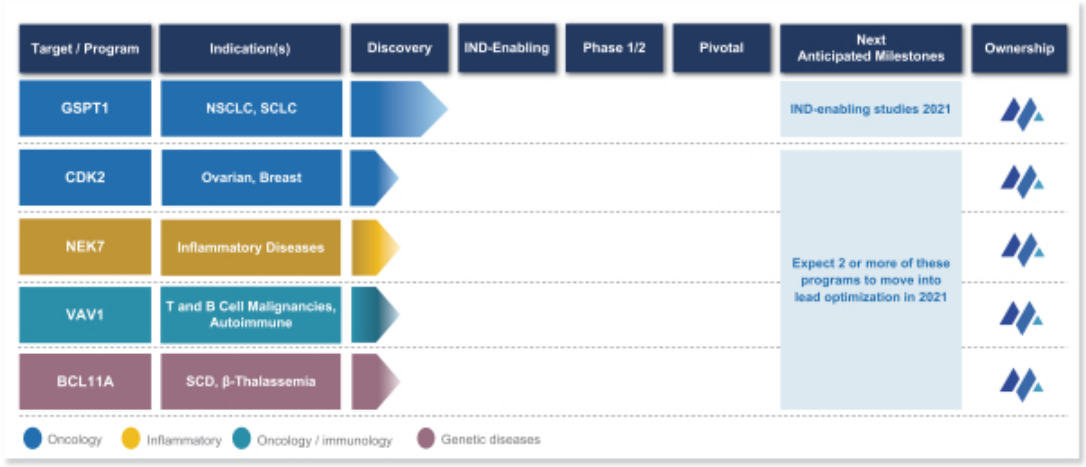
While the mechanism of action for these two drugs was discovered years after their introduction into the clinic, we are leveraging our platform to rationally and efficiently design MGDs. Our MGDs are drug-like, non-heterobifunctional small molecules that bring together a therapeutically-relevant target protein and an E3 ligase, leading to degradation of the target protein. Non-heterobifunctional molecules are those that do not contain two different protein binding domains joined together with a chemical linker. We believe our product candidates have the potential to address targets that have been considered undruggable or inadequately drugged, while possessing attractive pharmaceutical properties.

Our proprietary QuEEN platform enables us to rationally design and develop small molecule MGDs that lead to the destruction of a therapeutically-relevant target protein by facilitating its tagging for removal. Our MGDs are drug-like small molecules that bring together a therapeutically-relevant target protein and an E3 ligase, leading to degradation of the target protein via the intracellular protein degradation system, called the proteasome. Our MGDs are non-heterobifunctional, in contrast to PROTACs. Central to our QuEEN platform is a detailed understanding of the molecular interactions promoted by our small molecule MGDs between E3 ligases and structural features, or degrons, on the surface of therapeutically-relevant proteins which have been considered undruggable or inadequately drugged. Key components of our QuEEN platform are:

- ***Degron encyclopedia***: A growing catalogue of target proteins identified through our proprietary artificial intelligence, or AI, approach that enables us to identify structural features on protein surfaces that can serve as degrons for highly validated and therapeutically-relevant, but otherwise undruggable or inadequately drugged, proteins
- ***Proprietary MGD library***: A diverse and continuously growing chemical library of drug-like MGDs that are rationally designed based on our expertise in molecular glue anatomy
- ***Glue-omics toolbox***: A tailored suite of biochemical, structural biology, cellular, proteomics and *in silico* screening tools that enable the discovery and optimization of MGD product candidates that efficiently recruit neosubstrates to E3 ligases utilizing degrons discovered through our AI approach

Our pipeline

Our internal discovery programs are focused on delivering precision medicine-based therapies to targets that have been considered undruggable or inadequately drugged in well-characterized biological pathways across clinical indications in oncology, inflammation, immunology and genetic diseases with high unmet needs. We currently retain worldwide rights to the programs shown in the chart below.



We are developing an oral MGD that targets GSPT1, a translational termination factor and degron-containing protein, for the treatment of cancers overexpressing one of the Myc family genes (c-Myc, N-Myc and L-Myc). The Myc transcription factors are some of the most frequently mutated, translocated and overexpressed oncogenes in human cancers. For example, around 10% of non-small cell lung cancer, or NSCLC, overexpress N-Myc and over 50% of small cell lung cancer, or SCLC, overexpress L-Myc. Myc-driven cancer cells are highly addicted to protein translation. Because of the key role of GSPT1 in protein synthesis, selective GSPT1 degradation by our MGD in these cells leads to cell death. In multiple Myc-driven preclinical models, we have shown that our lead GSPT1-directed MGD molecules are potent, selective, and well-tolerated, inducing tumor regression after oral administration. We anticipate initiating IND-enabling studies in and expect to submit an IND to the FDA in .

In addition to our oral GSPT1-directed MGD program, we are also advancing discovery programs identified with our QuEEN platform against multiple additional degron-containing targets that are highly validated and therapeutically-relevant, but otherwise considered undruggable or inadequately drugged. We have been able to identify selective MGD molecules for CDK2, an oncology target whose activation is associated with poor prognoses in cancers such as ovarian, uterine, and breast cancer. We have also identified potential targets outside of oncology as exemplified by our NEK7 program. NEK7 is an activator of the NLRP3 inflammasome, a central regulator of cellular inflammatory responses to pathogens, damage and stress. Aberrant NLRP3 inflammasome activation is implicated in the pathogenesis of multiple autoimmune diseases, including Crohn's disease, neurodegenerative diseases, diabetes and liver disease. We have identified MGD molecules from our library that selectively degrade NEK7 in cells. Similarly, we have identified MGD molecules for VAV1, a target protein in autoimmune disease, and BCL11A, a therapeutically-relevant protein in hemoglobinopathies. We expect two or more of these discovery programs to move into lead optimization in 2021.

We believe we have identified a large number of therapeutically-relevant targets that are amenable to degradation by the MGDs discovered through our QuEEN platform. Applying our unique structural biology and

computational tools, we have built and continue to grow an encyclopedia of over 1500 degron-containing proteins, many of which have robust links to human diseases. The majority of these proteins have been considered undruggable because they lack suitable small molecule binding pockets, which our MGDs do not require. We are systematically validating and rapidly advancing the most compelling of these targets while prioritizing those with a strong established therapeutic rationale for inclusion in our pipeline.

Our team

We are led by an experienced team of drug discovery and development experts with decades of experience in targeted protein degradation, molecular glues, chemistry, structural biology, data science, disease biology, translational medicine, and clinical development. We were founded by Professor Raj Chopra and Professor Ian Collins of The Institute for Cancer Research, UK, pioneers in the field of MGDs, and Versant Ventures. Since our inception, we have raised over $220 million in equity capital from leading investors including Aisling Capital, Amzak Health, Avoro Capital Advisors, funds and accounts managed by BlackRock, Cambridge Asset Management, Casdin Capital, Cormorant Asset Management, Fidelity Management & Research Company LLC, GV, HBM Healthcare Investments, New Enterprise Associates, funds and accounts advised by RTW Investments, LP, Sixty Degree Capital, funds and accounts advised by T. Rowe Price Associates, Inc., and Versant Ventures.

Our strategy

Our mission is to reshape disease treatment paradigms by discovering and developing a precision medicine-based portfolio of novel small molecule MGDs that selectively eliminate therapeutically-relevant proteins in a broad range of indications with significant unmet medical need. We believe the product candidates identified through our proprietary QuEEN platform can provide distinct advantages over other modalities to address targets that have been considered undruggable or inadequately drugged. In order to achieve our mission, key elements of our strategy include:

- Continue to advance our GSPT1-directed MGD program into and through clinical development and seek regulatory approval
- Further expand the capabilities of our QuEEN platform to unlock the full therapeutic potential of MGDs
- Develop a pipeline of rationally designed MGDs to transform the treatment of diseases in multiple therapeutic areas
- Expand and protect our proprietary know-how and intellectual property
- Consider strategic collaborations in select therapeutic areas to fully realize the potential of our QuEEN platform

Risks associated with our business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled “Risk factors” in this prospectus. These risks include, among others:

- We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from drug sales, and may never become profitable

- We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future
- We are very early in our development efforts. All of our programs are still in the preclinical stages of drug discovery. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed
- Our approach to the discovery and development of product candidates based on our QuEEN platform is novel, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any products
- We may not be successful in our efforts to identify or discover additional product candidates or 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
- Even if we receive marketing authorization for our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates
- If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market
- We own patent applications related to our QuEEN platform and our GSPT1 program, including GSPT1-directed MGDs, biomarkers related to these compounds, and methods of reading through nonsense mutations. We currently do not own any issued patents. Further, patent prosecution related to our pending patent applications is in the early stages and, as such, no patent examiner has yet fully scrutinized the merits of any of our pending patent applications
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel
- Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses in our internal control over financial reporting, it could have an adverse effect on our company
- Our executive officers, directors, principal stockholders and their affiliates will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control. In addition, six of our directors, including our chief executive officer, are affiliated with our principal stockholders

Corporate information

We were incorporated under the laws of the State of Delaware in November 2019 under the name Monte Rosa Therapeutics, Inc. Our principal executive offices are located at 645 Summer Street, Suite 102, Boston, MA 02210, and our telephone number is (617) 949-2643.

Prior to April 2020, we operated exclusively through Monte Rosa Therapeutics AG, a company incorporated under the laws of Switzerland in April 2018. In April 2020 and September 2020, Monte Rosa Therapeutics, Inc. entered into two separate Contribution and Exchange Agreements with the shareholders of record of Monte Rosa Therapeutics AG, whereby all such shareholders contributed, and Monte Rosa Therapeutics, Inc. acquired, all of such shareholders' right, title and interest in and to their shares of Monte Rosa Therapeutics AG, and, in consideration therefor, such shareholders received shares of the capital stock of Monte Rosa Therapeutics, Inc. As a result of the contribution and exchange transactions, Monte Rosa Therapeutics AG became a wholly-owned subsidiary of Monte Rosa Therapeutics, Inc., and we continued operations through, and under the name, Monte Rosa Therapeutics, Inc.

We have one additional subsidiary: Monte Rosa Therapeutics Securities Corp., formed in November 2020 under the laws of the Commonwealth of Massachusetts.

Our website address is https://www.monterosatx.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of being an emerging growth company and a smaller reporting company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

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

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or

(iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock.

We are also a “smaller reporting company,” meaning that the market value of our shares held by nonaffiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our shares held by nonaffiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

The offering

Shares of common stock offered by us	shares.
Shares of our common stock to be outstanding after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares	We have granted the underwriters a 30-day option to purchase up to additional shares of our common stock at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Use of proceeds	We estimate that the net proceeds to us from the sale of shares of our common stock in this offering will be approximately $ million, or $ million if the underwriters exercise their option to purchase additional shares in full, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents to fund the continued development of our discovery programs and for working capital and other general corporate purposes. See "Use of proceeds."
Proposed Nasdaq Global Market symbol	"GLUE"
Risk factors	Investment in our common stock involves substantial risks. You should read this prospectus carefully, including the section entitled "Risk factors" and the financial statements and the related notes to those statements included in this prospectus, before investing in our common stock.

The number of shares of our common stock outstanding after this offering is based on 6,079,905 shares of our common stock outstanding as of March 31, 2021, which gives effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 109,686,035 shares of our common stock upon the completion of this offering, and excludes:

- 6,464,649 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2021, with a weighted-average exercise price of $0.57 per share under our 2020 Stock Option and Grant Plan;
- 9,470,232 shares of our common stock issuable upon the exercise of stock options granted after March 31, 2021, with a weighted-average exercise price of $1.76 per share under our 2020 Stock Option and Grant Plan; and

- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of (i) shares of common stock reserved for future issuance under our 2020 Stock Option and Grant Plan as of March 31, 2021, (ii) shares of common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, which will become effective on the date immediately prior to the date of this prospectus, and (iii) shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, which will become effective on the date immediately prior to the date of this prospectus.

Except as otherwise noted, all information in this prospectus:

- gives effect to a 1-for- reverse stock split of our common stock effected on ;
- assumes no exercise of the underwriters' option to purchase up to additional shares of common stock in this offering;
- assumes no exercise of the outstanding options described above; and
- assumes the filing of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, which will occur upon the closing of this offering.

Summary financial information

The following tables present the summary financial information for our business. We derived the summary combined and consolidated statements of operations information for the years ended December 31, 2020 and 2019 from our audited combined and consolidated financial statements appearing elsewhere in this prospectus. We derived the summary combined and consolidated statements of operations information for the three months ended March 31, 2021 and 2020 and the summary combined and consolidated balance sheet data as of March 31, 2021 from our unaudited condensed combined and consolidated financial statements and related notes included elsewhere in this prospectus The following summary financial information should be read with "Selected financial Information," "Management's discussion and analysis of financial condition and results of operations" and our combined and consolidated financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in any future period and our interim results are not necessarily indicative of the results that may be expected for the full fiscal year. The summary financial information included in this section are not intended to replace the combined and consolidated financial statements and are qualified in their entirety by the combined and consolidated financial statements and related notes included elsewhere in this prospectus.

	Three months ended March 31,		Year ended December 31,	
(in thousands, except share and per share data)	**2021**	**2020**	**2020**	**2019**
Combined and Consolidated Statements of Operations Information:				
Operating expenses:				
Research and development	$ 9,273	$ 3,815	$ 24,005	$ 7,350
General and administrative	2,231	478	4,005	644
Total operating expenses	11,504	4,293	28,010	7,994
Loss from operations	(11,504)	(4,293)	(28,010)	(7,994)
Other income (expense):				
Interest income (expense), net	6	(3)	9	(1)
Foreign currency exchange loss, net	182	(6)	(198)	(21)
Changes in fair value of preferred stock tranche obligations, net	(960)	—	(7,680)	276
Total other (expense) income	(772)	(9)	(7,869)	254
Net loss	$ (12,276)	$ (4,302)	$ (35,879)	$ (7,740)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (2.03)	$ (0.86)	$ (6.70)	$ (1.55)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted(1)	6,034,427	5,000,000	5,355,459	5,000,000
Pro forma net loss per common share—basic and diluted(1)	$ (0.16)		$ (0.91)	
Weighted-average number of shares used in computing pro forma net loss per common share—basic and diluted(1)	76,745,329		39,345,241	

(1) See Note 13 to our combined and consolidated financial statements for the years ended December 31, 2020 and 2019 and Note 9 to our unaudited condensed combined and consolidated financial statements for the three months ended March 31, 2021 and 2020 appearing elsewhere in this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders. The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 and the three months ended March 31, 2021 have been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into common stock as if the proposed initial public offering had occurred on the later of the beginning of each period or the issuance date of the convertible preferred stock.

	As of March 31, 2021		
(in thousands)	**Actual**	**Pro forma(1)**	**Pro forma as adjusted(2)(3)**
Combined and Consolidated Balance Sheet Information:			
Cash and cash equivalents	$168,436	$ 168,436	$
Total assets	180,603	180,603	
Working capital(4)	162,616	162,616	
Total liabilities	10,047	10,047	
Convertible preferred stock	231,172	—	
Total stockholders' (deficit) equity	(60,616)	170,556	

(1) The pro forma balance sheet data give effect to the automatic conversion of all outstanding shares of our convertible preferred stock as of March 31, 2021 into an aggregate of 109,686,035 shares of common stock upon the closing of this offering.

(2) The pro forma as adjusted balance sheet data give effect to (i) the pro forma adjustments above described in footnote (1) and (ii) the receipt of $ million in estimated net proceeds from the sale of shares of common stock in this offering, at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses.

(3) Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, total assets, working capital and total stockholders' equity (deficit) by approximately $ million, assuming that the number of shares offered, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, total assets, working capital and total stockholders' equity (deficit) by approximately $ million, assuming the assumed initial public offering price per share as set forth on the cover of this prospectus remains the same and after deducting estimated underwriting discounts and commissions. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

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

Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, as well as the other information in this prospectus, including our combined and consolidated financial statements and related notes appearing elsewhere in this prospectus and the sections of this prospectus entitled "Management's discussion and analysis of financial condition and results of operations" and "Special note regarding forward-looking statements," before you make an investment decision. The risks described below are not the only risks that we face. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks related to our financial position and capital needs

We are a biopharmaceutical company with a limited operating history and have not generated any revenue to date from drug sales, and may never become profitable.

Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. Since our formation as Monte Rosa Therapeutics AG in 2018, our operations have been limited primarily to organizing and staffing our company, business planning, raising capital, researching and developing our Quantitative and Engineered Elimination of Neosubstrates drug discovery platform, or the QuEEN platform, developing our pipeline, building our intellectual property portfolio and undertaking preclinical studies of our lead program molecules. We have never generated any revenue from drug sales. We have not obtained regulatory approvals for any of our current or future product candidates.

Typically, it takes many years to develop one new pharmaceutical drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions we make about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors, such as the COVID-19 pandemic. We will need to transition from a company focused on research and early stage development to a company capable of supporting late stage development and commercial activities. We may not be successful in such a transition.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

Since our inception, we have focused substantially all of our efforts and financial resources on developing our proprietary QuEEN platform, and our initial pipeline. To date, we have financed our operations primarily through the issuance and sale of convertible promissory notes and our convertible preferred stock to outside investors in private equity financings. From our inception through the date hereof, we raised an aggregate of $223.5 million of gross proceeds from such transactions. As of December 31, 2020, our cash and cash equivalents and investments were $41.7 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $48.1 million as of December 31, 2020. For the years ended December 31, 2020 and 2019, we reported net losses of $35.9 million and $7.7 million, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and initial pipeline programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses over the next several years and for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse

effect on our stockholders' deficit and working capital. We expect our expenses to significantly increase in connection with our ongoing activities, as we:

- submit a planned IND application with the U.S. Food and Drug Administration, or FDA, for a GSPT1-directed MGD molecule in and, if allowed to proceed, initiate a clinical trial;
- continue preclinical activities for our initial GSPT1, NEK7, CDK2, VAV1 and BCL11A programs;
- prepare and submit IND applications with the FDA for other current and future product candidates;
- complete preclinical studies for current or future product candidates;
- progress MGD molecules from our initial programs through lead optimization;
- initiate and complete clinical trials for current or future product candidates;
- expand and improve the capabilities of our QuEEN platform;
- contract to manufacture our product candidates;
- advance research and development related activities to expand our product pipeline;
- seek regulatory approval for our product candidates that successfully complete clinical development;
- develop and scale up our capabilities to support our ongoing preclinical activities and future clinical trials for our product candidates and commercialization of any of our product candidates for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional staff, including clinical, scientific and management personnel;
- secure facilities to support continued growth in our research, development and commercialization efforts; and
- incur additional costs associated with operating as a public company upon the completion of this offering.

In addition, if we obtain marketing approval for our current or future product candidates, we will incur significant expenses relating to sales, marketing, product manufacturing and distribution. Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, including in light of the ongoing evolution of the COVID-19 pandemic, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

Even if we achieve profitability, we may not be able to sustain or increase our 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 development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We are very early in our development efforts. All of our programs are still in the preclinical stages of drug discovery. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

Our ability to become profitable depends upon our ability to generate revenue. To date we have not generated any revenue from our product candidates, and we do not expect to generate any revenue from the sale of drugs

in the near future. We do not expect to generate revenue from product sales unless and until we complete the development of, obtain marketing approval for, and begin to sell, one or more of our product candidates. We are also unable to predict when, if ever, we will be able to generate revenue from such product candidates due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- our plans to submit IND applications to the FDA for the GSPT1 product candidate and future product candidates;
- our ability to timely and successfully complete preclinical studies and clinical trials for our GSPT1, NEK7, CDK2, VAV1 and BCL11A programs, and other current or future product candidates;
- our ability to advance MGD molecules from our non-lead programs through lead optimization;
- our successful initiation, enrollment in and completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- our ability to demonstrate, to the satisfaction of the FDA and comparable regulatory authorities the safety, efficacy, consistent manufacturing quality and acceptable risk-benefit profile of our product candidates for their intended uses;
- our ability to timely receive necessary regulatory approvals from applicable regulatory authorities, including the FDA;
- the costs associated with the development of any additional development programs we identify in-house or acquire through collaborations or other arrangements;
- our ability to establish manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our current and future product candidates;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- the terms and timing of any additional collaboration, license or other arrangement, including the terms and timing of any payments thereunder;
- our ability to enforce and defend intellectual property rights and claims; and
- our ability maintain a continued acceptable safety profile of our product candidates following approval.

We expect to incur significant sales and marketing costs as we prepare to commercialize our current or future product candidates. Even if we initiate and successfully complete pivotal or registration-enabling clinical trials of our current or future product candidates, and our current or future product candidates are approved for commercial sale, and despite expending these costs, our current or future product candidates may not be commercially successful. We may not achieve profitability soon after generating drug sales, if ever. If we are unable to generate revenue, we will not become profitable and may be unable to continue operations without continued funding.

Even if we consummate this offering, we will need to raise substantial additional funding. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, scale back or discontinue some of our product candidate development programs or future commercialization efforts.

We are currently advancing multiple discovery programs through the preclinical stages of drug discovery across a number of potential indications and we have one program in lead optimization. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current or future product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, upon the closing of this offering, we expect to incur significant additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. However, we have estimated our current additional funding needs based on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We cannot be certain that additional funding will be available on acceptable terms, or at all. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of public or private equity offerings, debt financings, governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties. If we are unable to raise capital or generate revenue when needed or on attractive terms, we would be forced to delay, reduce or eliminate our discovery and preclinical development programs or any future commercialization efforts. 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 common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities, will be sufficient to fund our operations through . We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. This estimate also assumes that we do not obtain any additional funding through collaborations or other strategic alliances. Our future capital requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our current or future product candidates;
- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and planned clinical trials for our current or future product candidates, including additional expenses attributable to adjusting our development plans (including any supply related matters) in response to the COVID-19 pandemic;
- our ability to establish and maintain additional collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other current or future product candidates and technologies;
- the costs of securing manufacturing arrangements for commercial production; and
- the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory clearances to market our current or future product candidates.

Identifying potential current or future product candidates and conducting preclinical studies 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 marketing approval and achieve drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Risks related to our business and industry

Risks related to drug development and regulatory approval

Our approach to the discovery and development of product candidates based on our QuEEN platform is novel, which makes it difficult to predict the time, cost of development and likelihood of successfully developing any product candidates.

Our QuEEN platform is a relatively new technology. Our future success depends on the successful development of this novel product candidate development approach. We have not yet succeeded and may not succeed in demonstrating the efficacy and safety of any of our product candidates in clinical trials or in obtaining marketing approval thereafter. In particular, our ability to successfully target therapeutically-relevant proteins using MGDs requires the successful development of non-heterobifunctional molecules that were rationally designed using our QuEEN platform with a rational drug development process and developing those molecules with the right combination of target proteins and E3 ligases. This is a complex process requiring a number of component parts or biological mechanisms to work in unison to achieve the desired effect. We cannot be certain that we will be able to discover MGDs by matching the right target and its degron with the ideal E3 ligase in a timely manner, or at all. We have not yet initiated a clinical trial of any product candidate and we have not yet assessed the safety of any product candidate in humans. As such, there may be adverse effects from treatment with any of our current or future product candidates that we cannot predict at this time.

As a result of these factors, it is more difficult for us to predict the time and cost of product candidate development, and we cannot predict whether the application of our QuEEN platform will result in the development and marketing approval of any product candidates. Any development problems we experience in the future related to our QuEEN platform or any of our discovery programs may cause significant delays or unanticipated costs or may prevent the development of a commercially viable product. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

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

A key element of our strategy is to apply our QuEEN platform and product pipeline to address a broad array of targets in various therapeutic areas. The discovery activities that we are conducting may not be successful in

identifying product candidates that are useful in treating oncology, inflammatory, immunologic and genetic diseases, and neurodegenerative or other neurologic diseases. Our discovery programs may be unsuccessful in identifying potential product candidates, or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval.

Because we have limited financial and management resources, we focus on a limited number of discovery programs and product candidates at a time. As a result, we may forego or delay pursuit of opportunities with other current or future product candidates or for other indications that later 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 products. 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 royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Our business is dependent on the success of our lead program, and any other product candidates that we advance into the clinic. We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.

All of our pipeline progams are in early stages of preclinical drug discovery, including our lead molecules from the GSPT1 program. The preclinical studies and future clinical trials of our current or future product candidates are, and the manufacturing and marketing of our current or future product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test or, if approved, market any of our current or future product candidates. Before obtaining regulatory approvals for the commercial sale of any of our current or future product candidates, we must demonstrate through preclinical studies and clinical trials that each product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our preclinical studies and clinical trials. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources beyond the proceeds we raise in this offering. Of the large number of drugs in development in the U.S., only a small percentage will successfully complete the FDA regulatory approval process and will be commercialized, with similarly low rates of success for drugs in development in the European Union obtaining regulatory approval from the European Medicines Agency, or EMA. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and preclinical studies and clinical trials, we cannot assure you that any of our current or future product candidates will be successfully developed or commercialized.

We are not permitted to market our current or future product candidates in the U.S. until we receive approval of a New Drug Application, or an NDA, from the FDA, in the European Economic Area, or EEA, until we receive approval of a marketing authorization applications, or an MAA, from the EMA, or in any other foreign countries until we receive the requisite approval from such countries. Obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of any of our current or future product candidates for many reasons, including, among others:

- we may not be able to demonstrate that our current or future product candidates are safe and effective in treating their target indications to the satisfaction of the FDA or applicable foreign regulatory agency;
- the results of our preclinical studies and clinical trials may not meet the level of statistical or clinical significance required by the FDA or applicable foreign regulatory agency for marketing approval;

- the FDA or applicable foreign regulatory agency may disagree with the number, design, size, conduct or implementation of our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may require that we conduct additional preclinical studies and clinical trials;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or applicable foreign regulatory agency may not approve the formulation, labeling or specifications of any of our current or future product candidates;
- the contract research organizations, or CROs, that we retain to conduct our preclinical studies and clinical trials may take actions outside of our control that materially adversely impact our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may find the data from preclinical studies and clinical trials insufficient to demonstrate that our current or future product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or applicable foreign regulatory agency may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA or applicable foreign regulatory agency may not accept data generated at our preclinical studies and clinical trial sites;
- if our NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA or the applicable foreign regulatory agency may determine that the manufacturing processes or facilities of third-party manufacturers with which we contract do not conform to applicable requirements, including current Good Manufacturing Practices, or cGMPs;
- the FDA or applicable foreign regulatory agency may be delayed in their review processes due to staffing or other constraints arising from the COVID-19 pandemic; or
- the FDA or applicable foreign regulatory agency may change its approval policies or adopt new regulations.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market our current or future product candidates. Any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

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

We may not be able to initiate or continue our planned clinical trials on a timely basis or at all for our product candidates if we are unable to recruit and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S. Patient enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Moreover, some of our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our current or future product candidates, and this competition reduces the number and types of patients available to us, as some patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' current or future product candidates. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. There may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a study.

Patient enrollment for any of our future clinical trials may be affected by other factors including:

- the size and nature of the patient population;
- competition with other companies for clinical sites or patients;
- the willingness of participants to enroll in our clinical trials in our countries of interest;
- the severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- the eligibility criteria for the clinical trial in question as defined in the protocol;
- the availability of an appropriate screening test for the indications we are pursuing;
- the perceived risks and benefits of the product candidate under study in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the efforts to facilitate timely enrollment in and completion of clinical trials;
- delays in or temporary suspension of the enrollment of patients in our future clinical trials due to the COVID-19 pandemic;
- ability to obtain and maintain patient consents;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

The incidence and prevalence for target patient populations of our product candidates have not been established with precision. If the market opportunities for our product candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and prevalence for the indications being pursued by our current and future product candidates is currently unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. Our GSPT1 program will develop a product candidate for the treatment of cancers overexpressing one of the Myc family genes, our NEK7 program will develop a product candidate for the treatment of inflammatory diseases, our CDK2 program will develop a product candidate for the treatment of cancers such as ovarian and breast cancers, our VAV1 program will develop a product candidate for the treatment of T and B cell malignancies and autoimmune diseases and our BCL11A program will develop a product candidate for the treatment of sickle cell disease and ß-Thalassemia. The total addressable market opportunity for product candidates from these discovery programs and future product candidates will ultimately depend upon, among other things, its proven safety and efficacy, the diagnosis criteria included in the final label for each, whether our product candidates are approved for sale for these indications, acceptance by the medical community and patient access, product pricing and reimbursement. The number of patients for our product candidates in the United States and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our preclinical and clinical programs may experience delays or may never advance, which would adversely affect our ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business.

In order to obtain FDA approval to market a new small molecule product, we must demonstrate the safety and efficacy of our product candidates in humans to the satisfaction of the FDA. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Clinical testing is expensive, time-consuming and subject to uncertainty. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical studies that support our planned and future INDs in the United States. We are currently selecting lead development candidates for preclinical development. We cannot be certain of the timely completion or outcome of our preclinical studies and cannot predict if the FDA will allow our proposed clinical programs to proceed or if the outcome of our preclinical studies will ultimately support further development of our programs. We have not yet received authorization to proceed under an IND for any product candidate, and we cannot be sure that we will be able to submit INDs or similar applications with respect to our other product candidates on the timelines we expect, if at all, and we cannot be sure that submission of IND or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Conducting preclinical testing and clinical trials represents is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical studies may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other *in vivo* or *in vitro* data to support the initiation of clinical studies;

- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with the FDA's good laboratory practice requirements and other applicable regulations;
- approval by an independent Institutional Review Board, or IRB, ethics committee at each clinical site before each trial may be initiated;
- delays in reaching a consensus with regulatory agencies on study design and obtaining regulatory authorization to commence clinical trials;
- delays in reaching agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in recruiting suitable patients to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is deficient to meet its stated objectives;
- delays in recruiting, screening and enrolling patients and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow-up;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform clinical trials in accordance with the FDA's good clinical practice requirements, or GCPs, or applicable regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in a trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites dropping out of a trial;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- the cost of clinical trials of our product candidates being greater than we anticipate;

- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, and delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and
- third parties being unwilling or unable to satisfy their contractual obligations to us.

Further, 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 protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Delays in the completion of any preclinical studies or clinical trials of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate product revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Any delays to our preclinical studies or clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

The results of preclinical testing and early clinical trials may not be predictive of the results of later preclinical studies and clinical trials, and the results of our planned and future clinical trials may not satisfy the requirements of the FDA or other comparable regulatory authorities. If we cannot replicate the positive results from our preclinical studies of our current or future product candidates in our future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our current or future product candidates.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective before we can seek marketing approvals for their commercial sale. Positive results from our preclinical studies of our current or future product candidates, and any positive results we may obtain from our early clinical trials of our current or future product candidates, may not necessarily be predictive of the results from required subsequent preclinical studies and clinical trials. Similarly, even if we are able to complete our planned preclinical studies or any clinical trials of our current or future product candidates according to our current development timeline, the positive results from such preclinical studies and clinical trials of our current or future product candidates may not be replicated in subsequent preclinical studies or clinical trial results.

Many companies in the pharmaceutical 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 believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain approval from the FDA or a comparable foreign regulatory authority. If we fail to produce positive results in our

planned preclinical studies or clinical trials of any of our current or future product candidates, the development timeline and regulatory approval and commercialization prospects for our current or future product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected. Thus, even if the results from our initial research and preclinical activities appear positive, we do not know whether subsequent clinical studies we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any product candidates.

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

From time to time, we may publicly disclose interim, topline or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim, topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, such data should be viewed with caution until the final data are available. Adverse differences between preliminary, interim or topline data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our current or future product candidates, we will not be able to commercialize, or will be delayed in commercializing, our current or future product candidates, and our ability to generate revenue will be materially impaired.

Our current or future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export, are subject to comprehensive regulation by the FDA and other regulatory agencies in the U.S. and by comparable authorities in other countries. Before we can commercialize any of our current or future product candidates, we must obtain marketing approval from the regulatory authorities in the relevant jurisdictions. We have not received approval to market any of our current or future product candidates from regulatory authorities in any jurisdiction, and it is possible that none of our current product candidates, nor any product candidates we may seek to develop in the future, will ever obtain regulatory approval. Securing regulatory approval requires the submission of

extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our current or future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our current or future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our drugs, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our current or future product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our current or future product candidates, the commercial prospects for our current or future product candidates may be harmed and our ability to generate revenues will be materially impaired.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

In December 2019, a novel strain of the coronavirus disease, COVID-19, was identified in Wuhan, China. This virus has since spread globally and in March 2020, the World Health Organization declared COVID-19 a pandemic. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. In response to the spread of COVID-19, we have implemented policies at our locations to mitigate the risk of exposure to COVID-19 by our personnel, including by limiting the number of staff in any given research and development laboratory or manufacturing facility, a work-from-home policy applicable to our non-laboratory based employees, such as clinical, manufacturing, finance, administrative, quality, regulatory and program managers, and a phased approach to bringing personnel back to our locations over time. As a result of the COVID-19 pandemic, we have experienced and we expect to continue to experience disruptions that could severely impact our business, preclinical studies, including:

- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations, or CMOs, due to staffing shortages, production slowdowns or stoppages, disruptions in delivery systems and the diversion of resources to prioritize manufacturing products that are related to treating or preventing COVID-19;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility and those of our sub-contractors;
- delays in necessary interactions with local regulators, institutional review board, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;

- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our preclinical studies are conducted, which may result in unexpected costs, or to discontinue such preclinical studies altogether; and
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

Health regulatory agencies globally may experience disruptions in their operations as a result of the COVID-19 pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced and review, inspection, and other timelines may be materially delayed. As of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee goals. On July 16, 2020, the FDA stated that it is continuing to expedite oncology product development with its staff teleworking full-time. However, the FDA may not be able to continue its current pace and approval timelines could be extended. It is unknown how long these disruptions could continue, were they to occur. Since March 2020, foreign and domestic inspections by the FDA have largely been on hold with the FDA announcing plans in July 2020 to resume prioritized domestic inspections. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Any delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which COVID-19 impacts our business, results of operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, duration of the outbreak, travel restrictions, new information that may emerge concerning the severity of COVID-19 or the effectiveness of actions taken in the United States and other countries to contain COVID-19 or treat its impact, among others. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, service providers, regulators and other third parties with whom we conduct business, were to experience prolonged business shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

Our current or future product candidates may cause adverse or other undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

We have not evaluated any product candidates in human clinical trials. Undesirable side effects caused by our current or future 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 other regulatory authorities. As is the case with many treatments for cancer, inflammatory and autoimmune diseases, neurodegeneration or genetic diseases it is likely that there may be adverse side effects associated with the use of our product candidates. Additionally, a potential risk in any protein degradation product is that healthy proteins or proteins not targeted for degradation will be degraded or that the degradation of the targeted protein, in itself, could cause adverse events, undesirable side effects, or unexpected consequences. It is possible that healthy proteins or proteins not targeted for degradation could be degraded using our degrader molecules in any of our planned or future clinical studies. There is also the potential risk of delayed adverse events following treatment using any of our current or future product candidates.

These side effects could arise due to off-target activity, allergic reactions in trial subjects or unwanted on-target effects in the body. Results of our planned clinical 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 current or future product candidates for any or all targeted indications. The drug-related side effects could 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, our current or future product candidates could cause undesirable side effects in clinical trials related to on-target toxicity. If on-target toxicity is observed, or if our current or future product candidates have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage testing for treating cancer or other diseases have later been found to cause side effects that prevented further development of the compound.

In addition, clinical trials by their nature utilize 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 current or future product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. In any such event, our studies 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. The side effects experienced could affect patient recruitment or the ability of enrolled subjects to complete the study or result in potential product liability claims. Moreover, if we elect, or are required, not to initiate, or to delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly.

In addition, if our current or future product candidates receive marketing approval and we or others identify undesirable side effects caused by such current or future product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such current or future product candidates, or seek an injunction against their manufacture or distribution;
- regulatory authorities may require the addition of labeling statements or warnings, such as a “boxed” warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such current or future product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the current or future product candidates;
- we may be required to conduct post-marketing studies or change the way the product is administered;
- 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 subject to regulatory investigations and government enforcement actions;

- we may decide to remove such current or future product candidates from the market;
- we could be sued and held liable for injury caused to individuals exposed to or taking our current or future product candidates;
- we may be subject to fines, injunctions or imposition of criminal penalties; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our current or future product candidates, if approved, and significantly impact our ability to successfully commercialize our current or future product candidates and generate revenues.

We may seek and fail to obtain Breakthrough Therapy Designation or Fast Track Designation from the FDA for our current or future product candidates. Even if granted for any of our current or future product candidates, these programs may not lead to a faster development, regulatory review or approval process, and such designations do not increase the likelihood that any of our product candidates will receive marketing approval in the United States.

We may seek a Breakthrough Therapy Designation for one or more of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug 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 drugs 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. Product candidates designated as breakthrough therapies by the FDA may also be eligible for priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our current or future product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a current or future product candidate may not result in a faster development process, review or approval compared to drugs 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 current or future product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind the designation or decide that the time period for FDA review or approval will not be shortened.

We may also seek Fast Track Designation for one or more of our current or future product candidates. If a product candidate is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The sponsor of a product candidate with Fast Track Designation has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. Such product candidate may also be eligible for rolling review, where the FDA may consider to review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular current or future product candidate is eligible for this designation, we cannot assure you that the FDA would

decide to grant it. Even if we do receive Fast Track Designation for certain current or future product candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may rescind fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

We may seek Orphan Drug Designation for certain of our current or future product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.

As part of our business strategy, we may seek Orphan Drug Designation for certain indications of our current or future product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug 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 U.S., or a patient population of 200,000 or more in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the U.S., Orphan Drug Designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in Europe, the European Commission, upon the recommendation of the EMA's Committee for Orphan Medicinal Products, grants Orphan Drug Designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than 5 in 10,000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation entitles a party to financial incentives such as reduction of fees or fee waivers.

Generally, if a product with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off-label. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable

indications for our current and any future product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations.

Even if we receive marketing authorization for our product candidates, we will be subject to extensive ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, and continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. Any regulatory approvals that we receive for our current or future product candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug. Later discovery of previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance during remediation;
- revisions to the labeling, including limitation on approved uses or the addition of warnings, contraindications, or other safety information, including boxed warnings;
- imposition of a REMS, which may include distribution or use restrictions;
- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

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

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current or future product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if we receive marketing approval for our current or future product candidates in the U.S., we may never receive regulatory approval to market our current or future product candidates outside of the U.S.

We plan to seek regulatory approval of our current or future product candidates outside of the U.S. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction.

For example, even if the FDA grants marketing approval of a product candidate, we may not obtain approvals in other jurisdictions, and comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among countries and can involve additional product candidate testing and administrative review periods different from those in the United States. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. In particular, in many countries outside of the U.S., products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with regulatory requirements in international markets or fail to receive applicable marketing approvals, it would reduce the size of our potential market, which could have a material adverse impact on our business, results of operations and prospects.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties that could materially adversely affect our business.

We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Such requirements govern, among other things, clinical trials and commercial sales, and pricing and distribution of our current or future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current or future product candidates and ultimately commercialize our current or future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- differing regulatory requirements in foreign countries, such that obtaining regulatory approvals outside of the U.S. may take longer and be more costly than obtaining approval in the U.S.;
- our customers' ability to obtain reimbursement for our current or future product candidates in foreign markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- 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;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute;
- 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.

Foreign sales of our current or future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Changes in funding or disruptions at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and on March 18, 2020 the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Since March 2020, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections and resumed inspections in China and India in early 2021. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Should the FDA determine that a manufacturing or bioresearch monitoring inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be appropriate, the agency has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, the FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may in the future conduct clinical trials for current or future product candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more clinical trials outside the U.S., including in Europe. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or

comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which we collectively refer to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations.

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

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidates. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Risks related to commercialization

Even if we receive marketing approval for our current or future product candidates, our current or future product candidates may not achieve broad market acceptance, which would limit the revenue that we generate from their sales.

The commercial success of our current or future product candidates, if approved by the FDA or other applicable regulatory authorities, will depend upon the awareness and acceptance of our current or future product candidates among the medical community, including physicians, patients and healthcare payors. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. Market acceptance of our current or future product candidates, if approved, will depend on a number of factors, including, among others:

- the efficacy of our current or future product candidates as demonstrated in clinical trials, and, if required by any applicable regulatory authority in connection with the approval for the applicable indications, to provide patients with incremental health benefits, as compared with other available medicines;
- the timing of market introduction of the product candidates and potential advantages to alternative treatments;
- limitations or warnings contained in the labeling approved for our current or future product candidates by the FDA or other applicable regulatory authorities;
- the clinical indications for which our current or future product candidates are approved;
- availability of alternative treatments already approved or expected to be commercially launched in the near future;
- the potential and perceived advantages of our current or future product candidates over current treatment options or alternative treatments, including future alternative treatments;
- the willingness of the target patient population to try new therapies or treatment methods and of physicians to prescribe these therapies or methods;
- the need to dose such product candidates in combination with other therapeutic agents, and related costs;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments;
- pricing and cost effectiveness;
- the effectiveness of our sales and marketing strategies;
- our ability to increase awareness of our current or future product candidates;
- our ability to obtain sufficient third-party coverage or reimbursement; or
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If our current or future product candidates are approved but do not achieve an adequate level of acceptance by patients, physicians and payors, we may not generate sufficient revenue from our current or future product candidates to become or remain profitable. Before granting reimbursement approval, healthcare payors may require us to demonstrate that our current or future product candidates, in addition to treating these target

indications, also provide incremental health benefits to patients. Our efforts to educate the medical community, patient organizations and third-party payors about the benefits of our current or future product candidates may require significant resources and may never be successful.

If we are unable to establish sales, marketing and distribution capabilities for any product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for any product candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market some of our product candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The market opportunities for any current or future product candidate we develop, if and when approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Cancer therapies are sometimes characterized as first-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, first-line therapy, usually chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. We expect to initially seek approval of our product candidates we develop as a therapy for patients who have received one or more prior treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval potentially as a first-

line therapy, but there is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future product candidates in both oncology and non-oncology indications may be limited, if and when approved. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

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

The development and commercialization of new drugs is highly competitive. We face and will continue to face competition from third parties that use protein degradation, antibody therapy, inhibitory nucleic acid, gene editing or gene therapy development platforms and from companies focused on more traditional therapeutic modalities, such as small molecule inhibitors. 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 of new drugs.

We are aware of several biotechnology companies focused on developing molecular glue degraders or MGD therapeutics for patients, including BioTheryX Therapeutics, C4 Therapeutics, Inc., Nurix Therapeutics, Inc., Kymera Therapeutics, Inc., Arvinas, Inc. and Seed Therapeutics, Inc., all of which are currently in development. In addition, lenalidomide and pomalidomide, which are both marketed by Bristol-Myers Squibb, are believed to function as MGDs. Further, several large pharmaceutical companies have disclosed investments in this field.

Many of our current or future competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement and marketing of approved drugs than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel and establishing clinical trial sites and patient recruitment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our current or future product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any current or future product candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our current or future product candidates in human clinical trials and will face an even greater risk if we commercially sell any current or

future product candidates that we may develop. If we cannot successfully defend ourselves against claims that our current or future product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any current or future product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any current or future product candidates that we may develop.

We do not yet maintain product liability insurance, and we anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Even if we are able to commercialize any current or future product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the U.S. and in other countries, sales of any products for which we may receive regulatory marketing approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government healthcare programs (e.g., Medicare and Medicaid), managed care providers, private health insurers, health maintenance organizations and other organizations. These third-party payors decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as targeted protein degradation therapies.

In the United States, no uniform policy exists for coverage and reimbursement for products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

One third-party payor's decision to cover a particular product or service does not ensure that other payors will also provide coverage for the medical product or service. Third-party payors may limit coverage to specific products on an approved list or formulary, which may not include all FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded product on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. We cannot be sure that coverage will be available for any product candidate that we commercialize.

Moreover, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate a payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. If coverage is available, but reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

Further, third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Despite our best efforts, our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover an approved product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Finally, in some foreign countries, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the European Union, or EU, pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU Member States' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices and reimbursement levels of medicinal products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A country may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product candidates launched in some foreign countries, such as some countries in the EU, do not follow price structures of the U.S. and prices generally tend to be significantly lower.

Current and future healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes intended to broaden access to healthcare, improve the quality of healthcare, and contain or lower the cost of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the

ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjected drug products to potential competition by lower-cost biosimilars, expanded the types of entities eligible for the 340B drug discount program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. Various portions of the ACA are currently undergoing legal and constitutional challenges in the United States Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the ACA. The United States Supreme Court is expected to rule on a legal challenge to the constitutionality of the ACA in early 2021. The implementation of the ACA is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, 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. Proposed legislation, if enacted, would extend this suspension through the end of the year; the Centers for Medicare & Medicaid Services, or CMS, has signaled that it is delaying the processing of claims in April 2021 to allow Congress to prevent the reimposition of the 2% cuts during the pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for pharmaceutical and biological products. At the federal level, the previous administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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 healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. It is difficult to

predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects. However, we expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our current or future product candidates or additional pricing pressures. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our relationships with customers, health care providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished future profits and earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any current or future product candidates for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors and customers may expose us to broadly applicable federal and state laws relating to fraud and abuse, as well as other healthcare laws and regulations. These laws may impact, among other things, the business or financial arrangements and relationships through which we market, sell and distribute any current or future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include, among others:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, offering, receiving, providing or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, or arranging for, any item, good, facility, or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations can result in significant civil monetary and criminal penalties for each violation, plus up to three times the amount of remuneration, imprisonment, and exclusion from government healthcare programs. Further, a violation of the federal Anti-Kickback Statute can also form the basis for False Claims Act liability. On December 2, 2020, OIG published further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. Implementation of this change and

new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees has been delayed by the Biden administration until January 1, 2023, and may be amended or repealed. We continue to evaluate what effect, if any, the rule will have on our business;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which prohibits 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. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties for each false claim and three times the amount of the government's damages. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes additional criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private); and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency laws, including the federal Physician Payment Sunshine Act created under the ACA, which requires manufacturers of certain drugs, devices, biologics and medical supplies, among others, to track and disclose payments under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) and other transfers of value they make to U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. This information is subsequently made publicly available in a searchable format on a CMS website. Failure to disclose required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, including the final omnibus rule published on January 25, 2013, which imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain, transmit, or obtain, protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the

privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and

- analogous state law equivalents of each of the above U.S. federal laws, such as state anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require the reporting of information related to drug pricing; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the licensure and/or registration of pharmaceutical sales representatives; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

It is possible that governmental authorities will conclude that our business practices, including our arrangements with certain physicians, some of whom are compensated in the form of stock or stock options for services provided to us, do 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 to be 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, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions.

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 also prohibited in the EU. The provision of benefits or advantages to physicians is governed by the national anti-bribery laws of EU Member States, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Risks related to our dependence on third parties

We currently rely, and plan to rely on in the future, on third parties to conduct and support our preclinical studies, and we expect to rely on third parties to conduct our clinical trials for our current and future product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our current and potential future product candidates and our business could be substantially harmed.

We utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs and strategic partners to help conduct our preclinical studies. For example, we contract with Ridgeline Therapeutics GmbH, or Ridgeline, for services related to our drug discovery and preclinical work, but we are continuing to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities to assume activities conducted by Ridgeline on our behalf. We do not have the ability to independently conduct clinical trials. We expect to rely on medical institutions, clinical investigators, contract laboratories, and other third parties, including collaboration partners, to conduct or otherwise support clinical trials for our current or future product candidates. We expect to rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities.

We and any third parties that we contract with are required to comply with regulations and requirements, including GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or the third parties we contract with fail to comply with applicable GCP 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 perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP requirements. In addition, our clinical trials must be conducted with current or future product candidates produced under cGMP regulations and will require a large number of study subjects. Our failure or the failure of third parties that we may contract with to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat some aspects of a specific, or an entire, clinical trial, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial's protocol, on a government-sponsored database, ClinicalTrials.gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our current or future product candidates, or be involved in the design when other parties sponsor the trials, we anticipate that third parties will conduct all of our clinical trials. As a result, many important aspects of our clinical development, including their conduct, timing and response to the ongoing COVID-19 pandemic, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff, and we cannot control whether or not they will devote sufficient time and resources to our product candidates. 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. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;

- experience regulatory compliance issues; and
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our current or future product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our current or future product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs on commercially reasonable terms, or at all. If our CROs 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our current or future product candidates. As a result, we believe that our financial results and the commercial prospects for our current or future product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

The third parties upon whom we rely on for the supply of drug product and starting materials used in our product candidates are limited in number, and the loss of any of these suppliers, or their noncompliance with regulatory requirements or our quality standards, could significantly harm our business.

The drug substance and drug product in our product candidates are supplied to us from a small number of suppliers, and in some cases sole source suppliers. Our ability to successfully develop our current or future product candidates, and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing.

The facilities used by our contract manufacturers to manufacture our product candidates will be identified in, and subject to inspections that will be conducted after we submit, any marketing application to the FDA or other comparable foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMP requirements and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve our marketing applications identifying these facilities for the manufacture of our product candidates or if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require that we incur significant additional costs and materially adversely affect our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third-party manufacturers on which we will rely fail to manufacture quantities of our product candidates at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected.

Further, we do not currently have arrangements in place for a redundant or second-source supply of all drug product or drug substance in the event any of our current suppliers of such drug product and drug substance cease their operations for any reason. Any delays in the delivery of our drug substance, drug product or starting materials could have an adverse effect and potentially harm our business.

For all of our current or future product candidates, we intend to identify and qualify additional manufacturers to provide drug product and drug substance prior to submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source and dual source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the drug product and drug substance used in our current or future product candidates, if required, may not be accomplished quickly. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original supplier and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

While we seek to maintain adequate inventory of the drug product and drug substance used in our current or future product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain drug product and drug substance from alternate sources at acceptable prices in a timely manner, could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

Our success is dependent on our executive management team's ability to successfully pursue business development, strategic partnerships and investment opportunities as our company matures. ***We may also form or seek strategic alliances or acquisitions or enter into additional collaboration and licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, acquisitions or licensing arrangements.***

We may in the future form or seek strategic alliances or acquisitions, create joint ventures, or enter into additional collaboration and licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our current product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or acquisition or other alternative arrangements for our current or future 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 our current or future product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our technologies or current or future product candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our current or future product candidates or may elect not to continue or renew development or commercialization of our current or future product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, 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 current or future product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our current or future product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- collaborators may not pay milestones and royalties due to the company in a timely manner.

As a result, we may not be able to realize the benefits of our existing collaboration and licensing arrangements or any future strategic partnerships or acquisitions, collaborations or license arrangements we may enter into if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction, license, collaboration or other business development partnership, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our current or future product candidates could delay the development and commercialization of our current or future product candidates in certain geographies or for certain indications, which would harm our business prospects, financial condition and results of operations.

Manufacturing our current or future product candidates is complex and we may encounter difficulties in production. If we encounter such difficulties, our ability to provide supply of our current or future product candidates for preclinical studies and future clinical trials or for commercial purposes could be delayed or stopped.

The process of manufacturing of our current or future product candidates is complex and highly regulated. We do not have our own manufacturing facilities or personnel and currently rely, and expect to continue to rely, on third parties for the manufacture of our current or future product candidates. These third-party manufacturing providers may not be able to provide adequate resources or capacity to meet our needs and may incorporate their own proprietary processes into our product candidate manufacturing processes. We have limited control and oversight of a third party's proprietary process, and a third party may elect to modify its process without our consent or knowledge. These modifications could negatively impact our manufacturing, including product loss or failure that requires additional manufacturing runs or a change in manufacturer, either of which could significantly increase the cost of and significantly delay the manufacture of our current or future product candidates.

As our current or future product candidates progress through preclinical studies and clinical trials towards potential approval and commercialization, it is expected that various aspects of the manufacturing process will be altered in an effort to optimize processes and results. Such changes may require amendments to be made to regulatory applications which may further delay the timeframes under which modified manufacturing processes can be used for any of our current or future product candidates and additional bridging studies or trials may be required and may not be successful. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. Any such delay could have a material adverse impact on our business, results of operations and prospects.

Our manufacturing process needs to comply with FDA regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our preclinical and future clinical programs and suspension or withdrawal of any regulatory approvals.

In order to commercially produce our products either at our own facility or at a third party's facility, we will need to comply with the FDA's cGMP regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We and our third party manufacturers are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our current or future product candidates, including leading to significant delays in the availability of our product candidates for our future clinical trials or the termination of or suspension of a future clinical trial, or the delay or prevention of a filing or approval of marketing applications for our current or future product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our current or future product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical materials, by our third-party manufacturers. Our manufacturers are subject to federal, state

and local laws and regulations in the U.S. governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks related to intellectual property

If we are unable to obtain and maintain patent and other intellectual property protection for our technology and product candidates or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired, and we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our commercial success depends in part on our ability to obtain and maintain patent or other intellectual property protection in the U.S. and other countries for our current or future product candidates and our core technologies, including our proprietary QuEEN platform, our initial GSPT1, NEK7, CDK2, VAV1 and BCL11A programs, which are our five most advanced preclinical stage pipeline programs, as well as our proprietary compound library and other know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business.

We own patent applications related to our QuEEN platform and our GSPT1 program, including GSPT1-directed MGDs, biomarkers related to these compounds, and methods of reading through nonsense mutations. We currently do not own any issued patents. Further, patent prosecution related to our pending patent applications is in the early stages and, as such, no patent examiner has yet fully scrutinized the merits of any of our pending patent applications.

As of April 19, 2021, our patent portfolio covering GSPT1-directed MGDs includes five patent families. Patent term adjustments, supplementary protection certificate filings, or patent term extensions could result in later expiration dates in various countries, while terminal disclaimers could result in earlier expiration dates in the U.S.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As such, we cannot guarantee that our pending and future patent applications will result in patents being issued or that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

The degree of patent protection we require to successfully commercialize our current or future product candidates 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 pending patent applications that mature into issued patents will include claims with a scope sufficient to protect our QuEEN platform and our current or future product candidates. In addition, if the breadth or strength of protection provided by our patent applications or any patents we may own or in-license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Other parties have developed technologies that may be related or competitive to our own, and such parties may have filed or may file patent applications, or may have acquired or may acquire patents, claiming inventions that may overlap or conflict with those claimed in our own patent applications or issued patents, with respect to either the same compounds, methods, formulations or other subject matter, in either case that we may rely upon to dominate our patent position in the market. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until at least 18 months after the earliest priority date of the patent filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in patents we may own or in-license patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the USPTO might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

In addition, the patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Further, with respect to certain pending patent applications covering our current or future product candidates or technologies, prosecution has yet to commence and as such, no patent examiner has scrutinized the merits of such pending patent applications. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the relevant patent office(s) may be significantly narrowed by the time they issue, if they ever do. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Even if we acquire patent protection that we expect should enable us to establish and/or maintain a competitive advantage, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. We may become involved in opposition, derivation, reexamination, *inter partes* review, or post-grant review proceedings challenging our patent rights or the patent rights of others from whom we may in the future obtain licenses to such rights, in the U.S. Patent and Trademark Office, or USPTO, the European Patent Office, or EPO, or the relevant patent authorities in other countries. In addition, we may be subject to third-party submissions to the USPTO, the EPO, or elsewhere, that may reduce the scope or preclude the granting of claims from our pending patent applications. Competitors may challenge our issued patents or may file patent applications before we do. Competitors may also claim that we are infringing their patents and that we therefore cannot practice our technology as claimed under our patents or patent applications. Competitors may also contest our patents by arguing before an administrative patent authority or judge that the invention was not patent-eligible, was not novel, was obvious, and/or lacked inventive steps, and/or that the patent application failed to meet relevant requirements relating to description, basis, enablement, and/or support; in litigation, a competitor could assert that our patents are not valid or are

unenforceable for a number of reasons. If a court or administrative patent authority agrees, we would lose our protection of those challenged patents.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, without payment to us, or could limit the duration of the patent protection covering our technology and current or future product candidates. Such challenges may also result in our inability to manufacture or commercialize our current or future product candidates without infringing third-party patent rights. 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.

Even if they are unchallenged, our issued patents and our pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent patents we may own or in-license by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug or product that provides benefits similar to one or more of our current or future product candidates but that has a different composition or otherwise 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 current or future product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our current or future product candidates could be negatively affected, which would harm our business.

Obtaining and maintaining our patent protection, including patent term, depends on compliance with various procedural, document submission, deadlines, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we miss a filing deadline for patent protection on these inventions or otherwise fail to comply with these requirements.

The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after issuance of any patent. In addition, periodic maintenance fees, renewal fees, annuity fees and/or various other government fees are required to be paid periodically. While an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our maintenance vendors, can in some 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 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 with similar or identical products or platforms, which could have a material adverse effect on our business prospects and financial condition.

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

Patents have a limited lifespan. In the U.S., and most other jurisdictions in which we have undertaken patent filings, the natural expiration of a patent is generally twenty years after it is filed, assuming all maintenance fees are paid. Various extensions may be available, on a jurisdiction-by-jurisdiction basis; however, the life of a patent, and thus 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. As a result, patents we may own or in-license may not provide us with adequate and continuing patent protection sufficient to exclude others from

commercializing drugs similar or identical to our current or future product candidates, including generic versions of such drugs.

Depending upon the timing, duration and specifics of FDA marketing approval of our current or future product candidates, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Different laws govern the extension of patents on approved pharmaceutical products in Europe and other jurisdictions. However, we may not be granted a patent 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. For example, we may not be granted an extension in the U.S. if all of our patents covering an approved product expire more than fourteen years from the date of NDA approval for a product covered by those patents. 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 restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our ability to generate revenues could be materially adversely affected.

If our trademarks and trade names for our products or company name are not adequately protected in one or more countries where we intend to market our products, we may delay the launch of product brand names, use different trademarks or tradenames in different countries, or face other potentially adverse consequences to building our product brand recognition.

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to 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 or from comparable agencies in foreign jurisdictions objecting to the registration of our trademark. 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 trademark applications or registrations, and our trademark applications or registrations may not survive such proceedings. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long run, if we are unable to obtain a registered trademark or 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.

Additionally, we may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

If we are unable to adequately protect and enforce our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents we may own or in-license, we seek to rely on trade secret protection, confidentiality agreements, and license agreements to protect proprietary know-how that may not

be 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 may not be covered by patents. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into non-disclosure and confidentiality agreements, trade secrets can be difficult to protect and we have limited control over the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information.

Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access (such as through a cybersecurity breach) to our trade secrets or independently develop substantially equivalent information and techniques. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. 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. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the U.S. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. 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, financial condition, results of operations and future prospects.

We may initiate, become a defendant in, or otherwise become party to lawsuits to protect or enforce our intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate any patents or other intellectual property we may own or in-license. In addition, any patents we may own or in-license also may become involved in inventorship, priority, validity or unenforceability disputes. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. In patent litigation in the U.S. and in some other jurisdictions, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith. The outcome following such a challenge is unpredictable. Moreover, with respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution.

We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, in an infringement proceeding, a court may decide that one or more of any patents we may own or in-license is not valid or is unenforceable or that the other party’s use of our technology that may be patented falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). There is also the risk that, even if the validity of these patents is upheld, the court may refuse to stop

the other party from using the technology at issue on the grounds that any patents we may own or in-license do not cover the technology in question or that such third party's activities do not infringe our patent applications or any patents we may own or in-license. An adverse result in any litigation or defense proceedings could put one or more of any patents we may own or in-license at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, patient support or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. Post-grant proceedings, including post-grant review, *inter partes* review and derivation 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 patent applications or any patents we may own or in-license. These proceedings are expensive and 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. In addition to potential USPTO post-grant proceedings, we may become a party to patent opposition proceedings in the EPO, or similar proceedings in other foreign patent offices or courts where our patents may be challenged. The costs of these proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result in a post-grant challenge proceeding may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business. Litigation or post-grant proceedings within patent offices 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.

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.

We may not be able to detect infringement against any patents we may own or in-license. Even if we detect infringement by a third party of any patents we may own or in-license, we may choose not to pursue litigation against or settlement with the third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us to enforce any patents we may own or in-license against such third party.

Intellectual property litigation and administrative patent office patent validity challenges in one or more countries could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to

raise the funds necessary to continue our preclinical studies and future clinical trials, continue our discovery programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our current or future product candidates, if approved.

In addition, if our product candidates are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

Any of the foregoing events would harm our business, financial condition, results of operations and prospects.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our current and future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our licensors are 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 the case of employees, we enter into agreements providing that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain. Defending against such law suits will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

The intellectual property landscape relevant to our products and programs is crowded, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current and future product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property 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 derivation, interference, reexamination, *inter partes* review and post grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We or any of our current or future licensors or strategic partners may be party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that our current or future product candidates and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. We cannot assure you that our current or future product candidates, the QuEEN platform, and other technologies that we have developed, are developing or may develop in the future do not or will not infringe, misappropriate or otherwise violate existing or future patents or other intellectual property rights owned by third parties.

While certain activities related to development and preclinical and clinical testing of our current or future product candidates may be subject to safe harbor of patent infringement under 35 U.S.C. §271(e)(1), upon receiving FDA approval for such candidates we or any of our future licensors or strategic partners may immediately become party to, exposed to, or threatened with, future adversarial proceedings or litigation by third parties having patent or other intellectual property rights alleging that such product candidates infringe, misappropriate or otherwise violate 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 current or future product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our current or future 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 current or future product candidates, technologies or methods.

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

- infringement, misappropriation 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 and may impact our reputation;
- substantial damages for infringement, misappropriation or other violations, which we may have to pay if a court decides that the product candidate or technology at issue infringes, misappropriates 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 current or future product candidates, or from using our proprietary technologies, including our QuEEN platform, unless the third-party licenses its product rights to us, which it is not required to do on commercially reasonable terms or at all;
- 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, or the license to us may be non-exclusive, which would permit third parties to use the same intellectual property to compete with us;
- redesigning our current or future product candidates or processes so they do not infringe, misappropriate or violate third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time; and
- there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted in U.S. courts 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 current or future product candidates. Patent applications can take many years to issue. In addition, because some patent applications in the U.S. may be maintained in secrecy until the patents are issued, patent applications in the U.S. and many foreign jurisdictions are typically not published until 18 months after their earliest priority filing date, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications covering our current or future product candidates or technology. If any such patent applications issue as patents, and if such patents have priority over our patent applications or patents we may own or in-license, we may be required to obtain rights to such patents owned by third parties which may not be available on commercially reasonable terms or at all, or may only be available on a non-exclusive basis. There may be currently pending third-party patent applications which may later result in issued patents that our current or future product candidates may infringe. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our current or future product candidates or other technologies, could be found to be infringed by our current or future product candidates or other technologies. 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 current or future product candidates, 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 current or future product candidates or the QuEEN platform may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to us.

In addition, 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 current or future 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, misappropriation or other violation 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 at all or whether it would be available on commercially reasonable terms. 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 current or future product candidates, which licenses may not be available on commercially reasonable terms, or at all. In that event, we would be unable to further develop and commercialize our current or future product candidates or technologies, which could harm our business significantly.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending and we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We may also be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants and advisors, even those related to one or more of our current or future product candidates, the QuEEN platform, or other technologies, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities.

We will not obtain patent or other intellectual property protection for any current or future product candidates in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We may not be able to pursue patent coverage of our current or future product candidates, the QuEEN platform, or other technologies in all countries. Filing, prosecuting and defending patents on current or future product candidates, the QuEEN platform, and other technologies in all countries throughout the world would be prohibitively expensive, and intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from infringing on our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. 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 where enforcement is not as strong as that in the U.S. These products may compete with our current or future product candidates and in jurisdictions where we do not have any issued patents our patent applications or other intellectual property rights may not be effective or sufficient to prevent them from competing. Much 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 pharmaceutical products, which could make it difficult for us to stop the infringement of any patents we may own or in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce any rights we may have in our patent applications or any patents we may own or in-license in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents we may own or in-license 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.

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

We may not obtain or grant licenses or sublicenses to intellectual property rights in all markets on equally or sufficiently favorable terms with third parties.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. The licensing of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. More established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected current or future product candidates, which could materially harm our business, and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation. 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. Any of the foregoing could harm our competitive position, business, financial condition, results of operations and prospects.

Further, our licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse. In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. If, in the future, we co-own or license in technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

If we fail to comply with our obligations in our current or any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are dependent on patents, know-how and proprietary technology, both our own and in-licensed from collaborators. We may in the future enter into more license agreements with third parties under which we receive rights to intellectual property that are important to our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our current or future product candidates and use our and our licensors’ proprietary technologies without infringing the proprietary rights of third parties. Our success will also depend in part on the ability of our licensors to obtain, maintain and enforce patent protection for our licensed intellectual property, in particular, those patents to which we have secured exclusive rights. Our licensors may not successfully prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Further, we may have limited control over these activities or any other intellectual property that may be in-licensed. For example, we cannot be certain that such activities by licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors’ infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. In the event our licensors fail to adequately pursue and maintain patent protection for patents and applications they control, and to timely cede control of such prosecution to us, our competitors might be able to enter the market, which would have a material adverse effect on our business.

In addition, our current and future intellectual property license agreements may require us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements (including as a result of COVID-19 impacting our operations), we use the licensed intellectual property in an unauthorized manner or we

are subject to bankruptcy-related proceedings, the terms of the licenses may be materially modified, such as by rendering currently exclusive licenses non-exclusive, or it may give our licensors the right to terminate their respective agreement with us. Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our current or future product candidates, the QuEEN platform, or other technologies, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours, and we may be required to cease our development and commercialization of certain of our current or future product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Disputes may also arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our current or future product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the priority of invention of any patented technology; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners.

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

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

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States

transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

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

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending patent application in the U.S. and abroad that is relevant to or necessary for the commercialization of our current or future product candidates in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. As mentioned above, patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our current or future product candidates could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our current or future product candidates or the use of our current or future product

candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our current or future product candidates. We may incorrectly determine that our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our current or future product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our current or future product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, which may be significant, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates or technologies that are held to be infringing. We might, if possible, also be forced to redesign current or future product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not guarantee commercial success of current or future product candidates or other business activities. 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 following examples are illustrative:

- patent applications that we own or may in-license may not lead to issued patents;
- patents, should they issue, that we may own or in-license, may not provide us with any competitive advantages, may be narrowed in scope, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology, including compounds that are similar to the chemical compositions of our current or future product candidates, that is similar to our technology or aspects of our technology but that is not covered by the claims of any patents we may own or in-license, should any patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by a patent application that we own or may in-license;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing, misappropriating or otherwise violating our intellectual property rights;

- our competitors might conduct research and development activities in the U.S. and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- 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 choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;
- 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, financial condition, results of operations and prospects.

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

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

We are highly dependent on the research and development, clinical and business development expertise of Markus Warmuth, M.D., our Chief Executive Officer, Owen Wallace, Ph.D., our Chief Scientific Officer, John Castle, Ph.D., our Chief Data Scientist, Sharon Townson, our Chief Technology Officer and Ajim Tamboli, our Chief Financial Officer, as well as the other principal members of our management and scientific teams. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization 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.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be 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 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 of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. In addition, in order to induce employees to continue their employment with us, we have provided equity awards that vest

over time and the value to our employees of such equity awards may be significantly affected by movements in our stock price that are beyond our control and may be at any time insufficient to counteract more lucrative offers from other companies. If we are unable to continue to attract and retain high quality personnel, the rate and success at which we can develop and commercialize product candidates will be limited.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of April 19, 2021, we had 60 full-time employees. We also contract for the services of 3.2 full-time equivalent employees through our agreement with Ridgeline. We intend to hire new employees to assume activities and responsibilities from Ridgeline personnel and conduct our research and development activities in the future. Any delay in hiring such new employees or disruption in the transition of activities and responsibilities from Ridgeline personnel could result in delays in our research and development activities and would harm our business. In connection with becoming a public company, we expect to increase our number of employees and the scope of our operations, including the areas of data sciences, platform biology and chemistry, drug discovery, clinical development, finance, business development, and legal. To manage our anticipated development and expansion, 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. Our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This 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. The expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We have offices in multiple countries and we may further expand in the future, which presents challenges in managing our business operations.

We are headquartered in Boston, Massachusetts and have offices in Basel, Switzerland. Conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including, among other things:

- the increased complexity and costs inherent in managing international operations;
- diverse regulatory, financial and legal requirements, and any future changes to such requirements, in one or more countries where we are located or do business;
- country-specific tax, labor and employment laws and regulations;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and other regulations;
- liabilities for activities of, or related to, our international operations or product candidates;
- changes in currency rates; and

- regulations relating to data security and the unauthorized use of, or access to, commercial and personal information.

We continue to expand our operations, and our corporate structure and tax structure is complex. In connection with our current and future potential partnerships, we are actively engaged in developing and applying technologies and intellectual property with a view toward commercialization of products globally, often with commercialization partners. In connection with those activities, we already have and will likely continue to engage in complex cross-border and global transactions involving our technology, intellectual property and other assets, between us and other entities such as partners and licensees, and between us and our subsidiaries. Such cross-border and global arrangements are both difficult to manage and can potentially give rise to complexities in areas such as tax treatment, particularly since we are subject to multiple tax regimes and different tax authorities can also take different views from each other, even as regards the same cross-border transaction or arrangement. There can be no assurance that we will effectively manage this increased complexity without experiencing operating inefficiencies, control deficiencies or tax liabilities. Significant management time and effort is required to effectively manage the increased complexity of our company, and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We or the third parties upon whom we depend may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities on which we rely, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. For example, following Hurricane Maria, shortages in production and delays in a number of medical supplies produced in Puerto Rico resulted, and any similar interruption due to a natural disaster affecting us or any of our third-party manufacturers could materially delay our operations.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, including most recently in connection with the COVID-19 pandemic. There can be no assurance that further volatility in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets continue to be volatile it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and a general economic downturn.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our

current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, pandemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party 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 are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our current or future product candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of data from preclinical studies or future clinical trials for our current or future product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, other data or applications relating to our technology or current or future product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our current or future product candidates could be delayed.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a

material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (*e.g.*, state breach notification laws), federal (*e.g.*, HIPAA, as amended by HITECH), and international law (*e.g.*, the EU General Data Protection Regulation, or GDPR) and may cause a material adverse impact to our reputation, affect our ability to use collected data, conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above, as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading laws.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U.S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Other activities subject to these laws include the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We intend to adopt, prior to the completion of this offering, a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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 criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, reputational harm, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

As of December 31, 2020, we had federal and state net operating loss carryforwards of $2.8 million and $2.8 million, respectively, which begin to expire in various amounts in 2039 (other than federal net operating loss carryforwards arising in taxable years beginning after December 31, 2019, which are not subject to expiration). As of December 31, 2020, we had foreign net operating loss carryforwards of $38.5 million that expire in 2026. As of December 31, 2020, we also had federal and state research and development tax credit carryforwards of $0.3 million and $0.1 million, respectively, which begin to expire in 2034. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period.

Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits.

Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under "Risk factors—Risks related to our financial position and capital needs," we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know

whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards that are subject to limitation by Sections 382 and 383 of the Code.

Changes in tax law may adversely affect us or our investors.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service, or IRS, and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Risks related to our common stock and this offering

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of preclinical studies and clinical trials of our current or future product candidates or those of our competitors;
- unanticipated safety concerns related to the use of any of our product candidates;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our current or future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional current or future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- product liability claims or other litigation;
- changes in the structure of healthcare payment systems;

- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk factors” section.

The stock market in general, and the Nasdaq Global Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

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

Prior to this offering, there has been no public market for shares of our common stock. Although we intend to apply to list our common stock on The Nasdaq Global Market, an active trading market for our common stock may never develop or be sustained following this offering. The initial public offering price of our common stock was determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the assumed initial public offering price of $ per share, the midpoint of the range set forth on the cover of this prospectus, purchasers of common stock in this offering will experience immediate dilution of $ per share in net tangible book value of the common stock. In addition, investors purchasing common stock in this offering will contribute % of the total amount invested by stockholders since inception but will only own % of the shares of common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See the section of this prospectus entitled “Dilution” for a more detailed description of the dilution to new investors in the offering.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or current or future product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these

securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, discovery programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. In the event we do have research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. Additionally, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses in our internal control over financial reporting, it could have an adverse effect on our company.

We have identified material weaknesses in our internal control over financial reporting for the years ended December 31, 2020 and 2019. The material weaknesses we identified were (i) we did not maintain an effective control environment as we did not maintain a sufficient complement of accounting and financial reporting resources commensurate with our financial reporting requirements, (ii) we did not maintain an effective risk assessment process, which led to improperly designed controls, (iii) we did not maintain appropriate control activities to support the appropriate segregation of duties over the review of account reconciliations and manual journal entries, and (iv) we did not document, thoroughly communicate and monitor controls processes and relevant accounting policies and procedures. These material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. Had we performed an evaluation of our internal control over financial reporting in accordance with Section 404, additional control deficiencies may have been identified by management, and those control deficiencies could have also represented one or more material weaknesses.

In an effort to remediate the material weaknesses, we have retained an accounting consulting firm to provide additional depth and breadth in our technical accounting and financial reporting capabilities. We have also hired additional qualified accounting and finance personnel to provide needed levels of expertise in our internal accounting function and maintain appropriate segregation of duties. We intend to complete an appropriate risk assessment to identify relevant risks and specify needed objectives. We intend to formalize and communicate our policies and procedures surrounding our financial close, financial reporting and other accounting processes.

We intend to further develop and document necessary policies and procedures regarding our internal control over financial reporting, such that we are able to perform a Section 404 analysis of our internal control over financial reporting when and as required following the completion of this offering. We cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. We also cannot assure you that we have identified all or that we will not have additional material weaknesses in the future. Accordingly, a material weakness may still exist when we report on the effectiveness of our internal control over financial reporting for purposes of our attestation when required by reporting requirements under the Exchange Act or Section 404 after this offering. Further, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

We expect to incur additional costs to remediate these control deficiencies, though there can be no assurance that our efforts will be successful or avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing 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.

Our executive officers, directors, principal stockholders and their affiliates will continue to exercise significant influence over our company after this offering, which will limit your ability to influence corporate matters and could delay or prevent a change in corporate control.

Immediately following the completion of this offering, and disregarding any shares of common stock that they purchase in this offering, the existing holdings of our executive officers, directors, principal stockholders and their affiliates will represent beneficial ownership, in the aggregate, of approximately % of our outstanding common stock, assuming no exercise of the underwriters' option to acquire additional common stock in this offering and assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus. In addition, six of our directors, including our chief executive officer, are affiliated with our principal stockholders. As a result, these stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests with respect to their common stock that are different from those of investors in this offering. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock. 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 the section of this prospectus titled "Principal stockholders" for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

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.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Securities Exchange Act of 1934, as

amended, or the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as “say on pay” and proxy access. Emerging growth companies may implement many of these requirements over a longer period and up to five years from the pricing of this offering. We intend to take advantage of these extended transition periods, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our fourth amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and the effectiveness of our second amended and restated bylaws, which will become effective upon the effectiveness of the registration statement of which this prospectus is a part, will contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;

- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, or DGCL, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws that will become effective upon the effectiveness of our registration statement designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws that will become effective upon the effectiveness of our registration statement, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of or based on a breach of a fiduciary duty owed by any director, officer or other employee of ours to us or our stockholders; (iii) any action asserting a claim pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended, or the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while

the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in this prospectus lapse, the market price of our common stock could decline. Based upon the number of shares of common stock, on an as-converted basis, outstanding as of , upon the completion of this offering, we will have outstanding a total of shares of common stock, assuming no exercise of the underwriters' option to purchase an additional shares. Of these shares, as of the date of this prospectus, approximately shares of our common stock, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable, without restriction, in the public market immediately following this offering, assuming that current stockholders do not purchase shares in this offering. The representatives of the underwriters, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. After the lock-up agreements expire, based upon the number of shares of common stock, on an as-converted basis, outstanding as of , up to an additional shares of common stock will be eligible for sale in the public market, approximately % of which shares are held by directors, executive officers and other affiliates and will be subject to certain limitations of Rule 144 under the Securities Act.

Upon completion of this offering, shares of common stock that are either subject to outstanding options, reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

After this offering, the holders of approximately shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market our common stock.

We have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering and the concurrent private placements, 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 the net proceeds are being used appropriately. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering and the

concurrent private placements. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering and the concurrent private placements in a manner that does not produce income or that loses value.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our 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 generally accepted accounting principles. In connection with this offering, we intend to begin the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell any of our present or future product candidates that may receive regulatory approval.

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 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 controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the 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.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. 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 reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden

parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we complete this offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (ii) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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 elected to not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

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 many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

After the completion of this offering, we may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our operating results could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. If our assumptions change or if actual circumstances differ from our assumptions, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Special note regarding forward-looking statements

This prospectus, including the sections entitled “Prospectus summary,” “Risk factors,” “Management’s discussion and analysis of financial condition and results of operations,” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation, timing, progress, results, cost and success of our current and future research and development programs and preclinical studies, including our expectations for our GSPT1-directed MGD molecules;
- the initiation, timing, progress, results, cost and success of our future clinical trials, including statements regarding the period during which the results of the clinical trials will become available;
- our ability to continue to develop our proprietary protein degradation platform called QuEEN and to expand our proteomics and translational medicine capabilities;
- the potential advantages of our platform technology and product candidates;
- the extent to which our scientific approach and platform technology may target proteins that have been considered undruggable or inadequately drugged;
- our plans to submit an IND application to the FDA for our lead GSPT1-directed MGD product candidate and future product candidates;
- the potential benefits of strategic collaborations and our ability to enter into strategic collaborations with third parties who have the expertise to enable us to further develop our biological targets, product candidates and platform technology;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to manufacture, including through third-party manufacturers, our product candidates for preclinical use, future clinical trials and commercial use, if approved;
- our ability to commercialize our product candidates, including our ability to establish sales, marketing and distribution capabilities;
- the rate and degree of market acceptance of our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- our ability to establish and maintain intellectual property rights covering our current and future product candidates and technologies;
- the implementation of our business model and strategic plans for our business, product candidates, and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;

- our financial performance;
- developments in laws and regulations in the United States and foreign countries;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our use of the proceeds from this offering;
- the impact of the COVID-19 pandemic on our business and operations; and
- other risks and uncertainties, including those listed under the section entitled “Risk factors.”

In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus forms a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section entitled “Risk factors” and elsewhere in this prospectus.

Use of proceeds

We estimate that the net proceeds to us from the sale of shares of our common stock in this offering will be approximately $ million, or approximately $ if the underwriters exercise in full their option to purchase additional shares, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1.0 million shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) net proceeds to us from this offering by $ million, assuming no change in the assumed initial public offering price per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the offering price or the number of shares by these amounts would have a material effect on our intended uses of the net proceeds from this offering, although it may impact the amount of time prior to which we may need to seek additional capital.

As of March 31, 2021, we had cash and cash equivalents of $168.4 million. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to fund the development of our GSPT1 program through ;
- approximately $ million to continue to develop our QuEEN platform;
- approximately $ million for the continued development of our discovery programs through ; and
- the remaining proceeds for working capital and other general corporate purposes.

Based on our current plans, we believe our existing cash and cash equivalents, together with the net proceeds from this offering, will be sufficient to fund our operations and capital expenditure requirements through .

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. 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 closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the status of and results from pre-clinical studies or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, 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 any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our results of operations, financial condition, capital requirements and other factors deemed relevant by our board of directors.

Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of March 31, 2021 on:

- an actual basis;
- a pro forma basis to give effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 109,686,035 shares of common stock upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation in connection with the completion of this offering; and
- a pro forma as adjusted basis to give further effect to (i) the pro forma adjustments described above and (ii) the receipt of $ million in estimated net proceeds from the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with “Management’s discussion and analysis of financial condition and results of operations” and our audited financial statements and related notes, each included elsewhere in this prospectus.

	As of March 31, 2021		
(in thousands, except share amounts and par value share amounts)	**Actual**	**Pro forma**	**Pro forma as adjusted**
Cash and cash equivalents	$168,436	$ 168,436	$
Convertible preferred stock (Series A, A-2, B and C), $0.0001 par value; 109,686,035 shares authorized; 109,686,035 shares issued and outstanding, actual; shares authorized, issued and outstanding, pro forma and pro forma as adjusted	$231,172	$ —	$
Stockholders’ equity (deficit):			
Preferred stock, $0.0001 par value: no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding pro forma and pro forma as adjusted	—	—	
Common stock, $0.0001 par value: 136,654,851 shares authorized; 7,699,359 shares issued and outstanding, actual; 136,654,851 shares authorized, 117,385,394 shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1	12	
Additional paid-in capital	656	231,817	
Accumulated other comprehensive loss	(920)	(920)	
Accumulated deficit	(60,353)	(60,353)	
Total stockholders’ equity (deficit)	(60,616)	170,556	
Total capitalization	$170,556	$ 170,556	$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ equity (deficit) and total capitalization by approximately $ million, assuming that the number of shares offered, as set forth on the cover of this prospectus, remains the same and after deducting estimated

underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered would increase (decrease) each of our pro forma as adjusted cash and cash equivalents, total assets, additional paid-in capital, total stockholders' equity (deficit) and total capitalization by approximately $ million, assuming the assumed initial public offering price per share as set forth on the cover of this prospectus remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

The table above excludes the following shares:

- 6,464,649 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2021, with a weighted-average exercise price of $0.57 per share under our 2020 Stock Option and Grant Plan;
- 9,470,232 shares of our common stock issuable upon the exercise of stock options granted after March 31, 2021, with a weighted-average exercise price of $1.76 per share under our 2020 Stock Option and Grant Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of (i) shares of common stock reserved for future issuance under our 2020 Stock Option and Grant Plan as of March 31, 2021, (ii) shares of common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, which will become effective on the date immediately prior to the date of this prospectus, and (iii) shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, which will become effective on the date immediately prior to the date of this prospectus.

Dilution

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

Net tangible book value (deficit) per share is determined by dividing our total tangible assets (which excludes deferred offering costs) less our total liabilities and convertible preferred stock by the number of shares of common stock outstanding. Our historical net tangible book value (deficit) as of March 31, 2021 was $(60.6) million, or $(7.87) per share. Our pro forma net tangible book value as of March 31, 2021 was approximately $170.6 million, or $1.45 per share of common stock. Our pro forma net tangible book value per share represents the amount of our total tangible assets (which excludes deferred offering costs) reduced by the amount of our total liabilities and divided by the total number of shares of our common stock outstanding as of March 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 109,686,035 shares of common stock upon the closing of this offering.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of shares of common stock in this offering and the pro forma as adjusted net tangible book value per share of common stock immediately after completion of this offering. After giving effect to (i) the pro forma adjustments set forth above and (ii) our sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been approximately $ million, or $ per share of our common stock. This represents an immediate increase in pro forma net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to investors in this offering, as illustrated in the following table:

Assumed initial public offering price per share		$
Historical net tangible book value per share as of March 31, 2021	$	
Increase in net tangible book value per share attributable to the conversion of outstanding preferred stock		
Pro forma net tangible book value per share as of March 31, 2021		
Increase in pro forma net tangible book value per share attributable to new investors in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors in this offering		$

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) each of the pro forma as adjusted net tangible book value per share after this offering, and dilution per share to new investors in this offering by approximately $ million, assuming that the number of shares offered, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered would increase (decrease) each of the pro forma net tangible book value per share after this offering, and dilution per share to new investors in this offering by approximately $ million, assuming the assumed initial public offering price per share as set forth on the cover of this prospectus remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information is

illustrative only, and we will adjust this information based on the actual initial public offering price and other terms of this offering determined at pricing.

If the underwriters exercise their option in full to purchase additional shares, the pro forma as adjusted net tangible book value per share after this offering would be $ per share (representing an increase from the pro forma net tangible book value per share of $ per share to our existing stockholders) and the dilution to new investors in this offering would be $ per share.

The following table shows, as of March 31, 2021, on a pro forma as adjusted basis described above, the differences between the existing stockholders and the purchasers of shares in this offering with respect to the number of shares purchased from us, the total consideration paid to us (based on an assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover of this prospectus), which includes net proceeds received from the issuance of common and convertible preferred stock, cash received from the exercise of stock options, and the value of any stock issued for services and the average price paid per share (in thousands, except share and per share amounts, and percentages):

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New public investors					
Total		100%	$	100%	

Each $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the estimated price range set forth on the cover of this prospectus, would increase (decrease) total consideration paid by new investors and total consideration paid by all stockholders by approximately $ million, assuming that the number of shares offered, as set forth on the cover of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered in this offering would increase (decrease) total consideration paid by new investors and total consideration paid by all stockholders by approximately $ million, assuming the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions.

In addition, to the extent that any outstanding options or warrants are exercised, investors in this offering will experience further dilution.

Except as otherwise indicated, the above discussion and tables assume no exercise of the underwriters' option to purchase additional shares. If the underwriters exercise their option to purchase additional shares in full, our existing stockholders would own % and our new investors would own % of the total number of shares of our common stock outstanding upon the completion of this offering.

The number of shares of common stock outstanding as of March 31, 2021 excludes:

- 6,464,649 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2021, with a weighted-average exercise price of $0.57 per share under our 2020 Stock Option and Grant Plan;
- 9,470,232 shares of our common stock issuable upon the exercise of stock options granted after March 31, 2021, with a weighted-average exercise price of $1.76 per share under our 2020 Stock Option and Grant Plan; and
- shares of common stock reserved for future issuance under our stock-based compensation plans, consisting of (i) shares of common stock reserved for future issuance under our 2020 Stock Option

and Grant Plan as of March 31, 2021, (ii) shares of common stock reserved for future issuance under our 2021 Stock Option and Incentive Plan, which will become effective on the date immediately prior to the date of this prospectus, and (iii) shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan, which will become effective on the date immediately prior to the date of this prospectus.

Selected financial information

The following tables present the selected financial data for our business. The selected combined and consolidated statements of operations data for the years ended December 31, 2020 and 2019 and the selected combined and consolidated balance sheet data as of December 31, 2020 and 2019 have been derived from our audited combined and consolidated financial statements and related notes included elsewhere in this prospectus. The selected combined and consolidated statements of operations data for the three months ended March 31, 2021 and 2020 and the selected combined and consolidated balance sheet data as of March 31, 2021 have been derived from our unaudited condensed combined and consolidated financial statements and related notes included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and in the section of this prospectus entitled "Management's discussion and analysis of financial condition and results of operations." Our historical results are not necessarily indicative of the results to be expected in the future and our interim results are not are not necessarily indicative of the results that may be expected for the full fiscal year. The selected financial data included in this section are not intended to replace the combined and consolidated financial statements and are qualified in their entirety by the combined and consolidated financial statements and related notes included elsewhere in this prospectus.

	Three months ended March 31,		Year ended December 31,	
(in thousands, except share and per share data)	**2021**	**2020**	**2020**	**2019**
Combined and Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	$ 9,273	$ 3,815	$ 24,005	$ 7,350
General and administrative	2,231	478	4,005	644
Total operating expenses	11,504	4,293	28,010	7,994
Loss from operations	(11,504)	(4,293)	(28,010)	(7,994)
Other income (expense):				
Interest income (expense), net	6	(3)	9	(1)
Foreign currency exchange loss, net	182	(6)	(198)	(21)
Changes in fair value of preferred stock tranche obligations, net	(960)	0	(7,680)	276
Total other (expense) income	(772)	(9)	(7,869)	254
Net loss	$ (12,276)	$ (4,302)	$ (35,879)	$ (7,740)
Net loss per share attributable to common stockholders—basic and diluted(1)	$ (2.03)	$ (0.86)	$ (6.70)	$ (1.55)
Weighted-average number of shares used in computing net loss per common share—basic and diluted(1)	6,034,427	5,000,000	5,355,459	5,000,000
Pro forma net loss per common share—basic and diluted(1)	$ (0.16)		$ (0.91)	
Weighted-average number of shares used in computing pro forma net loss per common share—basic and diluted(1)	76,745,329		39,345,241	

(1) See Note 13 to our combined and consolidated financial statements for the years ended December 31, 2020 and 2019 and Note 9 to our unaudited condensed combined and consolidated financial statements for the three months ended March 31, 2021 and 2020 appearing elsewhere in this prospectus for further details on the calculation of basic and diluted net loss per share attributable to common stockholders. The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic

and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 and the three months ended March 31, 2021 have been prepared to give effect to the automatic conversion of all outstanding shares of convertible preferred stock into common stock as if the proposed initial public offering had occurred on the later of the beginning of each period or the issuance date of the convertible preferred stock.

(in thousands)	As of March 31, 2021	As of December 31, 2020	2019
Combined and Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 168,436	$ 41,699	$ 5,995
Total assets	180,603	49,378	11,094
Working capital(2)	162,616	14,316	5,467
Total liabilities	10,047	30,342	4,292
Convertible preferred stock	231,172	67,764	18,950
Total stockholders' deficit	(60,616)	(48,728)	(12,148)

(2) We define working capital as current assets less 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 "Selected financial information" and our combined and consolidated 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 "Special note regarding forward-looking statements."

Overview

We are a biopharmaceutical company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. We have developed a proprietary protein degradation platform, called QuEEN, that enables us to rapidly identify protein targets and molecular glue degrader, or MGD, product candidates that are designed to eliminate therapeutically-relevant proteins in a highly selective manner. We believe our small molecule MGDs may give us significant advantages over existing therapeutic modalities, including other protein degradation approaches, by allowing us to target proteins that have been considered undruggable or inadequately drugged. We focus on therapeutic targets backed by strong biological and genetic rationale with the goal of discovering and developing novel precision medicines.

We were incorporated in Delaware in November 2019 and are headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland. To date, we have been financed primarily by gross proceeds of approximately $223.5 million from the issuance of convertible promissory notes and convertible preferred stock, including our most recent sales and issuances of convertible preferred stock in February and March 2021.

Contribution and exchange

Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated in April 2018. Monte Rosa Therapeutics, Inc. was incorporated in November 2019. In 2020, Monte Rosa Therapeutics, Inc. and Monte Rosa Therapeutics AG, entities under common control since the incorporation of Monte Rosa Therapeutics, Inc., consummated a contribution and exchange agreement, or the Contribution and Exchange, whereby Monte Rosa Therapeutics, Inc. (i) acquired the net assets and shareholdings of Monte Rosa Therapeutics AG via a one-for-one exchange of equity between Monte Rosa Therapeutics, Inc. and the shareholders of Monte Rosa Therapeutics AG in a common control reorganization. Accordingly, the historical financial information has been retrospectively adjusted to include the historical results and financial position of the Company combined with Monte Rosa Therapeutics AG's historical results and financial position, after the elimination of all intercompany accounts and transactions. See the section entitled "Prospectus summary—Corporate information" for more information on the contribution and exchange transaction.

Liquidity

Since inception, we have had significant operating losses. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures and, to a lesser extent, general and administrative expenditures. Our net loss was $35.9 million and $7.7 million for the years ended December 31, 2020 and 2019, respectively, and our net loss was $12.3 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of $60.4 million and $168.4 million in cash and cash equivalents. In February 2021, we issued 24,000,000 shares of our Series B Preferred Stock pursuant to the Company's Series B Preferred Stock tranche obligation for aggregate gross proceeds of $48.0 million. In March 2021, we authorized the sale of up to 32,054,521 shares of its Series C convertible preferred stock at a price of $2.9637 per share, or Series C Preferred, and issued the authorized shares of Series C Preferred to several new and existing investors for aggregate gross proceeds of $95.0 million.

Business effects of COVID-19

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. To date, our financial conditions and operations have not been significantly impacted by the COVID-19 outbreak; however, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations, liquidity and financial condition will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

To date, our vendors have been able to continue to provide services and supply reagents, materials, and products and currently do not anticipate any disruption in services or interruptions in supply. However, we are continuing to assess the potential impact of the COVID-19 pandemic on our business and operations, including our expenses, and our ability to hire and retain employees.

The COVID-19 pandemic has caused us to modify our business practices (including but not limited to curtailing or modifying employee travel, moving to partial remote work, and cancelling physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, patients and business partners.

Our office-based employees have been working from home since March 2020, while ensuring essential staffing levels in our operations remain in place, including maintaining key personnel in our laboratories.

For additional information on the various risks posed by the COVID-19 pandemic, please read the section entitled "Risk factors" in this prospectus.

Components of operating results

Research and development expenses

Our research and development expenses include:

- expenses incurred under agreements with consultants, third-party service providers that conduct research and development activities on our behalf;
- personnel costs, which include salaries, benefits, pension and stock-based compensation;

- laboratory and vendor expenses related to the execution of preclinical studies;
- laboratory supplies and materials used for internal research and development activities; and
- facilities and equipment costs.

Most of our research and development expenses have been related to the development of our QuEEN platform and discovery and lead optimization efforts of our GSPT1 program. We have not reported program costs since our inception because we have not historically tracked or recorded our research and development expenses on a program-by-program basis. We use our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as we advance our programs and conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects, the costs of related clinical development costs or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and administrative expenses

Our general and administrative expenses consist primarily of personnel costs and other expenses for outside professional services, including legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and other operating costs. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, and the potential commercialization of our product candidates and development of commercial infrastructure. We also anticipate our general and administrative costs will increase and with respect to the hiring of additional personnel, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC reporting requirements, insurance and investor relations costs.

Non-operating income and (expense)

Our non-operating income and (expense) includes (i) interest earned on our investments, including principally U.S. government-backed money-market funds; (ii) gains and losses on transactions of our Swiss subsidiary denominated in currencies other than the U.S. Dollar; and (iii) changes in the fair value of our preferred stock tranche obligations.

Results of operations for the three months ended March 31, 2021 and 2020

The following sets forth our results of operations:

(in thousands)	Three months ended March 31, 2021	2020	Dollar change
Operating expenses:			
Research and development	$ 9,273	$ 3,815	$ 5,385
General and administrative	2,231	478	1,826
Total operating expenses	11,504	4,293	7,211
Loss from operations	(11,504)	(4,293)	(7,211)
Other expense	(772)	(9)	(763)
Net loss	$(12,276)	$(4,302)	$ (7,974)

Research and development expenses

Research and development expenses were comprised of:

(in thousands)	Three months ended March 31, 2021	2020	Dollar change
External research and development services	$ 4,303	$ 3,567	$ 736
Personnel costs	2,785	58	2,727
Laboratory and related expenses	1,031	41	990
Facility costs and other expenses	1,154	149	1,005
Research and development expenses	$ 9,273	$ 3,815	$ 5,458

As of March 31, 2021, we had 45 employees engaged in research and development activities in our facilities in the United States and Switzerland. As of March 31, 2020, we had no research and development employees.

Our research and development activities consist primarily of costs associated with the development of our QuEEN platform and discovery and lead optimization efforts of our GSPT1 program. The increase for the three months ended March 31, 2021 as compared to 2020 was primarily due to the expansion of research and development activities in the United States and Switzerland including increased headcount and facilities, as well as corresponding increases in laboratory related expenses.

General and administrative expenses

General and administrative expenses to support our business activities were comprised of:

(in thousands)	Three months ended March 31, 2021	2020	Dollar change
Personnel costs	$ 1,484	$ 269	$ 1,215
Professional services	443	100	343
Facility costs and other expenses	304	109	268
General and administrative expenses	$ 2,231	$ 478	$ 1,826

As of March 31, 2021, we had 12 employees engaged in general and administrative activities principally in our U.S. facility. As of March 31, 2020, we had no general and administrative employees. Personnel and professional service costs increased in the three months ended March 31, 2021 as compared to 2020 as a result of increased headcount and expenses in support of our growth.

Other income (expense)

Other income (expense), net was comprised of:

	Three months ended March 31	
(in thousands)	**2021**	**2020**
Interest income (expense), net	$ 6	$ (3)
Foreign currency exchange gain (loss), net	182	(6)
Changes in fair value of preferred stock tranche obligations, net	(960)	0
Other income (expense)	$ (772)	$ (9)

Following the contribution and exchange transactions and our Series A-2 convertible preferred stock financing in April 2020, we began investing a portion of our capital in U.S. government backed money market funds held in a custodial account.

Foreign exchange gains on transactions of our Swiss subsidiary denominated in other than the U.S. dollar increased in the three months ended March 31, 2021 as to compared to the three months ended March 31, 2020 principally due to increased growth in operations compared to the prior year, combined with a strengthening of the U.S. Dollar with respect to, principally, the Swiss franc.

The changes in the fair value of our preferred stock tranche obligations is principally attributable to assumptions with respect to our overall enterprise value.

Results of operations for the years ended December 31, 2020 and 2019

The following sets forth our results of operations:

	Year ended December 31,		
(in thousands)	**2020**	**2019**	**Dollar change**
Operating expenses:			
Research and development	$ 24,005	$ 7,350	$ 16,655
General and administrative	4,005	644	3,361
Total operating expenses	28,010	7,994	20,016
Loss from operations	(28,010)	(7,994)	(20,016)
Other (expense) income	(7,869)	254	(8,123)
Net loss	$(35,879)	$(7,740)	$ (28,139)

Research and development expenses

Research and development expenses were comprised of:

(in thousands)	Year ended December 31, 2020	2019	Dollar change
External research and development services	$ 17,444	$ 7,165	$ 10,279
Personnel costs	3,293	—	3,293
Laboratory and related expenses	1,330	41	1,289
Facility costs and other expenses	1,938	144	1,794
Research and development expenses	$ 24,005	$ 7,350	$ 16,655

As of December 31, 2020, we had 30 employees engaged in research and development activities in our facilities in the U.S. and Switzerland. In 2019 we had no research and development employees.

Our research and development activities consist primarily of costs associated with the development of our QuEEN platform and discovery and lead optimization efforts of our GSPT1 program. The increase for the year ended December 31, 2020 as compared to 2019 was primarily due to the expansion of research and development activities in the United States and Switzerland including increased headcount and facilities as well as corresponding increases in laboratory related expenses.

General and administrative expenses

General and administrative expenses to support our business activities were comprised of:

(in thousands)	Year ended December 31, 2020	2019	Dollar change
Personnel costs	$ 2,564	$ 279	$ 2,285
Professional services	877	145	732
Facility costs and other expenses	564	220	344
General and administrative expenses	$ 4,005	$ 644	$ 3,361

As of December 31, 2020, we had 7 employees engaged in general and administrative activities principally in our US facility. In 2019 we had no general and administrative employees. Personnel and professional service costs increased in the year ended December 31, 2020 as compared to 2019 as a result of increased headcount and expenses in support of our growth.

Other expenses, net

Other income (expense), net was comprised of:

(in thousands)	Year ended December 31, 2020	2019
Interest income (expense), net	$ 9	$ (1)
Foreign currency exchange loss, net	(198)	(21)
Changes in fair value of preferred stock tranche obligations, net	(7,680)	276
Other (expense) income	$ (7,869)	$ 254

Following the contribution and exchange transactions and our Series A-2 convertible preferred stock financing in April 2020, we began investing a portion of our capital in U.S. government backed money market funds held in a custodial account.

Foreign exchange losses on transactions of our Swiss subsidiary denominated in other than the U.S. dollar increased in the year ended December 31, 2020 as to compared to the year ended December 31, 2019 principally due to increased growth in operations compared to the prior year, combined with a weakening of the U.S. Dollar with respect to, principally, the Swiss franc.

The changes in the fair value of our preferred stock tranche obligations is principally attributable to assumptions with respect to our overall enterprise value.

Liquidity and capital resources

Overview

We were incorporated in November 2019 and our operations to date have been financed primarily by gross proceeds of approximately $223.5 million from the sale of convertible promissory notes and our convertible preferred stock, including our most recent financings in February and March 2021. As of March 31, 2021, we had $168.4 million in cash and cash equivalents. We have incurred losses since our inception and, as of March 31, 2021, we had an accumulated deficit of $60.4 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Cash flows

The following table summarizes our cash flows for the periods indicated:

	Three months ended March 31,		Year ended December 31,	
(in thousands)	**2021**	**2020**	**2020**	**2019**
Net cash (used in) provided by:				
Operating activities	$ (13,815)	$ (3,376)	$ (23,053)	$ (6,173)
Investing activities	(2,217)	(13)	(3,389)	(1,385)
Financing activities	142,769	—	60,060	15,000
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 126,737	$ (3,389)	$ 33,618	$ 7,442

Operating activities

Net cash used in operating activities of $13.8 million during the three months ended March 31, 2021 was attributable to our net loss of $12.2 million and a net decrease in our working capital of $3.1 million, offset by non-cash charges of $1.5 million principally with respect to changes in fair value of our preferred stock tranche obligation, depreciation expense and stock-based compensation.

Net cash used in operating activities of $3.4 million during the three months ended March 31, 2020 was attributable to our net loss of $4.3 million, primarily offset by a $1.0 million net increase in our working capital.

Net cash used in operating activities of $23.1 million during the year ended December 31, 2020 was attributable to our net loss of $35.9 million, offset by a $4.2 million net increase in our working capital and non-cash charges of $8.6 million principally with respect to the changes in fair value of our preferred stock tranche obligations, depreciation expense and stock-based compensation.

Net cash used in operating activities of $6.2 million during the year ended December 31, 2019 was attributable to our net loss of $7.7 million, offset principally by increased working capital of $1.8 million and non-cash charges of $0.3 million principally with respect to the changes in fair value of our preferred stock tranche obligations.

Investing activities

For the three months ended March 31, 2021 and 2020, our investing activities consisted of purchases of property and equipment of $2.2 million and $13,000, respectively, as we expanded our operations.

For the years ended December 31, 2020 and 2019, our investing activities consisted of purchases of property and equipment of $3.4 million and $1.4 million, respectively, as we expanded our operations.

Financing activities

Net cash provided by financing activities for the three months ended March 31, 2021 amounted to $142.8 million comprised principally of aggregate net proceeds upon the issuance of our Series B and Series C convertible preferred stock in February and March 2021.

Net cash provided by financing activities for the year ended December 31, 2020 amounted to $60.1 million comprised principally of aggregate net proceeds upon the issuance of our Series A-2 and Series B convertible preferred stock in April and September 2020, respectively.

Net cash provided by financing activities for the year ended December 31, 2019 amounted to $15.0 million, which was comprised of $14.2 million aggregate net proceeds upon the issuance of our Series A convertible preferred stock, and $0.8 million received upon the issuance of convertible notes.

Funding requirements

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, costs relating to the build-out of our headquarters, laboratories and manufacturing facility, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, manufacturing costs, legal and other regulatory expenses and general overhead costs.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months. We base this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders, including investors in this offering, will be diluted, and the terms of these securities may

include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our current product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of manufacturing our lead product candidate or any future product candidates and any products we successfully commercialize, including costs associated with building-out our manufacturing capabilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the timing, receipt and amount of sales of any future approved or cleared products, if any; and
- the impact of the COVID-19 pandemic and the corresponding responses of businesses and governments.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our combined and consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these combined and consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and development expense and accruals

We record research and development expenses to operations as incurred. Research and development expenses represent costs incurred by us for development of our technology platform and the discovery and development of our product candidates and include: employee-related expenses, including salaries, benefits and non- cash stock-based compensation expense; external research and development expenses incurred under arrangements with third parties, including preclinical testing organizations, non-profit institutions and consultants; and other expenses, which include direct and allocated expenses for laboratory, facilities and other costs.

As part of the process of preparing financial statements, we are required to estimate and accrue expenses. We estimate costs of research and development activities conducted by service providers. Payments made prior to the receipt of goods or services to be used in research and development are deferred and recognized as expense in the period in which the related goods are received or services are rendered. If the costs have been prepaid, this expense reduces the prepaid expenses in the balance sheet, and if not yet invoiced, the costs are included in accrued liabilities in the balance sheet. We classify such prepaid assets as current or non-current assets based on our estimates of the timing of when the goods or services will be realized or consumed. These costs are a significant component of our research and development expenses.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established third-party service providers. We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from external third-party service providers. Amounts ultimately incurred in relation to amounts accrued for these services at a reporting date may be substantially higher or lower than our estimates.

We have and may continue to enter into license agreements to access and utilize certain technology. We evaluate if the license agreement is an acquisition of an asset or a business. To date none of our license agreements have been considered to be an acquisition of a business. For asset acquisitions, the upfront payments to acquire such licenses, as well as any future milestone payments made before product approval, are immediately recognized as research and development expense when due, provided there is no alternative future use of the rights in other research and development projects.

Preferred stock tranche obligations

Included in the terms of the Series A and Series B Preferred Stock Purchase Agreements were certain rights, or preferred stock tranche obligations, granted to the investors who purchased the Series A and Series B Preferred Stock. We concluded that the preferred stock tranche obligations met the definition of a freestanding financial instrument, as the preferred stock tranche obligations were legally detachable and separately exercisable from the Series A and Series B Preferred Stock. At initial recognition, we recorded these preferred stock tranche obligations as a liability on the balance sheets at their estimated fair value. The preferred stock tranche

obligations are subject to remeasurement at each balance sheet date, with changes in fair value recognized in our statements of operations.

Our preferred stock tranche obligations are measured at fair value using an option pricing valuation methodology. The fair value of preferred stock tranche obligations include inputs not observable in the market and thus represents a Level 3 measurement. The option pricing valuation methodology utilized requires inputs based on certain subjective assumptions, including (i) expected stock price volatility, (ii) calculation of an expected term, (iii) a risk-free interest rate, and (iv) expected dividends.

Significant judgment is used in determining these assumptions at initial recognition and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period.

Stock-based compensation

We recognize compensation costs related to stock-based awards to employees and non-employees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value of stock options, and the resulting stock-based compensation, using the Black-Scholes option-pricing model, or Black-Scholes. Stock-based compensation expense related to restricted stock granted to employees and non-employees is recognized based on the grant-date fair value of our common stock. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

We account for equity-based compensation in accordance with ASC 718, *Compensation-Stock Compensation*, or ASC 718. In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award.

We use a Black-Scholes option pricing model to determine fair value of our stock options. The Black-Scholes option pricing model includes various assumptions, including the fair value of common shares, expected life of our stock options, the expected volatility and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, stock-based compensation cost could have been materially impacted.

Furthermore, if we use different assumptions for future grants, stock-based compensation cost could be materially impacted in future periods.

We will continue to use judgment in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis. In addition to the assumptions used in Black-Scholes, the amount of stock-based compensation expense we recognize in our financial statements includes stock option forfeitures as they occurred.

Determination of the fair value of common stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors utilizing the valuation of our company’s enterprise value determined by a third party valuation expert, and in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

Our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status and results of preclinical studies for our product candidates;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the biopharmaceutical industry and trends within the biopharmaceutical industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company in light of prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Options granted

The following table sets forth, by grant date, the number of shares underlying options granted from January 1, 2020 through the date of this prospectus, the per share exercise price of options, the fair value per share of common stock on each grant date, and the estimated per share fair value of the options granted during the period:

Date of grant	Type of award	Number of common shares subject to options granted	Exercise price per share[1]	Fair value per share at grant date[2]	Estimated fair value per common share at grant date[1]
August 2020	Options	1,038,873	$ 0.32	$ 0.21	$ 0.32
December 2020	Options	6,747,273	$ 0.62	$ 0.41	$ 0.62
April 2021	Options	9,155,982	$ 1.74	$ 1.20	$ 1.74
May 2021	Options	314,250	$ 2.23	$ 1.53	$ 2.23

(1) The exercise price per share of common stock and fair value of our common stock represents the fair value of our common stock on the date of grant, as determined by our board of directors, after taking into account our most recently available contemporaneous valuation of our common stock as well as additional factors that may have changed since the date of such contemporaneous valuation through the date of grant.

(2) The estimated per share fair value of options reflects the weighted average fair value of options granted on each grant date, determined using the Black-Scholes option-pricing model.

Recently issued and adopted accounting pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to our combined and consolidated financial statements appearing elsewhere in this prospectus for a discussion of recent accounting pronouncements.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of December 31, 2020:

	Payments due by period				
(in thousands)	Total	Less than 1 Year	2 to 3 Years	4 to 5 Years	More than 5 Years
Operating lease commitments(1)	$8,896	$1,886	$3,370	$3,235	$ 405
Total	$8,896	$1,886	$3,370	$3,235	$ 405

(1) We lease facilities in Boston, Massachusetts under an operating lease through April 2021, and Basel, Switzerland under an operating lease through April 2024. In 2020, the Company entered into an agreement to lease a new facility in Boston commencing in March 2021 and moved into the new facility in April 2021. In April 2021, the Company entered into an agreement to lease a new facility in Basel, Switzerland commencing in April 2021.

License agreement

In April 2018, the Company entered into license, collaboration and investment agreements with CRT and the ICR for the purpose of development in the field of cereblon-mediated protein degradation or, the License and Collaboration. Pursuant to the License and Collaboration, CRT and the ICR granted the Company an exclusive and non-exclusive, worldwide, and sublicensable licenses under CRT's and the ICR's intellection property rights in the field of cereblon mediated protein degradation to discover, research, develop, have developed, use, keep, make, have made, market, import, offer for sale, and sell products in the field of cereblon-mediated protein degradation.

In consideration for the rights granted under the License Agreement, we issued an aggregate of 4,000,000 common shares to CRT, the ICR and affiliated founding scientists pursuant to the Formation and Investment Agreement at a price per share of CHF 0.01 for an aggregate purchase price of CHF 40,000 and paid CRT a technology access fee equal to approximately $42,000. The License Agreement will remain effective until terminated by written agreement between us, CRT and the ICR.

The Company is obligated to make milestone payments for achieving certain clinical progression events, aggregating up to $7 million for the first product candidate and $3.5 million for each subsequent product candidate. The aggregate amount of milestone payments and royalties to be paid will depend on whether or not the development candidates that the Company identifies are subject to the collaboration agreement with CRT and ICR. In addition, the Company is further required to pay low single-digit royalties on net sales for each product successfully developed and commercialized in the field of cereblon-mediated protein degradation under the terms of the License and Collaboration on a country by country basis until the later of (a) the date when the manufacture, use, offer for sale, sale or importation of a product is no longer covered by a valid claim in the country of sale, use or manufacture; (b) ten years from the first commercial sale of such product in the relevant country; and (c) the expiry of any extended exclusivity period granted with respect to an orphan drug designation, pediatric designation or other exclusivity in the relevant country. See the section entitled "Business—Our services, collaboration and licenses agreements" elsewhere in this prospectus as well as Note 6 to our annual combined and consolidated financial statements appearing elsewhere in this prospectus for a description of our collaboration and license agreements.

Off-balance sheet arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Quantitative and qualitative disclosures about market risk

Interest rate risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $168.4 million as of March 31, 2021. We generally have held our cash equivalents in interest-bearing, U.S. government backed money market funds. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Foreign currency exchange risk

Our results of operations are subject to foreign currency exchange rate fluctuations principally due to our operations in Switzerland. As a result, our combined and consolidated financial position, results of operations and cash flows can be affected by market fluctuations in foreign currency exchange rates, primarily with respect to the Swiss franc and the Euro. Fluctuations in the foreign currency exchange rates will affect our operating results, often in ways that are difficult to predict. In particular, as the U.S. dollar weakens versus other currencies the non-U.S. expense will increase when reported in U.S. dollars.

Emerging growth company status

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Therefore, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period and, as a result, we may adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-public companies instead of the dates required for other public companies. However, we may early adopt these standards.

Business

Overview

We are a biopharmaceutical company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. We have developed a proprietary protein degradation platform, called QuEEN, that enables us to rapidly identify protein targets and molecular glue degrader, or MGD, product candidates that are designed to eliminate therapeutically-relevant proteins in a highly selective manner. We believe our small molecule MGDs may give us significant advantages over existing therapeutic modalities, including other protein degradation approaches, by allowing us to target proteins that have been considered undruggable or inadequately drugged. We focus on therapeutic targets backed by strong biological and genetic rationale with the goal of discovering and developing novel precision medicines. These opportunities include oncology and non-oncology indications, including immunology, inflammation, neurological and genetic diseases. Our lead program is a series of potent, selective and orally bioavailable GSPT1-directed MGD molecules, one of which we plan to evaluate in molecularly-defined subsets of Myc-driven cancers. We expect to select a development candidate in and submit an Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or the FDA, in . Beyond our lead program, we have a number of discovery programs in our pipeline and intend to nominate at least two for lead optimization in 2021.

Our proprietary Quantitative and Engineered Elimination of Neosubstrates, or QuEEN, platform enables us to rationally design and develop small molecule MGDs that lead to the destruction of a therapeutically-relevant target protein by facilitating its tagging for removal. Our MGDs are drug-like small molecules that bring together a therapeutically-relevant target protein and an E3 ligase, leading to degradation of the target protein via the intracellular protein degradation system, called the proteasome. Our MGDs are non-heterobifunctional, in contrast to proteolysis targeting chimeras, or PROTACs. Central to our QuEEN platform is a detailed understanding of the molecular interactions promoted by our small molecule MGDs between E3 ligases and structural features, called degrons, on the surface of therapeutically-relevant proteins which have been considered undruggable or inadequately drugged. Key components of our QuEEN platform are:

- *Degron encyclopedia*: A growing catalogue of target proteins identified through our proprietary artificial intelligence, or AI, approach that enables us to identify structural features on protein surfaces that can serve as degrons for highly validated and therapeutically relevant, but otherwise undruggable or inadequately drugged, proteins
- *Proprietary MGD library*: A diverse and continuously growing chemical library of drug-like MGDs that are rationally designed based on our expertise in molecular glue anatomy
- *Glue-omics toolbox*: A tailored suite of biochemical, structural biology, cellular, proteomics and *in silico* screening tools that enable the discovery and optimization of MGD product candidates that efficiently recruit neosubstrates to E3 ligases utilizing degrons discovered through our AI approach

We are developing an oral MGD that targets GSPT1, a translational termination factor and degron-containing protein, for the treatment of cancers overexpressing one of the Myc family genes (c-Myc, N-Myc and L-Myc). The Myc transcription factors are some of the most frequently mutated, translocated and overexpressed oncogenes in human cancers. For example, around 10% of non-small cell lung cancer, or NSCLC, overexpress N-Myc and over 50% of small cell lung cancer, or SCLC, overexpress L-Myc. Myc-driven cancer cells are highly addicted to protein translation. Because of the key role of GSPT1 in protein synthesis, selective GSPT1 degradation by our MGD in these cells leads to cell death. In multiple Myc-driven preclinical models, we have shown that our lead GSPT1-directed MGD molecules are potent, selective, and well-tolerated, inducing tumor regression after oral administration. We anticipate initiating IND-enabling studies in and expect to submit an IND to the FDA in .

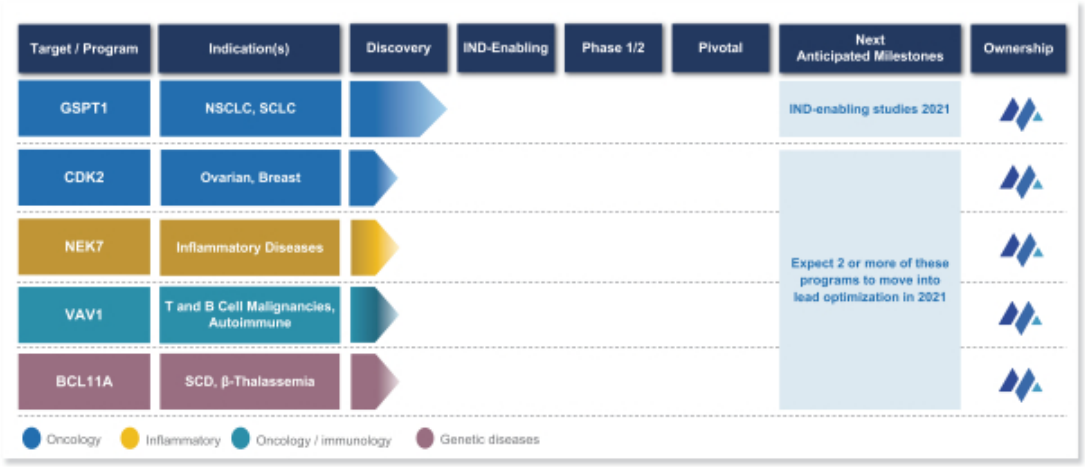
In addition to our oral GSPT1-directed MGD program, we are also advancing discovery programs identified with our QuEEN platform against multiple additional degron-containing targets that are highly validated and therapeutically relevant, but otherwise considered undruggable or inadequately drugged. We have been able to identify selective MGD molecules for CDK2, an oncology target whose activation is associated with poor prognoses in cancers such as ovarian, uterine, and breast cancer. We have also identified potential targets outside of oncology as exemplified by our NEK7 program. NEK7 is an activator of the NLRP3 inflammasome, a central regulator of cellular inflammatory responses to pathogens, damage and stress. Aberrant NLRP3 inflammasome activation is implicated in the pathogenesis of multiple autoimmune diseases, including Crohn's disease, neurodegenerative diseases, diabetes and liver disease. We have identified MGD molecules from our library that selectively degrade NEK7 in cells. Similarly, we have identified MGD molecules for VAV1, a target protein in autoimmune disease, and BCL11A, a therapeutically-relevant protein in hemoglobinopathies. We expect two or more of these discovery programs to move into lead optimization in 2021.

We believe we have identified a large number of therapeutically-relevant targets that are amenable to degradation by the MGDs discovered through our QuEEN platform. Applying our unique structural biology and computational tools, we have built and continue to grow an encyclopedia of over 1500 degron-containing proteins, many of which have robust links to human diseases. The majority of these proteins have been considered undruggable because they lack suitable small molecule binding pockets, which our MGDs do not require. We are systematically validating and rapidly advancing the most compelling of these targets while prioritizing those with a strong established therapeutic rationale for inclusion in our pipeline.

We are led by an experienced team of drug discovery and development experts with decades of experience in targeted protein degradation, molecular glues, chemistry, structural biology, data science, disease biology, translational medicine, and clinical development. We were founded by Professor Raj Chopra and Professor Ian Collins of The Institute for Cancer Research, UK, pioneers in the field of molecular glue degraders, and Versant Ventures. Since our inception, we have raised over $220 million in equity capital from leading investors including Aisling Capital, Amzak Health, Avoro Capital Advisors, funds and accounts managed by BlackRock, Cambridge Asset Management, Casdin Capital, Cormorant Asset Management, Fidelity Management & Research Company LLC, GV, HBM Healthcare Investments, New Enterprise Associates, funds and accounts advised by RTW Investments, LP, Sixty Degree Capital, funds and accounts advised by T. Rowe Price Associates, Inc, and Versant Ventures.

Our pipeline

Our internal discovery programs are focused on delivering precision medicine-based therapies to targets that have been considered undruggable or inadequately drugged in well-characterized biological pathways across clinical indications in oncology, inflammation, immunology and genetic diseases with high unmet needs. We currently retain worldwide rights to the programs shown in the chart below.



Our strategy

Our mission is to reshape disease treatment paradigms by discovering and developing a precision medicine-based portfolio of novel small molecule MGDs that selectively eliminate therapeutically-relevant proteins in a broad range of indications with significant unmet medical need. We believe the product candidates identified through our proprietary QuEEN platform can provide distinct advantages over other modalities to address targets that have been considered undruggable or inadequately drugged. In order to achieve our mission, key elements of our strategy include:

- *Continue to advance our GSPT1-directed MGD program into and through clinical development and seek regulatory approval*. We employ a core set of drug discovery and development principles to guide our target protein selection across various protein classes and therapeutic areas. We are specifically focused on delivering therapies to targets that have been considered undruggable or inadequately drugged in preclinically and clinically well-characterized biological pathways. We have generated data in preclinical models that demonstrate the potential of our GSPT1-directed MGDs to confer potent antitumor activity across multiple tumor types that are driven by the Myc family of transcription factors. Our lead molecules are potent, highly selective and orally bioavailable GSPT1-directed MGDs, one of which we plan to evaluate in molecularly-defined subsets of Myc-driven cancers. We expect to submit an IND for a development candidate in
- *Further expand the capabilities of our QuEEN platform to unlock the full therapeutic potential of MGDs*. Our QuEEN platform enables us to vastly expand the degradable proteome beyond conventionally druggable targets. Our approach is based on the computational identification of structural features on the surface of a protein, called degrons. We combine our AI-powered target discovery engine and proprietary library of rationally designed MGDs to selectively connect degron-containing targets to the E3 ligase protein, cereblon. QuEEN has the potential to help us better understand the optimal pairing of degron-containing proteins with ligases beyond cereblon to even further expand our target space. We will continue to invest in our QuEEN platform, including expanding our proteomics and translational medicine capabilities

- *Develop a pipeline of rationally designed MGDs to transform the treatment of diseases in multiple therapeutic areas*. Through our QuEEN platform, we have identified more than 1500 degron-containing proteins. Many of these have been highly credentialed as potential therapeutic targets through third-party preclinical and genetic studies; however, most have previously been inaccessible by existing drug modalities. We will continue to focus on therapeutic targets backed by strong biological and genetic rationale with the goal of producing novel precision medicines. These opportunities include oncology and non-oncology indications, including immunology and inflammation, neurological and genetic diseases. Beyond our lead program, we have a number of discovery programs in our pipeline and intend to nominate at least two for lead optimization in 2021
- *Expand and protect our proprietary know-how and intellectual property***.** We have developed a broad patent estate protecting our intellectual property, which we intend to expand to further protect our QuEEN platform and the product candidates we develop. Our intellectual property, which includes proprietary know-how and expected patents, applies not only to our product candidates but also, for example, to the AI discovery engine algorithm for our Degron Encyclopedia as well as to certain biomarkers and therapeutic applications for our potential product candidates
- *Consider strategic collaborations in select therapeutic areas to fully realize the potential of our QuEEN platform***.** Our goal is to become a fully-integrated biopharmaceutical company that delivers pioneering therapies for patients. We currently retain all rights to our programs and platform. To support our goal, we will selectively explore strategic partnerships where we can leverage complementary capabilities in discovery, development and commercialization in disease areas within and outside our core areas of therapeutic focus to bring transformative therapies to patients with high unmet medical needs

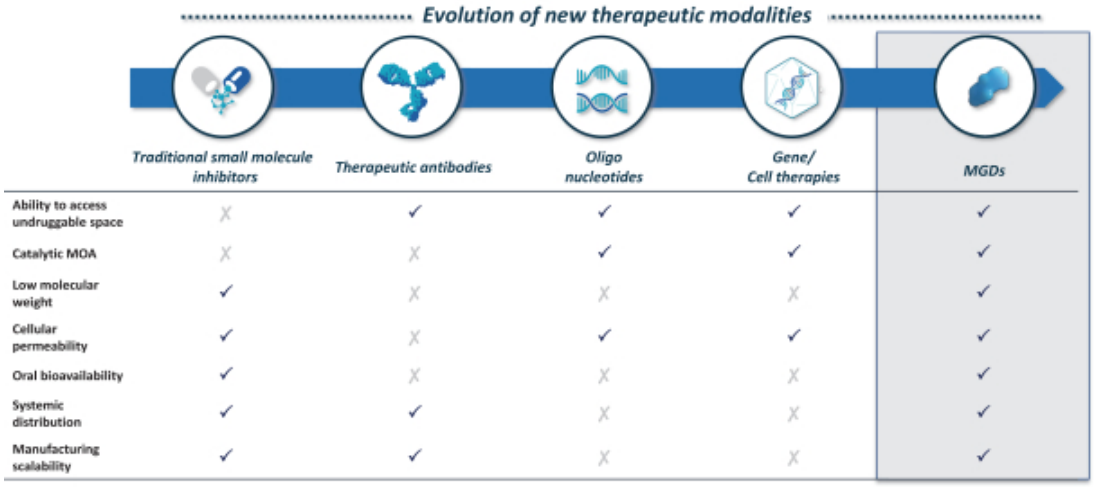
Background on targeted protein degradation and molecular glues

Proteins are large, complex molecules that are involved in essentially all of the biochemical reactions that take place in the body. Many human diseases are associated with abnormal intracellular protein behavior driven by modified functional activation or inactivation of the protein itself. Given their critical role, proteins are attractive therapeutic targets, particularly those that act inside the cell, not at its surface. While significant progress has been made in the development of therapeutics that address malfunctioning proteins, 85% of human proteins are considered undruggable by traditional small molecules.

Challenges with druggable vs. undruggable proteins

The most common methods of targeting proteins, including intracellular proteins, involve traditional small molecule inhibitors that bind to a pocket in the protein and, there, act to inhibit or modify the function of the protein. Having such a pocket is what has traditionally led to a protein being considered druggable yet most proteins lack suitably sized and shaped binding pockets. In particular, proteins such as transcription factors, those that act as scaffolding for other proteins and modulators of enzyme activity, all of which can play a critical role in disease, often don’t have binding pockets. The absence of a binding pocket presents a challenge to the development of traditional small molecule inhibitors. Furthermore, the features of therapeutic antibodies, oligo-based nucleotides and other genetic therapies limit their ability to address aberrant protein behavior.

Many of the aforementioned therapeutic modalities have meaningfully advanced the treatment of disease and improved the quality of life for millions of patients. However, these modalities face specific challenges related to their mode of delivery, scalability and their therapeutic application. A summary of these characteristics can be found below:

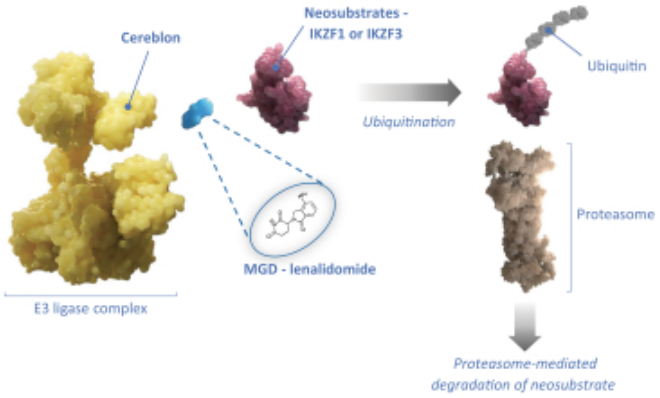


	Traditional small molecule inhibitors	Therapeutic antibodies	Oligo nucleotides	Gene/ Cell therapies	MGDs
Ability to access undruggable space	✗	✓	✓	✓	✓
Catalytic MOA	✗	✗	✓	✓	✓
Low molecular weight	✓	✗	✗	✗	✓
Cellular permeability	✓	✗	✓	✓	✓
Oral bioavailability	✓	✗	✗	✗	✓
Systemic distribution	✓	✓	✗	✗	✓
Manufacturing scalability	✓	✓	✗	✗	✓

Molecular glues: a new approach to protein degradation

A new and promising approach to modulating protein function using small molecules in cells was recently elucidated: protein degradation. Protein degradation is one of the body's natural processes by which proteins are eliminated from human cells through the attachment of a molecular tag, called ubiquitin, to a protein by any of the approximately 600 human E3 ligases, marking the protein for degradation by the proteasome in the cell. Protein degradation can be induced by small molecule-based degraders, including both PROTACs and MGDs. It was found that lenalidomide, now an approved best-selling drug in multiple indications with 2020 global sales of $12.1 billion, functioned as a small molecule-based degrader, or as an MGD, more specifically. In one of these indications, multiple myeloma, lenalidomide acts by causing two disease-driving transcription factors, IKZF1 and IKZF3, that lack druggable pockets, to bind to cereblon, an E3 ligase protein, resulting in their degradation.

Overview of protein degradation



We believe the targeted protein degradation approach offers many features that make it an attractive therapeutic modality:

- *Removal of a target protein*: partial or complete removal of a target protein can lead to more complete inhibition of signaling and metabolic pathways, thus resulting in more profound pharmacodynamic effects than traditional reversible or irreversible inhibition
- *Intracellular protein targetability*: small molecule-based protein degraders readily cross cell membranes or can be optimized to do so
- *Ease of delivery*: small molecule-based protein degraders can be delivered through various routes of administration, including oral
- *Systemic and tissue distribution*: since most small molecule-based degraders are low molecular weight compared to other therapeutic modalities, tissue distribution, and in particular, distribution into tumor tissues, poses less of an issue
- *Catalytic*: after inducing degradation of a target protein molecule, the small molecule protein degrader-E3 ligase complex is able to induce the degradation of another target protein. Thus, the small molecule protein degrader acts catalytically, unlike protein inhibition, causing the removal of many target protein molecules, thereby editing the cellular proteome
- *Event driven pharmacology*: unlike with inhibitors where prolonged engagement of the drug with the protein is required for efficacy, small molecule protein degraders only require engagement with the E3 ligase and the target protein long enough to induce tagging for degradation

As mentioned above, there are multiple advantages of the protein degradation approach, but one of the most beneficial is the potential to achieve greater therapeutic efficacy resulting from the removal of a target protein from the cellular proteome.

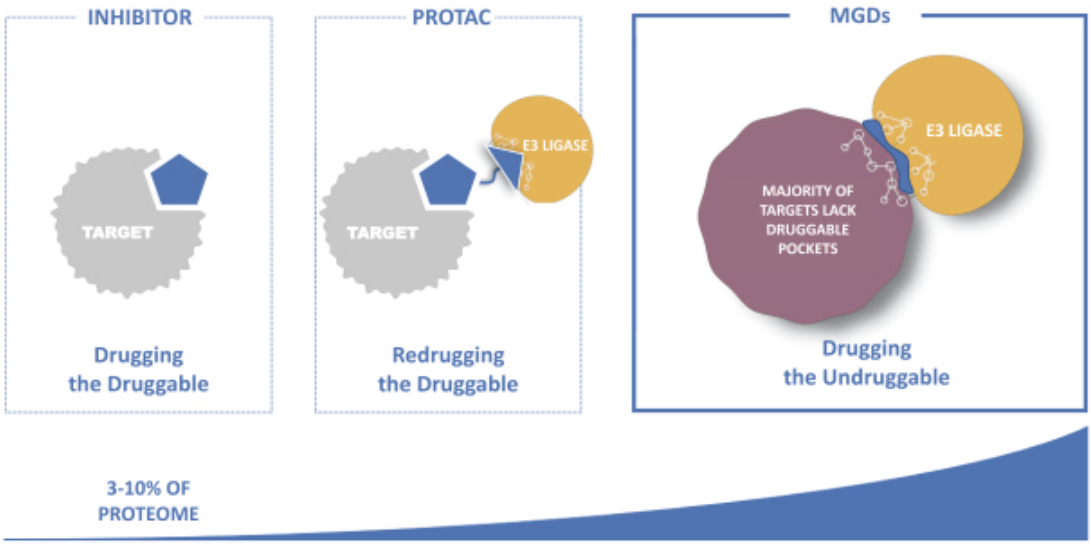
Current approaches to protein degradation

While lenalidomide is an MGD, the majority of recent drug discovery efforts in the design of protein degraders has been focused on PROTACs. These heterobifunctional degraders are composed of two separate small molecules connected by a chemical linker. One molecule binds to a necessary binding pocket on the target protein and the other to a component of the E3 ubiquitin ligase complex. Binding of the PROTAC to both the protein of interest and the E3 ligase brings the target protein into proximity of the E3 ligase, resulting in tagging of the protein of interest for degradation. While this represents a novel way to eliminate therapeutically-relevant proteins from cells, we believe an MGD approach offers the following advantages over PROTACs:

- *Ability to target undruggable proteins*: MGDs utilize the richness of molecular surface features across the proteome allowing access to a broader and differentiated target space. In contrast, PROTACs require identification of a small molecule that binds to a defined binding pocket, which today largely constrains the approach to the universe of proteins that can already be addressed with small molecule inhibitors
- *Favorable pharmaceutical properties*: The relative simplicity and size of an MGD generally allows for more rapid optimization for oral bioavailability. PROTACs often have a larger size and larger molecular weight due to their complex heterobifunctional structure, which may lead to challenges to develop the molecules into drugs suitable for oral dosing
- *Limited tissue distribution*: The physicochemical properties of PROTACs may also limit the drug distribution within the body, thereby reducing the potential in certain therapeutics areas such as central nervous systems disorders

- *No observable hook effect*: MGDs show a more typical concentration response where increasing concentrations elicit increasing efficacy caused by the catalytic interaction. In contrast, PROTACs require a precise concentration range to elicit efficacy due to the loss of degradation potential at higher concentrations caused by their heterobifunctional structure (also known as “hook effect”)

Comparison of the mode of action of protein-targeting small molecules



As shown above, MGDs are non-heterobifunctional and do not require an active site or binding pocket on target proteins. We believe these properties potentially expand the universe of druggable targets while also maintaining the favorable drug-like properties of small molecule therapeutics.

Our approach

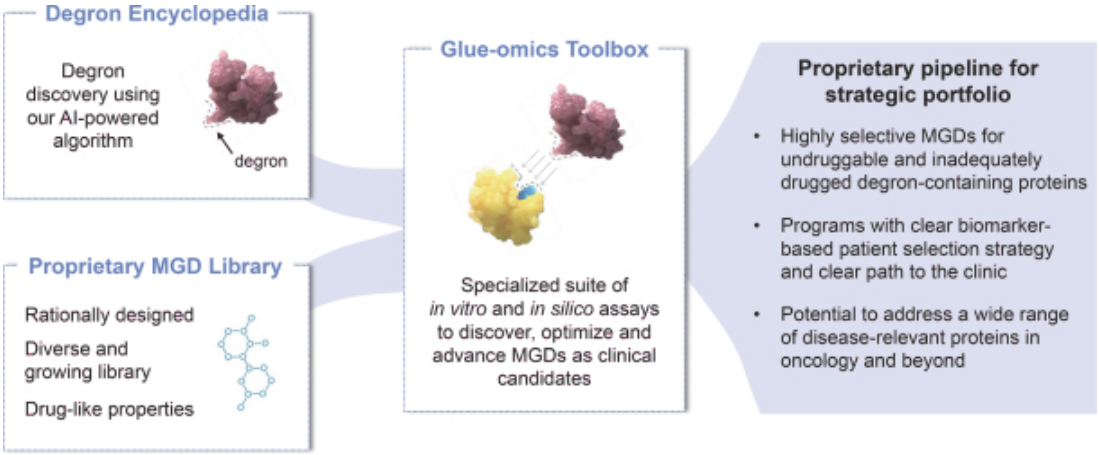
Our approach to protein degradation involves rationally designing and developing small molecule-based MGDs to precisely edit the human proteome. Molecular glues are small molecules that induce protein-protein interactions, but not all known and characterized molecular glues lead to degradation of target proteins. Lenalidomide and pomalidomide are two approved drugs that were subsequently found to function as MGDs by causing the degradation of therapeutically-relevant proteins through the induced interaction with a component of the E3 ligase cereblon. They provide clinical validation of the MGD approach.

While the mechanism of action for these two drugs was discovered years after their introduction into the clinic, we are leveraging our platform to rationally and efficiently design MGDs. Our MGDs are drug-like, non-heterobifunctional small molecules that bring together a therapeutically-relevant target protein and an E3 ligase, leading to degradation of the target protein. We believe our product candidates have the potential to address proteins that have been considered undruggable or inadequately drugged, while possessing attractive pharmaceutical properties.

Our QuEEN platform was purpose-built to support the discovery and development of drugs that degrade a wide landscape of therapeutically-relevant proteins by (i) systematically identifying therapeutically-relevant target proteins that may be amenable to MGD degradation; and (ii) rationally designing molecules that can be optimized towards high potency and selectivity, with favorable pharmaceutical properties. Our MGDs typically consist of structural features that bind to the ubiquitin ligase and the degron of the protein.

Our platform—QuEEN

Elements of our QuEEN platform



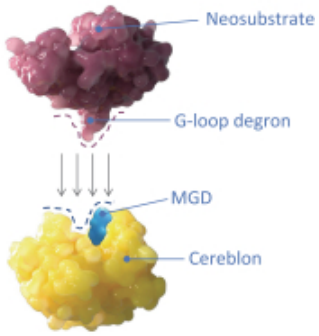
Our proprietary, Quantitative and Engineered Elimination of Neosubstrates, or QuEEN platform, encapsulates our team's deep and growing expert knowledge and discovery capabilities across biology, chemistry and computational sciences and from which we are generating our pipeline of MGD product candidates. Central to our QuEEN platform is a detailed understanding of the molecular interactions promoted by our small molecule MGDs between E3 ligases and therapeutically-relevant proteins, which have been considered undruggable or inadequately drugged. We believe this depth of knowledge allows us to leverage our platform to rationally design MGDs with favorable pharmaceutical properties that have the potential to translate into clinical success across multiple therapeutic areas. Our capabilities have been developed through the three key features of our QuEEN platform, which include the following:

- *Degron encyclopedia*: A growing catalogue of target proteins identified through our proprietary AI approach that enables us to identify structural features on protein surfaces that can serve as degrons for highly validated and therapeutically-relevant, but otherwise undruggable or inadequately drugged, proteins
- *Proprietary MGD library*: A diverse and continuously growing chemical library of drug-like MGDs rationally designed based on our expertise in basic glue anatomy
- *Glue-omics toolbox*: A tailored suite of biochemical, structural biology, cellular, proteomics and *in silico* screening tools that enable the discovery and optimization of MGD product candidates that efficiently recruit neosubstrates to E3 ligases utilizing degrons discovered through our AI approach

Degron encyclopedia

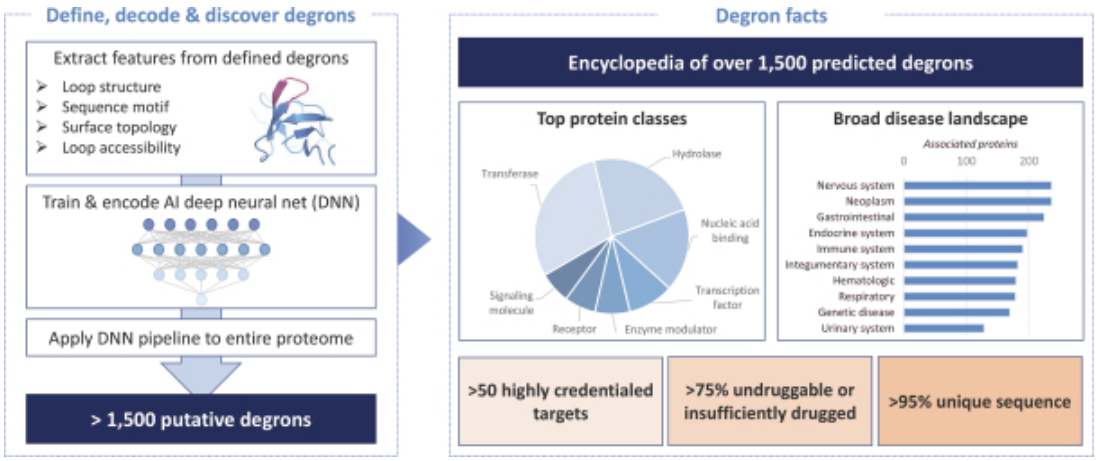
For proteins to be targeted by MGDs, they need to expose a structural feature on their surface that mediates their recruitment and degradation by an E3 ligase complex. These features are called degrons and the proteins exposing these degrons are called neosubstrates. One such example is the G-loop degron which is a protruding protein surface loop that mediates the interaction with an MGD and an E3 ligase protein called cereblon as shown below, and that contains a glycine amino acid, or G. Neosubstrates are proteins degraded only in the presence of an MGD and are not physiological substrates of the E3 ligase.

MGD-mediated cereblon-neosubstrate interaction



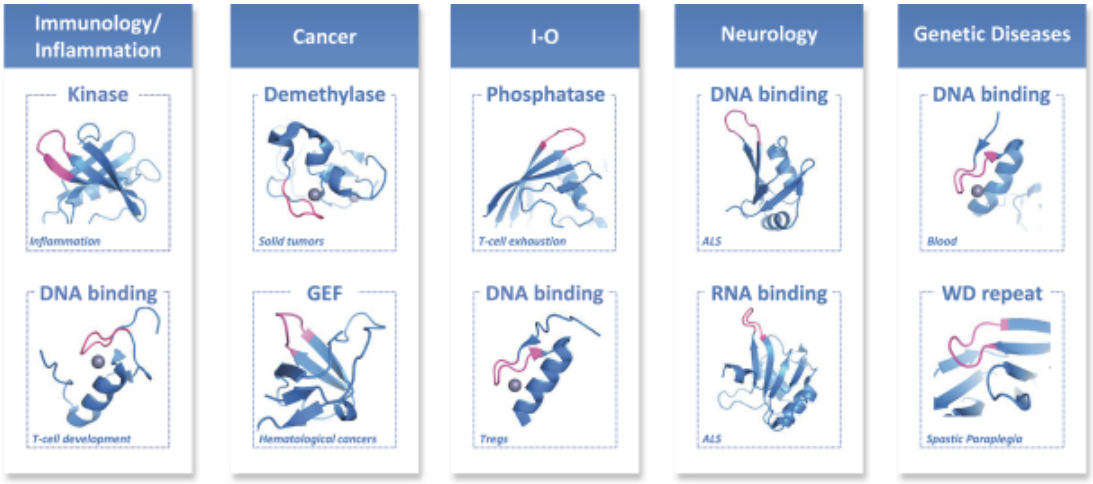
We have developed AI-powered algorithms that we use to mine databases of protein structures, as well as to model protein surfaces where three-dimensional structures are not available. We have identified the topological, structural and sequence features associated with established degrons and encoded these features in a deep neural network, or DNN. Using protein amino acid sequences and available three-dimensional structures as inputs, we have deployed our DNN to identify degrons. Our initial focus has been on identifying degrons for putative neosubstrates of cereblon. Based on the presence of structural regions with a high potential to function as degrons, we have identified over 1500 proteins which represent potential neosubstrates targetable by our MGDs. We call these degrons cereblon-accessible loops, with the G-loop being one particular subtype of a cereblon-accessible loop.

Our Degron Encyclopedia



These potential neosubstrates represent multiple protein classes including receptors, enzymes, scaffolding proteins and other regulatory proteins, transcription factors and transcriptional repressors. Of the more than 1500 potential neosubstrates, over 95% have a unique degron sequence. Because recruitment and degradation by an E3 ligase complex is mediated by both degron structure and sequence, the uniqueness of degron sequences suggests the possibility to selectively degrade each neosubstrate. Over three quarters of target candidates we identified are generally considered to be undruggable due to the lack of suitable drug binding pockets. Further, these degron-containing proteins are associated with a wide landscape of diseases, suggesting that MGDs may provide benefit to patients suffering many illnesses across therapeutic areas. The ability to use an MGD to selectively degrade these target proteins could lead to the redefinition of what constitutes a druggable target and a substantial expansion of the universe of intracellular targets that are amenable to small molecule pharmaceutical intervention to treat oncology and non-oncology diseases.

Degron-containing proteins and disease areas

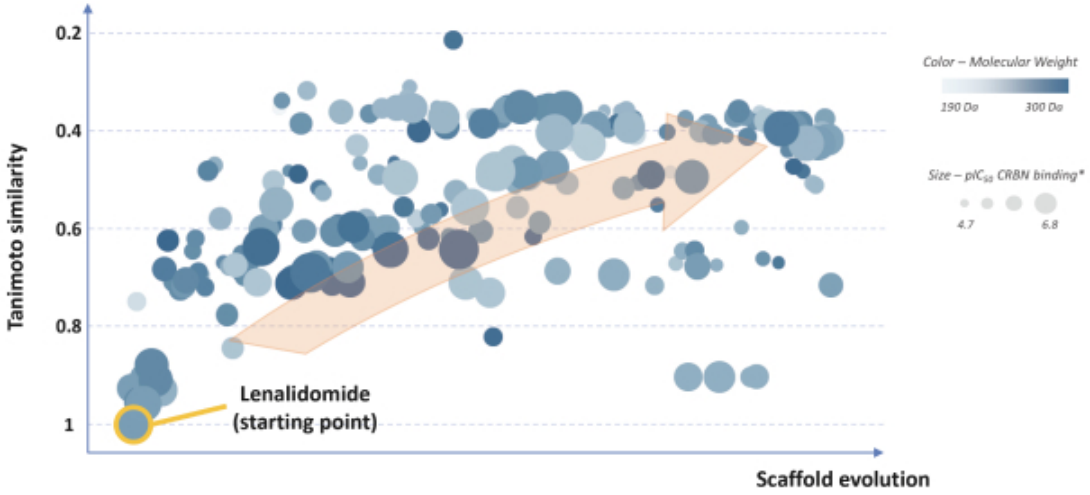


We prioritize target proteins based on their credentialed association with disease biology and advance the most promising targets into our drug discovery process.

Proprietary MGD library

We have generated a highly diverse library of MGDs by applying our computational chemistry tools combined with our knowledge of the cereblon-binding site and variations in degron structures. Our proprietary MGD library currently consists of over 200 unique drug scaffolds, each designed to probe different three-dimensional spaces. We use Tanimoto similarity scores, a standard way to assess compound diversity, as a design characteristic to enable the continued expansion of our diverse chemical library. Our proprietary MGD library currently consists of approximately 7,000 unique molecular compounds and we expect to increase this amount to more than 20,000 in 2021.

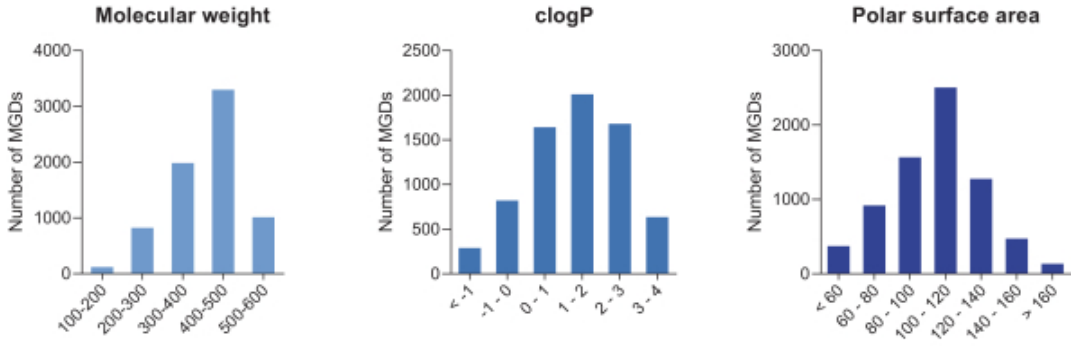
The evolution of our MGD scaffolds



We have shown in preclinical studies that increasing MGD diversity, while maintaining binding to cereblon and desirable pharmaceutical properties of each molecule, enabled binding to different degrons. We believe this allows us to address more target proteins and address different regions of the proteome.

We specifically designed this library to focus on molecules with properties that resemble those of approved drugs including molecular weight; solubility, as predicted by a metric known as the partition coefficient or clogP; and polar surface area. These molecular properties impact factors such as oral bioavailability, drug exposure and metabolism; making their understanding important for drug development. Because our proprietary compounds were rationally designed to have properties that are consistent with those that result in oral compounds, they offer highly optimized starting points for drug discovery programs thereby enabling potentially rapid progress in lead optimization. Using this library, we have found multiple starting points for proteins previously not reported to be degradable by a molecular glue-based approach.

Chemical properties of our mGDs



Glue-omics toolbox

We have assembled an experienced team of data scientists, structural biologists, biochemists, biologists and chemists. With our deep expertise, we have built proprietary tools designed to broadly screen our MGDs against degron-containing target proteins and validate these proteins as neosubstrates while optimizing MGD potency,

selectivity and other properties. Our MGD screening capabilities are driven by both *in silico* and laboratory-based assays that predict and assess the ability of our MGDs to induce the binding of targets to E3 ligase components, such as cereblon, and directly measure target degradation. More specifically, our toolbox comprises:

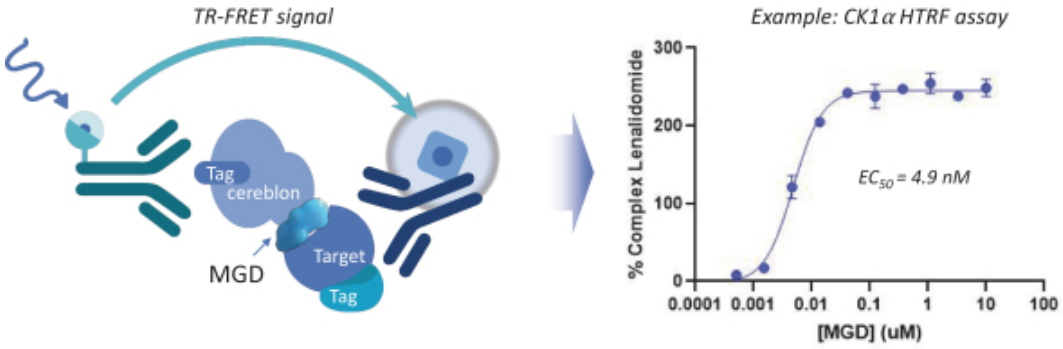
- *Quantitative biochemical and cellular assays*: A suite of assays that have been tailored to measure specific steps of the MGD induced protein degradation cascade, including ternary complex formation and target degradation
- *Quantitative proteomics profiling assays*: A portfolio of assays that have been developed to measure protein changes within the proteome, including spatial proximity to E3 ligases and degradation of neosubstrates. These assays allow us to identify new neosubstrates, to verify cellular degradation of known and predicted novel substrates, and to assess the selectivity of MGDs
- *In silico ternary complex modeling and screening*: A suite of proprietary AI-driven algorithms, called Rhapsody, to rapidly identify and prioritize MGDs that *in silico* are predicted to induce ternary complexes in a neosubstrate specific manner

Our proprietary *in silico* and laboratory-based toolbox allows us to rationally design MGDs, and to rapidly optimize their selectivity as well as chemical and biological properties, with the goal of constructing a robust pipeline of product candidates.

Quantitative biochemical and cellular assays

We have developed a suite of assays that have been tailored to measure specific steps of the MGD-induced protein degradation cascade. With our first set of assays, we can measure ternary complex formation and screen for MGDs which have the most efficient binding characteristics. We have developed a Homogeneous Time Resolved Fluorescence, or HTRF, assay to measure ternary complex formation, whereby the close proximity of cereblon and the target protein are detected by fluorescent energy transfer between antibodies binding to the two proteins. As shown below, we have used these types of assays to screen multiple targets using our proprietary MGD library. Our studies have validated the ability of MGDs to drive ternary complex formation in a concentration dependent manner. By measuring the dependency of ternary complex formation on MGD concentration, we generate concentration dependent curves, enabling us to calculate objective measures of potency such as the EC_{50}, or the concentration at which the effect is half of the maximum.

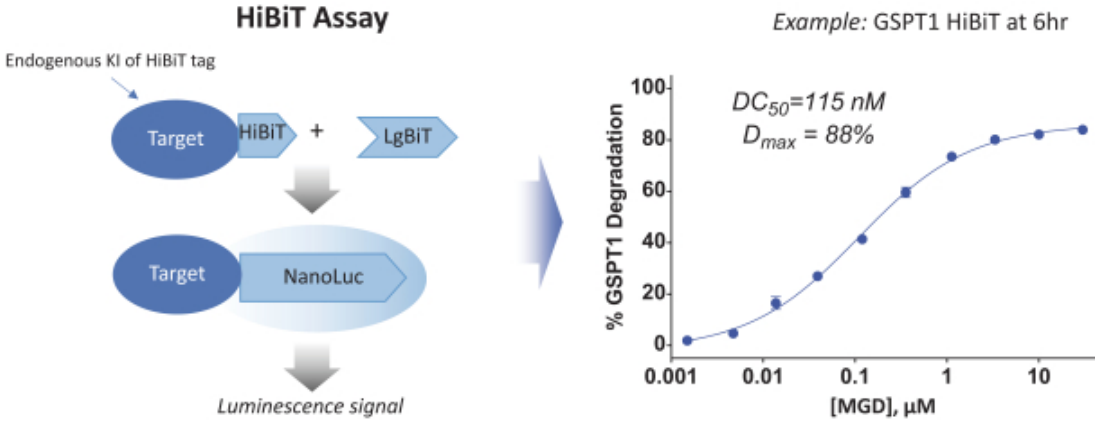
HTRF assay used for screening and potency determination



We have also developed multiple assays to measure degradation of targets in cells. The HIgh efficiency BInary Technology, or HiBiT, cellular assay is one example of a high-throughput assay that we have used to screen our

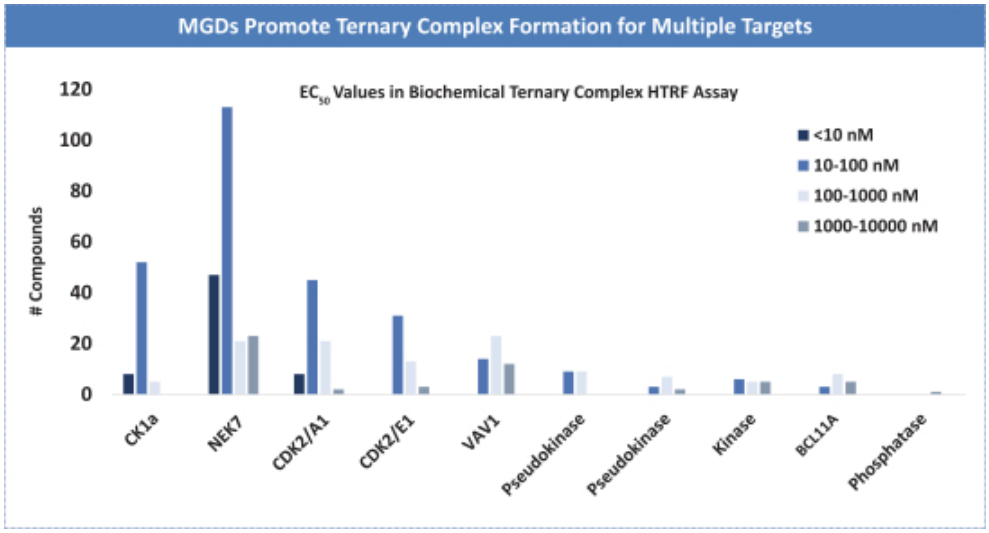
proprietary MGD chemical library and identify MGDs that promote cellular target degradation in a selective manner. As shown in the figure below, the assay measures the decrease in luminescence signal by using an endogenous HiBiT tag fused to the target of interest. Preclinical studies using our MGDs have shown these compounds drive target degradation in a concentration dependent manner. By measuring the dependency of target protein levels on MGD concentration, we generate concentration dependent curves, enabling us to calculate objective measures of potency such as the DC_{50}, or the concentration at which the degradation is half of the maximum, and the D_{max}, the maximum amount of target protein that is degraded.

HiBiT assay for screening and potency determination of MGDs



KI in the schematic above means “knock in”.

We are using our tailored suite of biochemical and cellular assays to screen, identify and rapidly optimize our MGDs. We have demonstrated that multiple targets from our Degron Encyclopedia can be engaged and/or degraded using MGDs from our proprietary MGD library. Several examples are highlighted below where we have identified MGDs that promote the association between a target protein and cereblon, including both undruggable targets and targets that have historically been inadequately drugged.

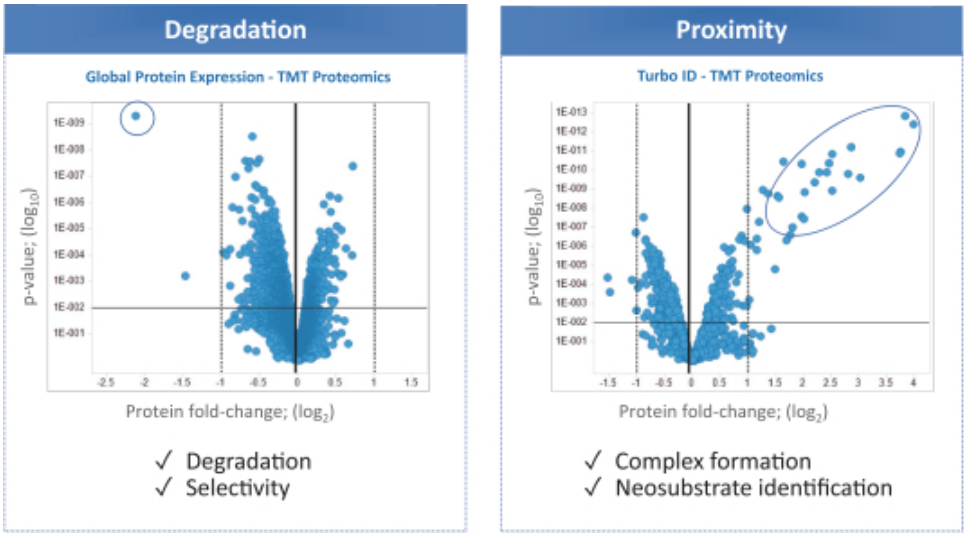


Quantitative proteomics profiling assays

Utilizing our expertise in mass-spectrometry-based proteomics, we have developed a suite of quantitative profiling assays to assess multiple parameters, including cellular target degradation, selectivity of degradation and ternary complex formation in cells, the latter allowing us to identify potential neosubstrates not predicted by our *in silico* approach. Data points in the upper corners of the plots shown below represent protein levels which change the most significantly on treatment of cells with an MGD. We utilize this information in multiple ways, including:

- *To assess target degradation and determine the selectivity of our MGDs:* The plot on the left shows which proteins are of lower abundance after cells are treated with the MGD
- *To validate complex formation of our MGDs in cells*: The plot on the right shows proteins that are induced by the MGD to be proximal to the E3 ligase, as measured in a proximity-based Turbo-ID assay. Spatial proximity is suggestive of cellular ternary complex formation.
- *To identify novel neosubstrates*: Screening of our MGD library with the proximity-based assay shown on the right provides additional data to train our computational degron prediction algorithms and further expand the target space

Quantitative proteomics assessment of target degradation, selectivity, cellular ternary complex formation and identification of novel neosubstrates



Examples of our capabilities are shown in the volcano plots above: each point represents one protein; the x-axis shows the magnitude in protein level change when the MGD is introduced (log2 fold change) and the statistical significance of each change is shown on the y-axis.

A p-value is an assessment of whether the observation is a result of change or the result of a random occurrence, with smaller p-values suggesting stronger evidence of an actual change. We highlight p-values smaller than 0.01.

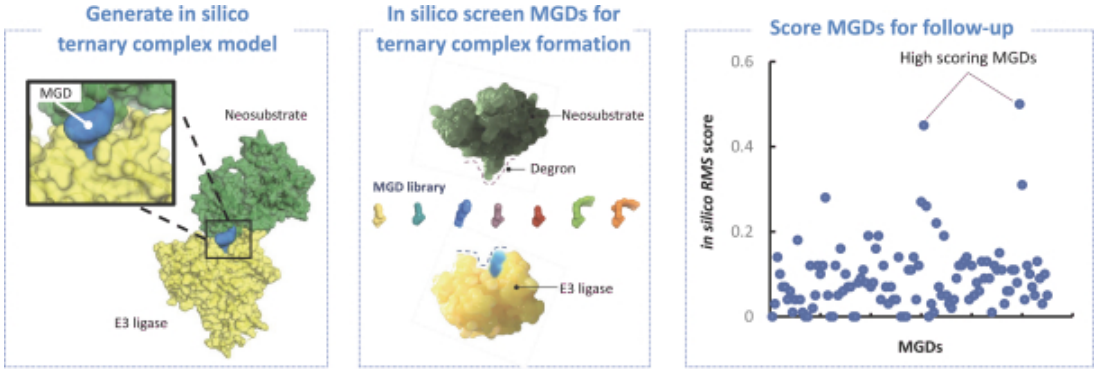
In silico Ternary Complex Modeling and Screening (Rhapsody)

Built on our expertise in AI and data sciences, computational chemistry, structural biology and software engineering, we have built proprietary AI-driven algorithms to rapidly identify, progress and prioritize MGDs that *in silico* induce ternary complexes in a neosubstrate specific manner. We have named this computational tool Rhapsody.

For *in silico* screening, we run Rhapsody on our custom-designed cloud computing infrastructure to rapidly screen MGDs, including both those MGDs already found in our physical MGD library as well as virtual MGD libraries. Rhapsody results are used to identify novel hits that are predicted to induce neosubstrate-specific ternary complex formation and to prioritize MGDs for follow-up experiments.

For MGD optimization, Rhapsody is used to generate an *in silico* model of the MGD-specific, MGD-induced ternary complex. Evaluation of the model allows us to rapidly predict which parts of the MGD anatomy are involved in target recruitment and which parts may be modified. This enables us to maintain or enhance the target-specific potency of the MGD, while optimizing its selectively and its chemical and biological properties.

The Rhapsody suite of in silico tools



QuEEN expansion opportunities

Our QuEEN platform to date has been focused on identifying and developing MGDs that induce the binding of degron-containing neosubstrates to cereblon as a means of targeting them for degradation. We are expanding the scope of QuEEN to increase the cereblon target space and to leverage additional E3 ligases for targeted protein degradation.

- *Expand the cereblon neosubstrate universe*: As we rationally designed our MGD compound library to increase diversity, we found in preclinical studies that there are degrons with a diversity of amino acid sequences that can be targeted and we have shown we can induce efficient protein degradation through these previously undisclosed degrons. We have used our proprietary AI-driven algorithms to predict the existence of degrons from the primary sequences and the topology of proteins and are using our rational design approach to expand chemical diversity of our MGD library so to be able to target this diverse set of cereblon-accessible loops
- *Utilize additional E3 ligases*: We believe that we will be able to reprogram other E3 ligases through the discovery of specific ligase-accessible degrons, which would enable us to generate ternary complexes with a further subset of the approximately 600 E3 ligases

Expanding the universe of neosubstrates and recruitment of neosubstrates to additional E3 ligases through the continued identification of degrons has the potential to bring more therapeutically-relevant proteins into the universe of druggable targets, which we anticipate will allow us to address additional therapeutic targets that are undruggable or insufficiently drugged.

Our precision medicine programs

GSPT1 degrader for Myc-driven diseases

We are developing an oral MGD molecule that selectively targets GSPT1, a G-loop degron-containing neosubstrate that has been identified as a potential target in oncology. GSPT1 is a translational termination factor and our GSPT1-directed MGD molecules have been observed to potently induce cell death in tumor cell lines addicted to high levels of protein translation, such as those driven by the Myc oncogenes. We have shown that once daily oral doses of our MGD molecules induced regression of Myc-driven tumors in human xenograft mouse models including models of NSCLC and SCLC. We anticipate selecting a development candidate in this program in , which we are planning to develop in biomarker-driven clinical trials.

Myc regulates transcription and translation of cancer-related genes

The Myc family of transcription factors has long been recognized as a driver of multiple human cancers and they are among the most frequently mutated, translocated and overexpressed oncogenes in human cancers. We believe that targeting the Myc pathways via downstream vulnerabilities is a viable approach to addressing Myc-driven tumors.

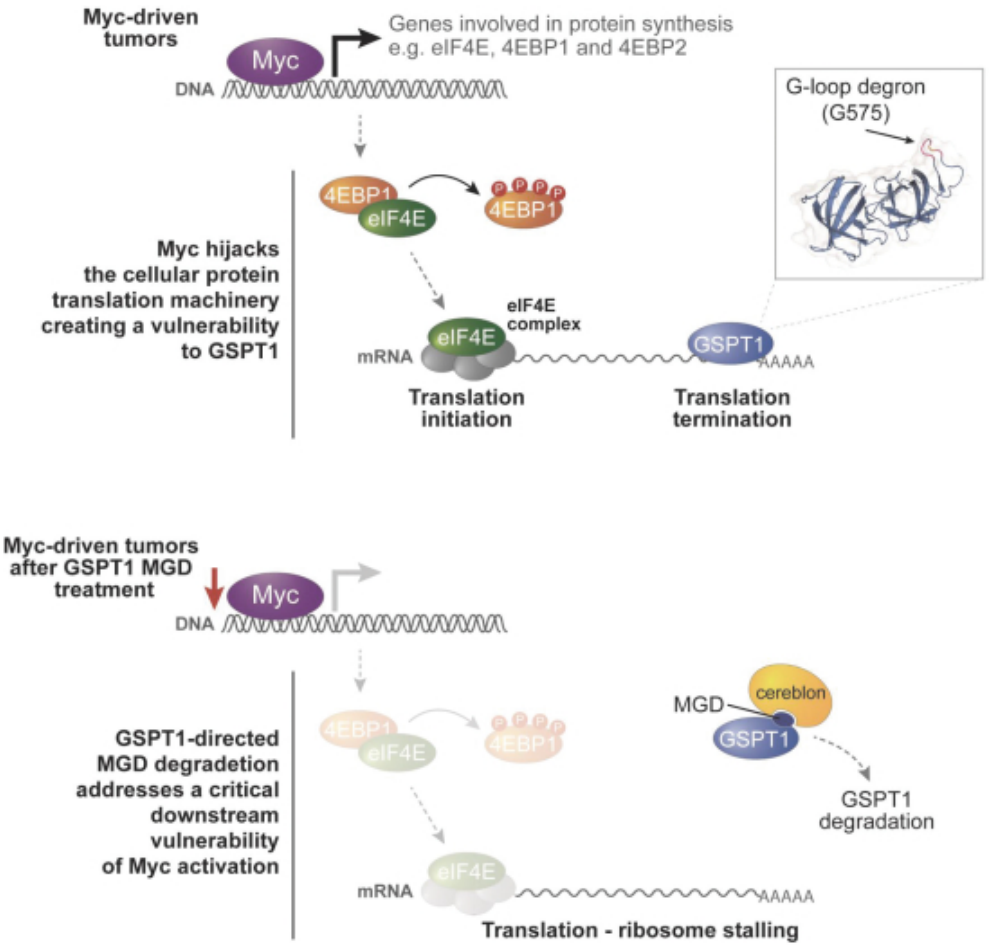
In humans, the Myc family of transcription factors comprises three proteins, c-Myc, N-Myc, and L-Myc, encoded by three different genes. Mutation, translocation or overexpression of any of these three proteins can lead to tumor development and progression. Extensive third-party studies on the role of Myc in cancer have provided insight on the mechanism by which mutations, translocations or overexpression of Myc result in uncontrolled cell growth. c-Myc is a transcription factor that is normally activated by growth factors to drive the expression of a number of genes involved in cell growth and proliferation. The aberrant activation of the gene encoding c-Myc can lead to constitutive, or always on, activation of the transcription of cell proliferation genes resulting in uncontrolled cell growth. As a consequence, there is an increasing realization that Myc-driven tumors critically rely on high translational output and the ramp up of the protein translational machinery to drive growth and proliferation.

Inhibition of Myc activity using genetic constructs has been observed to lead to strong antitumor responses in animal models of cancer. However, over forty years after the discovery of the Myc oncogene, there are no approved therapies that target the Myc family of transcription factors itself or its downstream pathways. We believe that the administration of our GSPT1-directed MGD product candidate will address a critical downstream vulnerability of Myc activation.

Development opportunity of GSPT1 degraders to target downstream vulnerabilities of Myc activation

Aberrant activation of Myc signaling in cancer cells leads to increased transcription and, as a consequence, dependence on high rates of protein translation. This addiction creates a vulnerability to changes to the protein translation machinery in Myc-driven tumors. Using our QuEEN platform, we confirmed GSPT1, a key player of protein synthesis, as a degron-containing protein and possible neosubstrate. To date, the GSPT1 protein has been considered undruggable using conventional small molecule approaches. Leveraging our GSPT1-directed MGD molecules, we observed changes in several downstream markers for the Myc pathway *in vitro*, which we believe demonstrates that GSPT1 degradation is a key vulnerability for Myc-driven cancers. We observed that GSPT1 degradation led to decreased translation, downregulation of Myc proteins itself and reduced Myc signaling.

Overview of Myc addiction and targeted degradation



Potential indications

Recent studies across 33 tumor types showed that 28% of solid cancers have an amplification of one of the Myc family genes. Amplification of c-Myc occurs most frequently in ovarian cancer (64%), esophageal cancer (45.3%), squamous lung cancer (37.2%) and breast cancer (30%). N-Myc amplifications or overexpression have been reported in approximately seven to ten percent of lung adenocarcinomas, or LUAD, the main subtype of NSCLC, in addition to tumors with neuroendocrine features such as neuroblastoma, retinoblastoma, medulloblastoma, or lung cancer and prostate cancer (neuroendocrine type, Lu-NET and NEPC, respectively). Similarly, L-Myc amplifications or overexpression have been observed in approximately 50% of SCLC. In hematological malignancies c-Myc was found to be translocated in 36% of patients with multiple myeloma, and different translocations were found at a rate between 70% and 100% in Burkitt lymphoma and to a lesser extent in other lymphomas. High N-Myc expression has also been reported in highly proliferative acute myeloid leukemia, or AML.

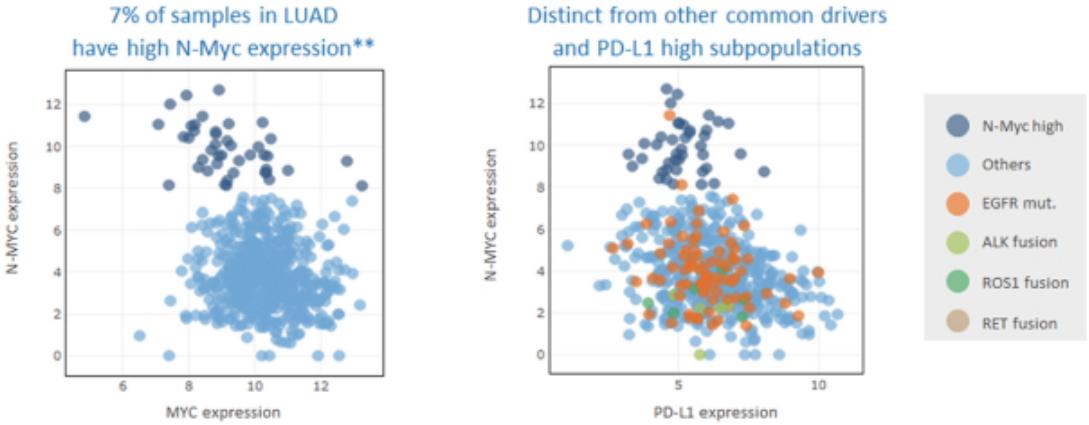
Non-small cell lung cancer

There are an estimated 228,000 new cases of lung cancer diagnosed in the United States each year. Also, lung cancer causes 143,000 deaths annually in the United States. NSCLC accounts for 80 to 85 percent of lung cancer

cases. While targeted therapies have been developed for patients with tumors containing alterations in epidermal growth factor receptor, or EGFR, ROS proto-oncogene 1, or ROS1, rearranged during transfection gene, or RET, anaplastic lymphoma kinase gene, or ALK, less than thirty percent of patients are eligible for these therapies. Patients who are ineligible or resistant to these therapies can be treated with immune checkpoint inhibitors that lead to significant improvements in progression free survival and overall survival compared to standard chemotherapy. However, despite the availability of these therapies, very few patients are cured of their disease and the prognosis in NSCLC remains poor, with an overall five-year survival rate for all patients diagnosed with NSCLC of 19 percent.

Our and others' analyses of molecular data from NSCLC tumors found that seven to ten percent, respectively, of these tumors have elevated N-Myc expression which our preclinical data suggests will sensitize them to GSPT1-directed MGD molecules. Furthermore, we found that there is little overlap between tumors that have high levels of N-Myc and those that have genetic changes that are targeted by approved drugs. Most N-Myc overexpressing lung tumors, for example, do not have alterations in genes encoding EGFR, ALK, ROS1 or RET.

N-Myc expression in lung adenocarcinoma



Small cell lung cancer

SCLC represents approximately fifteen percent of all lung cancers, accounting for 30,000 new cases a year in the United States. SCLC is a rapidly progressive disease with short overall survival after initial therapeutic responses. SCLC is derived from neuroendocrine cells and is distinguished clinically from NSCLC by its rapid doubling time and the early development of metastases. Most patients have metastatic disease at the time of their initial diagnoses. Unlike NSCLC, there are no targeted therapies approved for SCLC. First line therapy for these patients typically involves combination chemotherapy or radiation therapy. While patients initially respond to this chemotherapy, approximately 90 percent progress within one year and die within two years. The average five-year survival for newly diagnosed SCLC is seven percent. Immuno-oncology agents have received approval in SCLC, but their efficacy is limited compared to that in other tumors, and some agents, such as nivolumab and pembrolizumab, have been recently withdrawn from the market for this indication. Our analyses of molecular data from SCLC tumors found that over half of these tumors have elevated levels of L-Myc expression which our preclinical data suggests will sensitize them to GSPT1-directed MGD molecules.

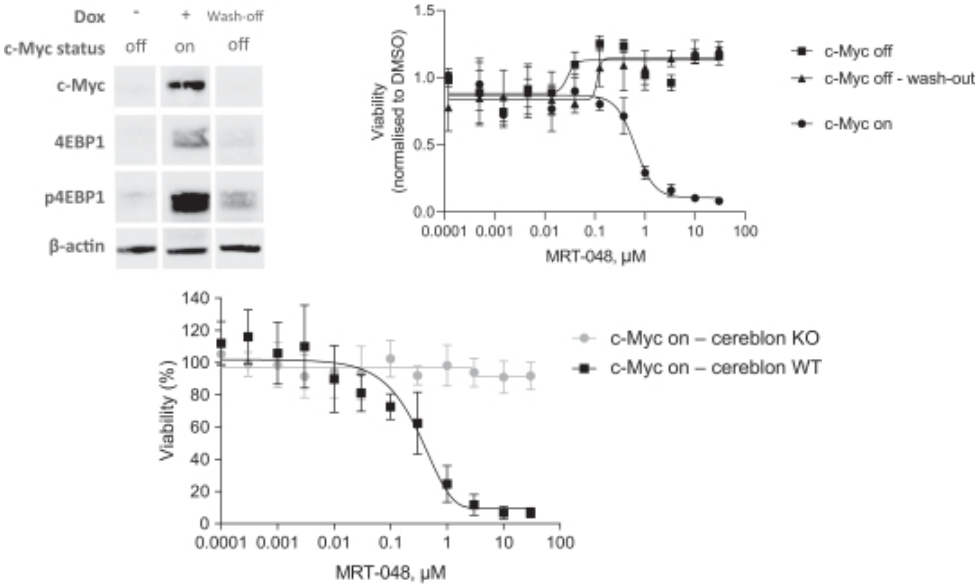
Preclinical studies and data

In support of future IND-enabling studies, we have observed high activity, selectivity and therapeutic potential in both *in vitro and in vivo* studies for versions of our GSPT1-directed MGD molecules, including MRT-048 and MRT-1577. We intend to select a development candidate in our GSPT1 program prior to moving forward with IND-enabling studies, and to submit an IND to the FDA in .

Targeting GSPT1 with our MGD molecules

We rationally designed potent and highly selective GSPT1-directed MGD molecules, of which MRT-048 is a representative molecule, for the treatment of Myc-driven cancers. We utilized engineered human mammary epithelial cells, or HMECs, overexpressing c-Myc in a doxycycline-inducible manner to evaluate the vulnerability of Myc-driven tumors to disruption of protein translation through degradation of GSPT1, a key player in protein synthesis. As shown in the figure on the left below, after c-Myc induction, the cells displayed key biomarkers of enhanced protein translation, including upregulation and phosphorylation of 4EBP1. In the figure on the right, we show that MRT-048 induced cell death with an EC_{50} of 0.64 µM in the presence of high c-Myc expression but did not induce cell death at the highest concentration tested of 30 µM in the absence of doxycycline-driven c-Myc expression or after doxycycline was washed out to remove c-Myc expression in cells that previously expressed c-Myc. In addition, as shown in the figure below, MRT-048 did not induce death in cells for which cereblon was knocked out, confirming cereblon-dependence of MRT-048's viability effect.

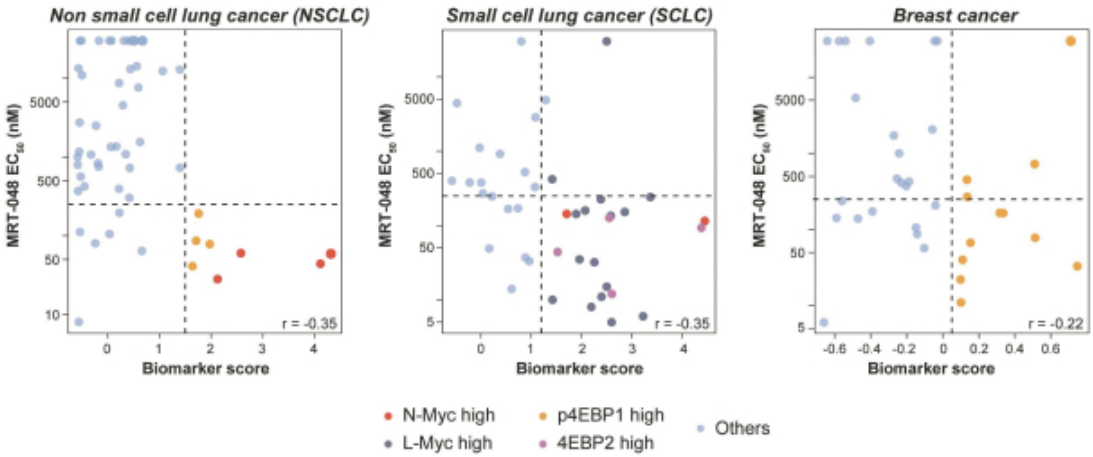
Vulnerability of c-Myc-driven tumors to cereblon-dependent GSPT1 degradation



KO and WT in lower graph above means "knock out" and "wild type".

After observing that cell death induced by GSPT1 degradation was dependent on Myc and cereblon expression, we tested MRT-048 in a panel of about 300 tumor cell lines. Shown in the figure below is MRT-048 viability data (represented as EC_{50}) in NSCLC, SCLC and breast cancer cell lines. Sensitivity to MRT-048 correlated with one or more of the following Myc signaling biomarkers: N- or L-Myc expression, 4EBP1 phosphorylation, or p4EBP1, or 4EBP2 expression. We observed that sensitivity to MRT-048 in NSCLC was associated with high levels of N-Myc expression or p4EBP1, and in SCLC cell lines correlated to high levels of 4EBP2, N- or L-Myc expression. In addition, sensitivity of breast cancer lines was associated with high levels of p4EBP1, one of the key biomarkers of c-Myc transformed tumor cells.

Sensitivity to MRT-048 in tumor cell lines



Mechanistically, we observed that GSPT1 degradation with MRT-048 led to ribosomal stalling at stop codons of distinct mRNAs. Additionally, polysome profiling of cancer cells treated with MRT-048 was associated with a global reduction of the intensities of the polysome peaks and concomitant increase in the monosome peaks as previously observed in GSPT1 knockdown experiments, suggesting that GSPT1 degradation by our MGD molecules affects both the termination stage of translation as well as the initial stage. In summary, we believe these data demonstrate that GSPT1 is a key vulnerability in Myc-driven tumors with a ramped up protein translation machinery.

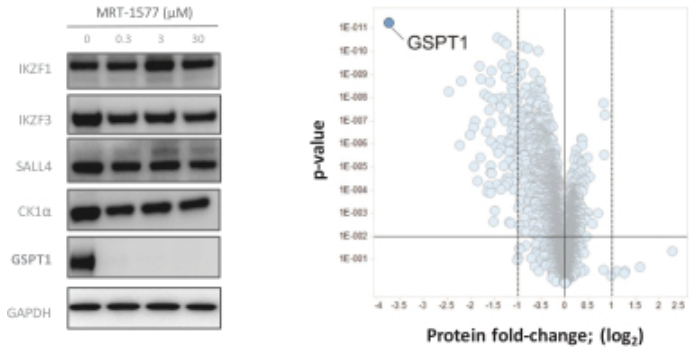
Generation of highly potent and orally bioavailable GSPT1-directed MGD molecules

We have generated a series of GSPT1-directed MGD molecules with improved potency and pharmacokinetic properties compared to our early lead, MRT-048. One of these molecules is MRT-1577, a potent, highly selective and orally bioavailable GSPT1-directed MGD molecule.

In vitro data

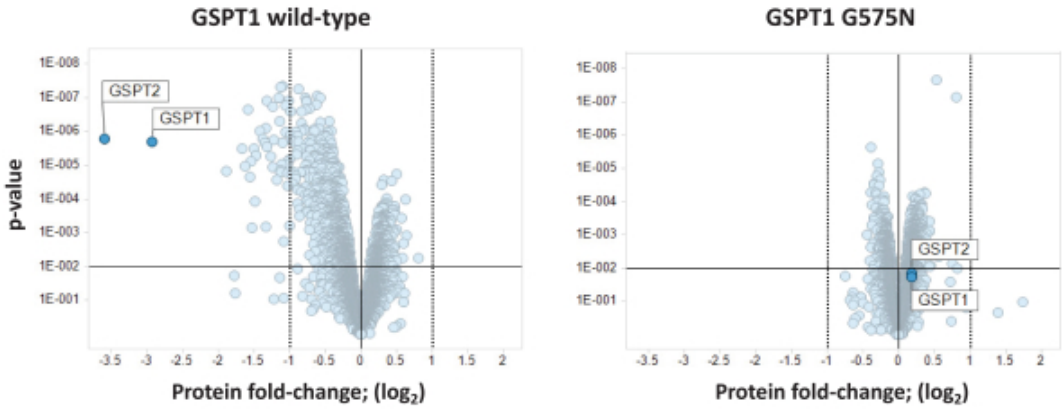
As we observed for MRT-048, MRT-1577 is a potent and highly selective degrader of GSPT1. On the left below, we show that MRT-1577 induced complete GSPT1 degradation in cells treated at a concentration of 0.3 µM. In contrast, none of the known cereblon-neosubstrates was degraded at the highest concentration tested of 30 µM. In addition, as shown on the right below, mass spectrometry-based proteomics analysis of a cancer cell line treated with MRT-1577 demonstrated that GSPT1 was the most statistically significant downregulated protein.

Induction of GSPT1 degradation and downregulation by MRT-1577



The selectivity of MRT-1577 was also determined using mass spectrometry-based proteomics analysis of cells engineered to express a non-degradable form of GSPT1, GSPT1 G575N. This G to N mutation at position 575 located in the GSPT1 G-loop creates a steric clash precluding its binding to the cereblon/MRT-1577 complex. In cells expressing the wild-type form of GSPT1, we observed that MRT-1577 selectively downregulated the GSPT1 protein, as shown in the volcano plot on the left. In cells expressing GSPT1 G575N we did not observe any statistically significant downregulated protein, which we believe suggests the high selectivity of MRT-1577.

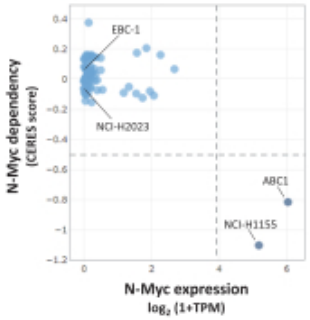
Degradation of GSPT1 by MRT-1577



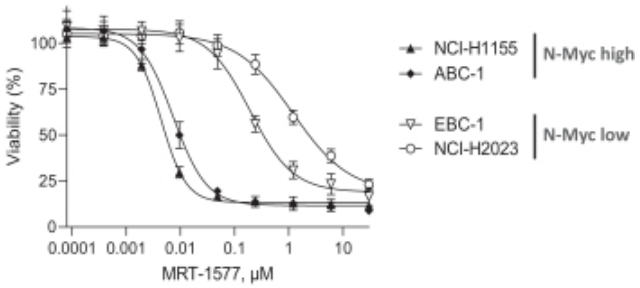
As shown on the left below, N-Myc dependency correlates with N-Myc expression levels. As shown on the right below, NSCLC cell lines expressing high levels of N-Myc were observed to be highly sensitive to MRT-1577 treatment, when compared to the cell lines expressing low levels of N-Myc. GSPT1 was degraded by MRT-1577 after six hours of treatment in high N-Myc NCI-H1155 and ABC-1 cells with a DC_{50} of 3 nM and 22 nM, respectively. In both cell lines, we observed complete degradation of GSPT1.

Table of Contents

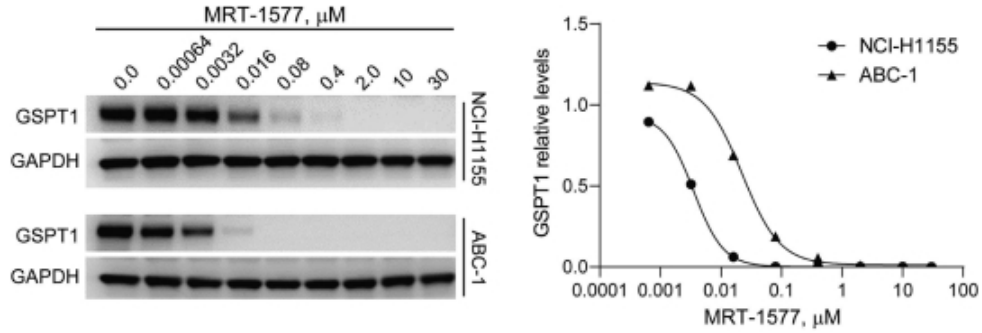
N-Myc dependency correlates with N-Myc expression levels



MRT-1577 sensitivity correlates with the expression of N-Myc in NSCLC cell lines

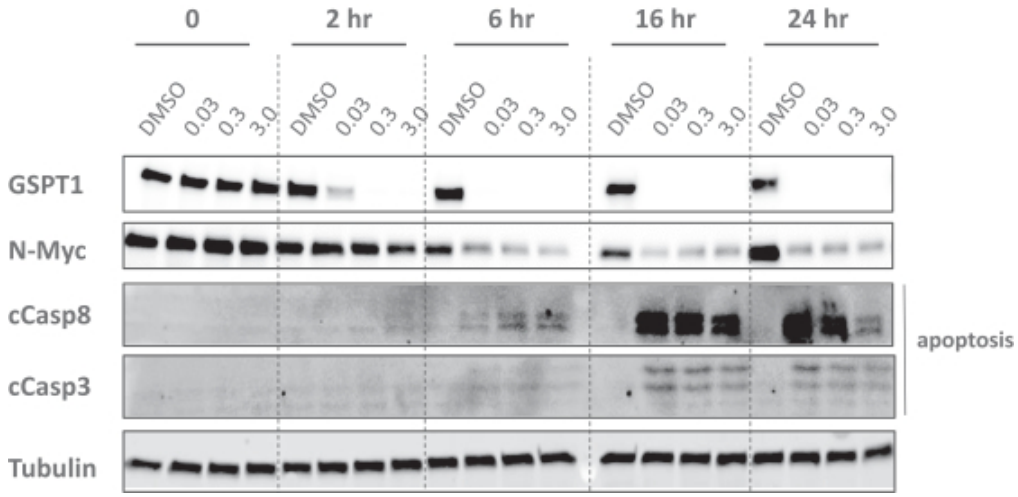


MRT-1577 degrades GSPT1 in a concentration dependent manner



Additionally, we observed sustained downregulation of N-Myc expression, which we believe is a consequence of the degradation of GSPT1, and induction of the known markers of cell death or apoptosis, Caspase 8 and Caspase 3 cleavage.

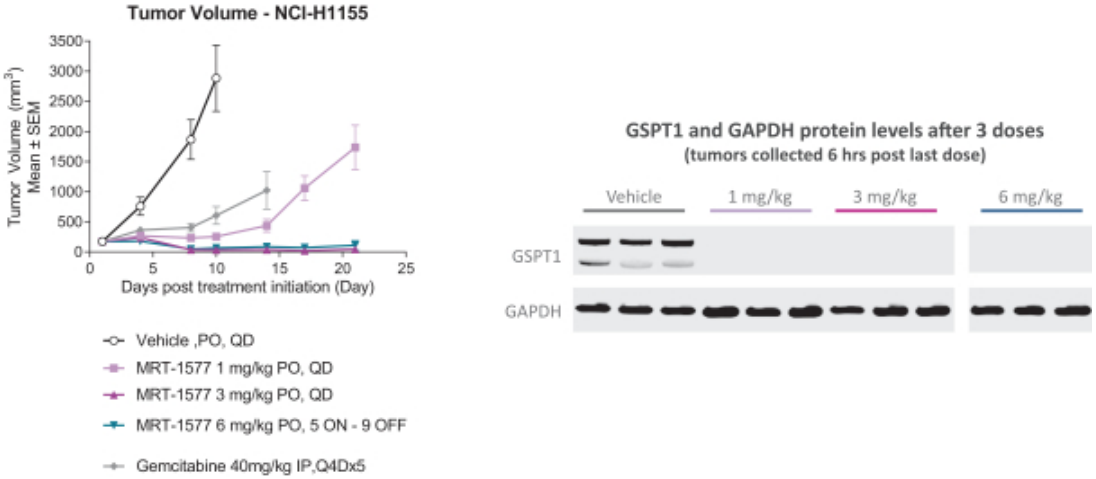
Sustained downregulation of N-Myc expression and induction of apoptosis



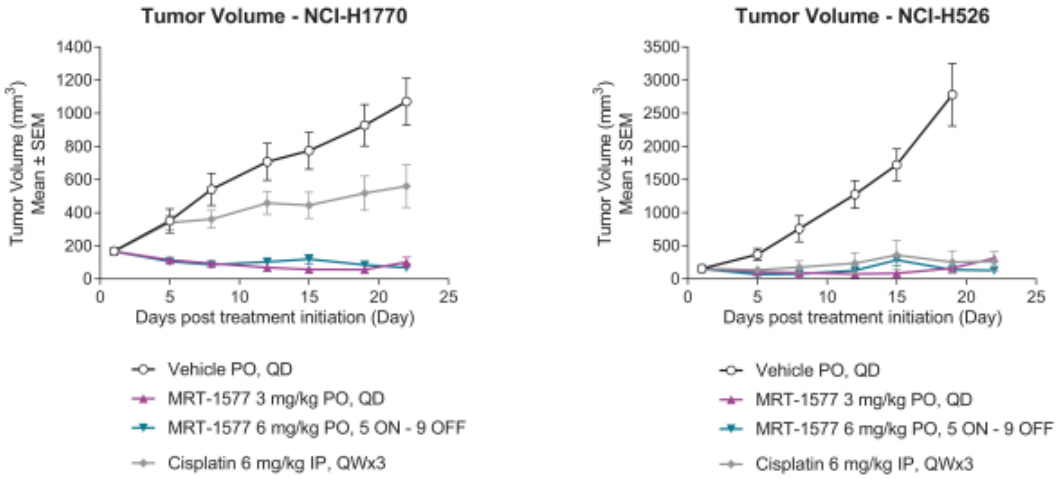
In vivo data

We observed that oral administration of MRT-1577 in the N-Myc-driven mouse xenograft model using the human cell line NCI-H1155 did not lead to body weight loss and led to tumor growth inhibition. Further, at a dose of 1 mg/kg once daily, tumor growth was suppressed for two weeks. At a dose of 3 mg/kg once daily or 6 mg/kg dosed for five days on and nine days off, tumor size decreased, became undetectable by day eight and remained so until the end of the study at day 21. Complete degradation of GSPT1 was observed in tumors of mice treated with MRT-1577 at all three dose levels as compared to mice treated with vehicle control. Similar results were observed in two additional xenograft models with high N-Myc levels, NCI-H1770 (NSCLC) and NCI-H526 (SCLC) shown below.

Antitumor activity of MRT-1577 in N-Myc high NSCLC



Antitumor activity of MRT-1577 in N-Myc high lung cancer



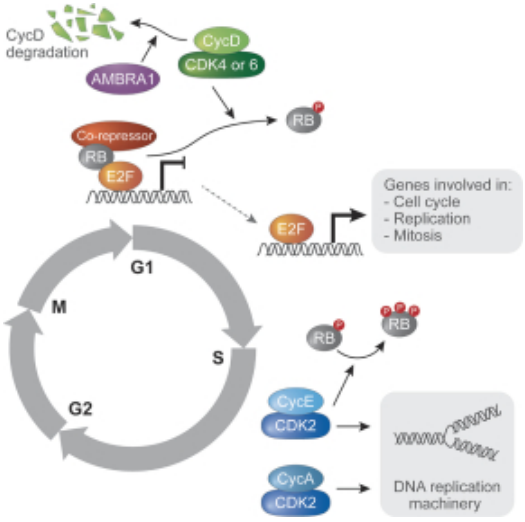
Clinical development plans for a GSPT1-directed MGD ***molecule***

We intend to advance a lead GSPT1-directed MGD development candidate into IND-enabling studies in with the goal of submitting an IND in and initiating a Phase 1 clinical trial shortly thereafter. Our planned Phase 1 trial is designed as a dose escalation trial to identify the recommended dose for expansion in

NSCLC patients selected for N-Myc overexpression. The primary endpoint of this trial will be to determine the safety and tolerability of the selected MGD molecule dosed orally and the secondary endpoints will be to characterize the PK/PD and anti-tumor activity in the biomarker positive patients.

CDK2-directed MGD molecules for the treatment of ovarian and breast cancer

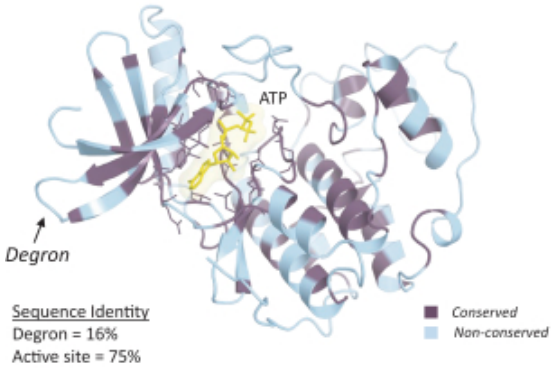
Cyclin dependent kinases, or CDKs, are a family of closely related kinases that regulate progression through the cell cycle. CDK activity is further modulated by levels of specific cyclins, for example, cyclin E1 activates cyclin-dependent kinase 2, or CDK2. Tumors with CDK2 are activated by (i) the amplification of Cyclin E1 or E2 or the loss of the AMBRA1 gene and (ii) the loss of retinoblastoma. Cyclin E1 dysregulation has been found in a number of cancers, including ovarian and triple negative breast cancer. In addition, cyclin E1 dysregulation and CDK2 activation has also been found to be one of the mechanisms of resistance in estrogen receptor positive breast cancer patients treated with CDK4/CDK6 inhibitors, such as palbociclib. Therefore, we believe selective elimination of CDK2 may provide benefit to these patients. Small molecule inhibitors and PROTACs of CDK2 have been limited in their selectivity due to the high degree of similarity among the active sites of CDKs. We have identified multiple MGD molecules that selectively promoted the association of CDK2 and cereblon *in vitro*, while avoiding other CDKs, and are in the process of optimizing the chemical leads.



Identification of CDK2 degron and MGD molecules

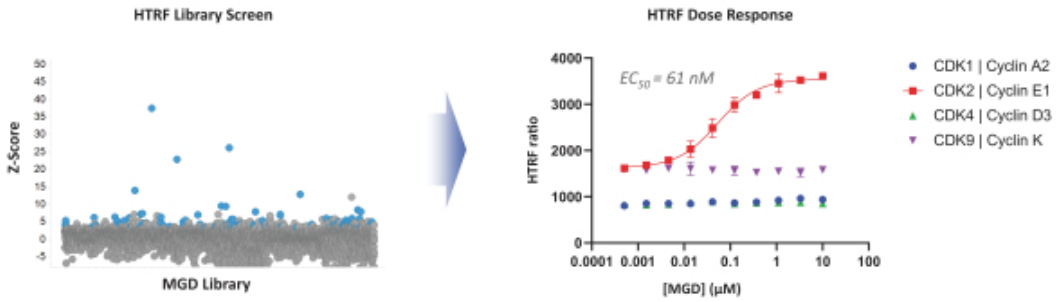
Our Degron Encyclopedia indicates that CDK2 contains a degron which has low amino acid sequence identity compared to other members of the CDK family and within the kinase family in general. This is in contrast to the high sequence similarity of the active site shared between all CDK family members. Shown below is a structural and amino acid sequence comparison between CDK2 and CDK4, demonstrating how the degron sequence is more different at a sequence level compared to the active site, despite the high structural similarity of both the active site and the degron of these two kinases.

Low sequence similarity between the CDK2 and CDK4 degrons



We screened a CDK2/cyclin E1 complex in a biochemical HTRF assay with our proprietary MGD molecule library and identified several MGD molecules that promoted the association of the CDK2/cyclin E1 complex with cereblon. We then confirmed that these MGD molecules showed concentration-dependent ternary complex formation. We also assessed the biochemical selectivity of our MGD molecules to other CDK family members, specifically CDK1, CDK4 and CDK9. As shown below, we did not detect any ternary complex formation of these CDK family members with our MGD molecules. A Z-score represents the number of standard deviations a given value is from the mean of all values, with larger Z-scores suggesting stronger evidence of an actual change. We highlight values with Z-scores greater than five as highly significant.

Identification of CDK2-directed MGD molecules



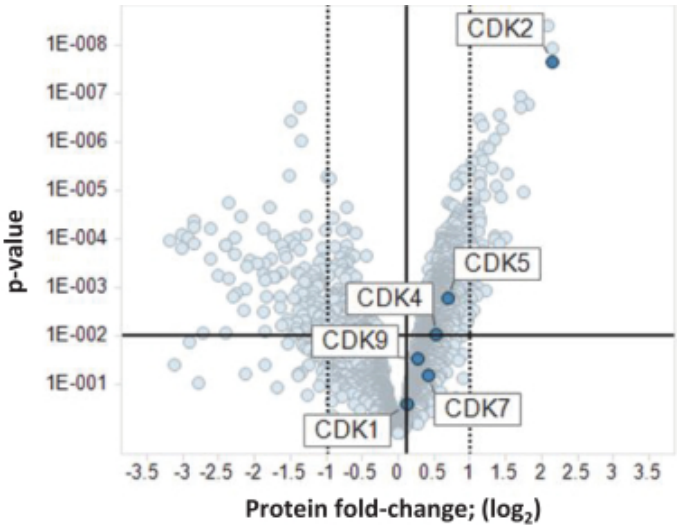
Preclinical studies and data

In support of future preclinical development activities, we have observed high selectivity potential in *in vitro* studies for our CDK2-directed MGD molecules.

In vitro data

We have identified several MGD molecules that promoted ternary complex in cells using our proximity-based Turbo-ID proteomics assay. We performed the experiment in HEK293 cells treated for six hours with our MGD molecule. As shown in the volcano plot below, CDK2 protein levels were significantly increased after treatment of cells with the CDK2-directed MGD molecule, indicating formation of ternary complex with cereblon. This was not observed with other CDK family members, highlighting the selectivity of our MGD molecule.

MGD molecule-induced spatial proximity of CDK2 to cereblon



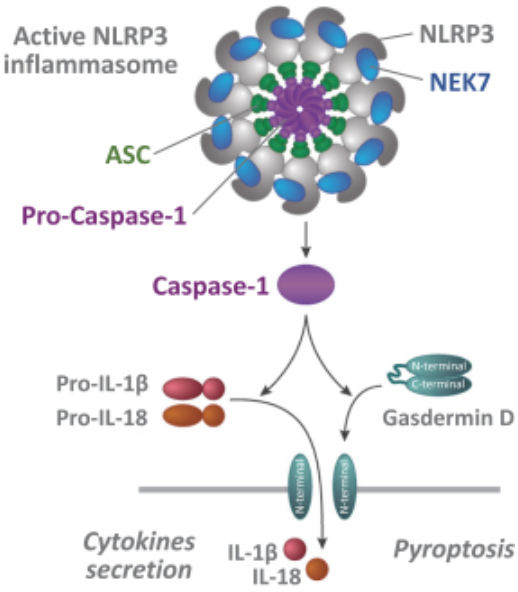
NEK7 degraders for inflammatory disease

The NLRP3 inflammasome is a multiprotein complex that serves as a central node to integrate cellular signals generated by pathogens, damage and stress, and triggers the generation of pro-inflammatory cytokines. Aberrant NLRP3 inflammasome activation has been implicated in a number of autoinflammatory disorders including Crohn's disease, neurodegenerative diseases, diabetes and liver disease. Additionally, multiple activating NLRP3 mutations have been shown to be associated with Cryopyrin-associated periodic syndromes. NIMA-Related Kinase 7, or NEK7, a serine/threonine-protein kinase, activates the NLRP3 inflammasome in a kinase independent manner, suggesting that degradation of NEK7 with an MGD molecule is an attractive therapeutic approach. We found that NEK7 contains a well-defined degron and have identified MGD molecules that are highly selective for NEK7 in *in vitro* models. We are currently optimizing chemical leads that are derived from multiple series of MGD molecules in this program.

Development opportunity of NEK7 degraders

NEK7 binding to NLRP3 is an essential step in promoting the assembly of the NLRP3 inflammasome. The assembly of NLRP3/NEK7 with ASC and pro-caspase 1 in a multi-protein complex induces cleavage of pro-caspase 1, which then activates multiple inflammatory responses including secretion of the cytokines interleukin-1ß and interleukin-18 and induction of pyroptosis. Knockout of NEK7 in animal models has been shown to decrease inflammatory signaling, which leads to decreased disease severity in models of inflammatory diseases. Activation of the NLRP3 inflammasome is driven through a kinase-independent function of NEK7, suggesting that inhibition of the catalytic activity of NEK7 would be ineffective in blocking NLRP3 inflammasome activation.

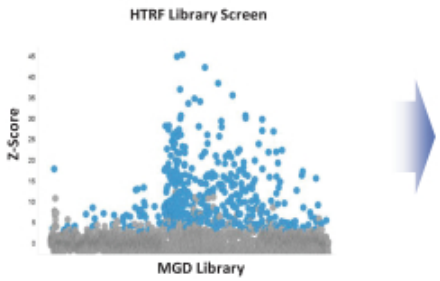
NEK7-mediated NLRP3 inflammasome assembly and activation

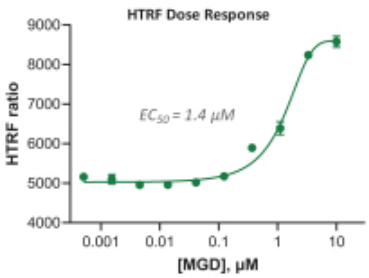


Identification of NEK7 degron and MGD molecules

NEK7 contains a well-defined degron, as identified using our proprietary Degron Encyclopedia. The amino acid sequence of the NEK7 degron is unique among the NEK family members, indicating the potential to identify MGD molecules that are highly selective for NEK7. Given the kinase independent role of NEK7 in activating the NLRP3 inflammasome, we believe our MGD molecules will have a therapeutic advantage by inducing degradation of NEK7. We screened NEK7 in a biochemical HTRF assay with our proprietary MGD molecule library and identified multiple MGD molecules that promoted association of NEK7 and cereblon. These MGD molecules showed concentration dependent ternary complex formation. In addition, these MGD molecules were highly selective over known and novel neosubstrates, including GSPT1 and CK1a.

Identification of NEK7-directed MGD molecules





Neosubstrate selectivity (Single-point HTRF)

Target	Z-score
NEK7	**16.2**
CK1α	-0.6
GSPT1	-0.1
VAV1	-0.7
CDK2/cycE1	0.0
BCL11A	0.6

"Z-score" in the table above is a measure of statistical significance.

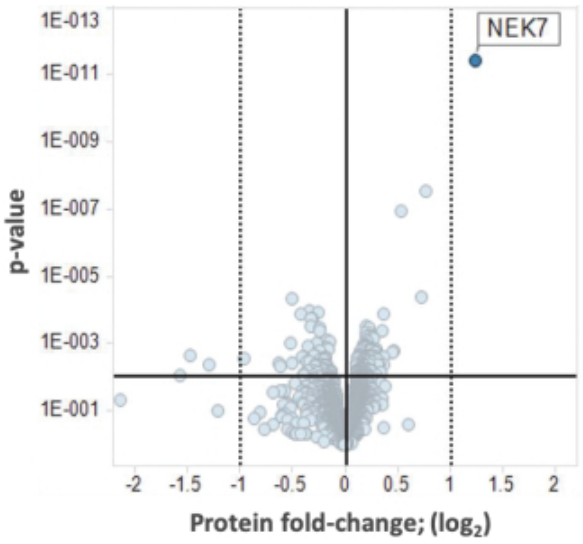
Preclinical studies and data

In support of future preclinical development activities, we have observed high selectivity potential in in vitro studies for our NEK7 MGD molecules.

In vitro data

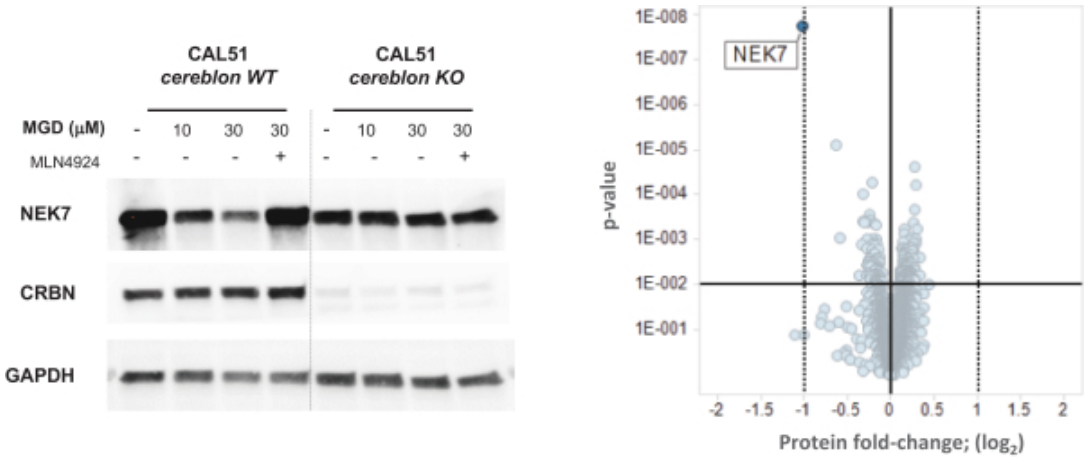
We have shown that several of our MGD molecules promoted ternary complex formation in cells. Highlighted below is a representative MGD molecule that led to association of NEK7 and cereblon in the CAL51 cell line. We performed a proximity-based Turbo-ID proteomics experiment in cells treated for six hours with our MGD molecule. As shown in the volcano plot below, NEK7 protein levels were significantly increased, compared to DMSO-treated cells, indicating that this MGD molecule promoted association of NEK7 and cereblon.

MGD-induced spatial proximity of NEK7 to cereblon



We have shown that MGD molecules that promoted ternary complex formation in cells also promoted degradation of NEK7 *in vitro*. Shown below on the left is an MGD molecule representative of those in our portfolio that led to the concentration-dependent degradation of NEK7 in the CAL51 cell line. The activity was observed to be dependent on cereblon as demonstrated by the lack of degradation in a cereblon knockout cell line. To assess selectivity in cells, we performed deep mass spectrometry-based proteomics in the same cell line, treated for 6 hours with our MGD molecule. Shown in the volcano plot below, NEK7 was observed to be the most statistically downregulated protein, compared to DMSO-treated cells, suggesting the potential selectivity of our MGD molecule for NEK7.

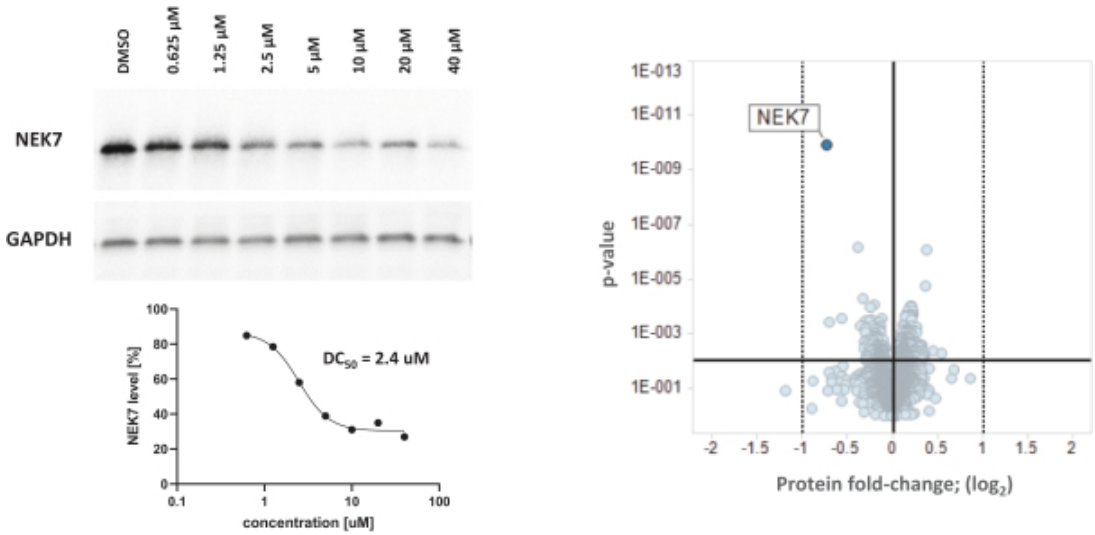
Our MGD molecules promote degradation of NEK7



KO and WT in figure above means “knock out” and “wild type”.

To determine the selectivity and activity in primary human cells, we treated human peripheral blood monocytes, or hPBMCs, from multiple donors with increasing concentrations of one of our MGD molecules. As shown below on the left, treatment with this MGD molecule led to a dose-dependent degradation of NEK7 in hPBMCs, with a DC_{50} of 2.4 μM. We also performed deep mass spectrometry-based proteomics in hPBMCs that had been treated for 24 hours with our MGD molecule. As shown in the volcano plot below, NEK7 was the most downregulated protein, suggesting the potential for activity and selectivity of this MGD molecule in at least two cellular systems.

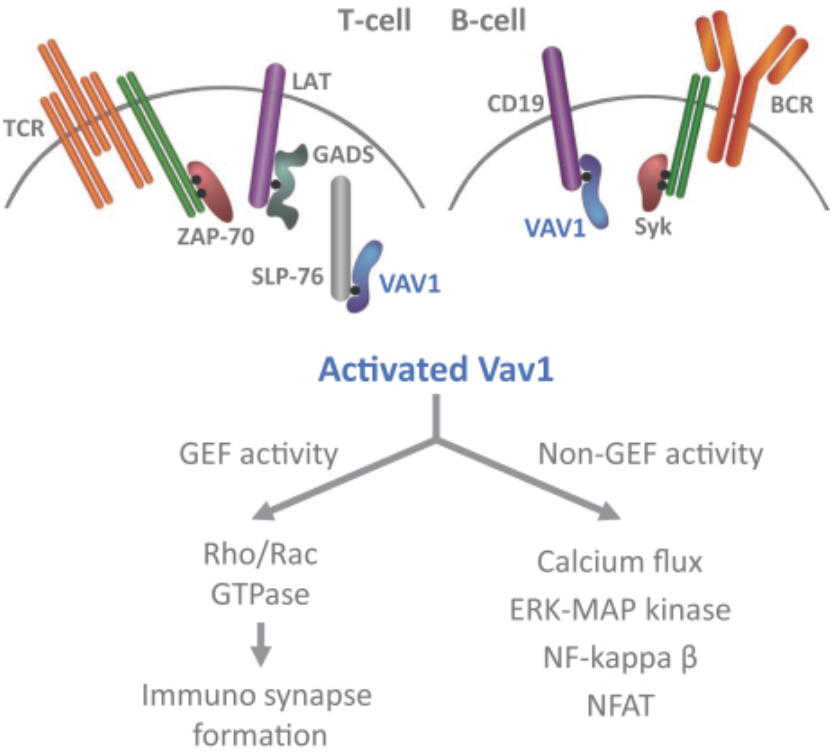
Our MGD molecules are active and selective across cellular systems



VAV1-directed MGD molecules for hematological cancers and autoimmune disease

VAV1, a Rho-family guanine nucleotide exchange factor, is expressed in immune cells including T and B cells and functions to activate T and B cell receptor signaling. VAV1 has also been implicated in hematological malignancies, including T-cell acute lymphoblastic leukemia, or T-ALL, diffuse large B-cell lymphoma, or DLBCL, and chronic lymphocytic leukemia, or CLL. Because of VAV1's function in both T and B cells, degradation could also provide therapeutic benefits in autoimmune diseases, such as multiple sclerosis and myasthenia gravis. While considered an undruggable protein, we identified VAV1 as a degron-containing protein and have discovered MGD molecules that promoted association of VAV1 and cereblon. We plan to optimize chemical leads that are derived from multiple series of MGD molecules.

VAVI plays a key role in T-cell and B-cell development and activation

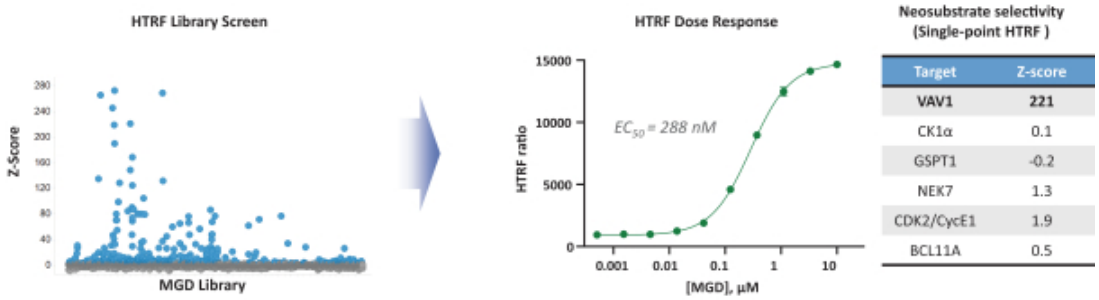


Identification of VAV1 degron and MGD molecules

Our Degron Encyclopedia indicates that VAV1 contains a degron that is unique compared to other members of the VAV family, suggesting we can target VAV1 selectively with our MGD molecules. Using the Glue-omics Rhapsody tool, we built a structural model of the VAV1 protein in complex with cereblon. The ternary complex model showed favorable interaction surfaces between the VAV1 and cereblon proteins, suggesting that an MGD molecule has the potential to promote degradation of VAV1.

We screened VAV1 in a biochemical HTRF assay with our proprietary MGD molecule library and identified multiple MGD molecules that promoted the association of VAV1 and cereblon. We then observed that these MGD molecules showed concentration-dependent ternary complex formation. These MGD molecules were also highly selective over several known and novel neosubstrates, including GSPT1 and CK1a.

Identification of VAV1-directed MGD molecules



Neosubstrate selectivity (Single-point HTRF)

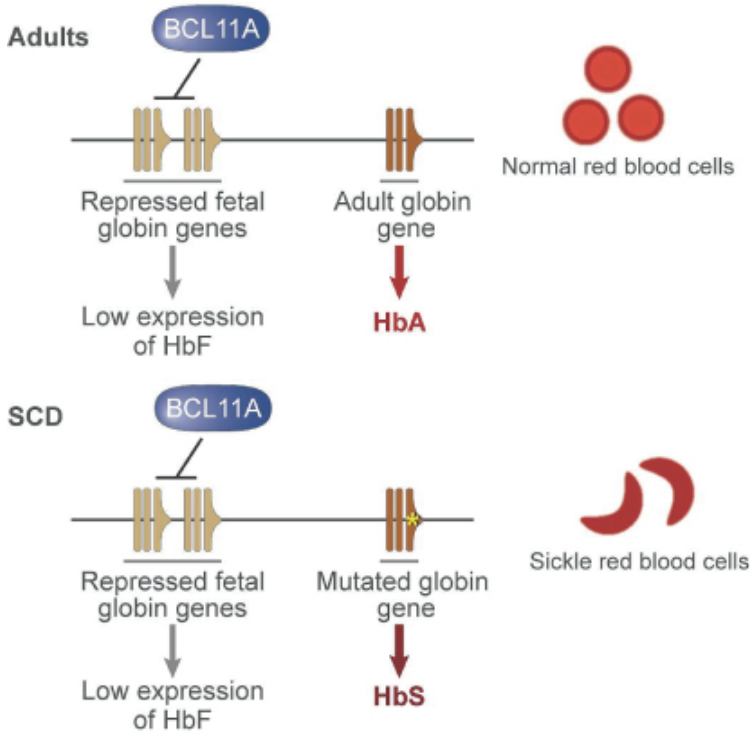
Target	Z-score
VAV1	221
CK1α	0.1
GSPT1	-0.2
NEK7	1.3
CDK2/CycE1	1.9
BCL11A	0.5

“Z-score” in the table above is a measure of statistical significance.

BCL11A-directed MGD molecules for the treatment of sickle cell disease and ß-Thalassemia

Sickle cell disease, or SCD, is caused by a mutation in a form of hemoglobin, leading to severe disease manifestations, including anemia and vaso-occlusive crises. However, in SCD patients, increasing levels of fetal hemoglobin, or HbF, are associated with fewer co-morbidities and a better prognosis. In adults, B-cell lymphoma/leukemia 11A, or BCL11A, represses transcription of the HBG gene, thereby silencing HbF expression. We believe that downregulation of BCL11A to reactivate HbF expression is a promising therapeutic strategy, and it is being clinically tested by third parties to treat SCD using adoptive cell therapy. BCL11A has to date been considered undruggable using small molecule therapies. We believe reactivation of HbF through MGD-mediated BCL11A degradation could be used as a therapeutic strategy for both SCD as well as other hemoglobinopathies, such as ß-Thalassemia. We identified BCL11A as a degron-containing protein and, in preclinical studies, we observed that our MGD molecules induced the association of BCL11A with cereblon. We plan to optimize chemical leads that are derived from multiple series of MGD molecules.

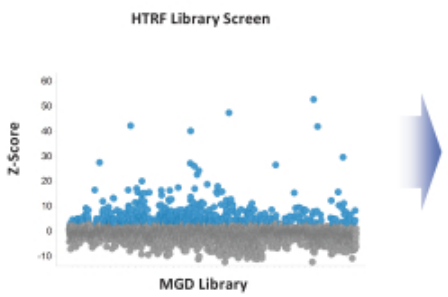
BCL11A is the zinc finger transcription repressor of the fetal globin genes

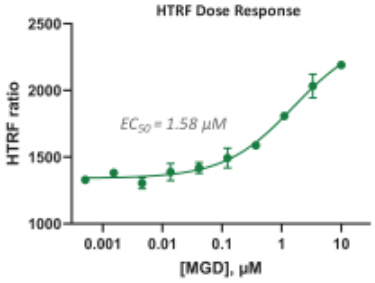


Identification of BCL11A degron and MGD molecules

Our Degron Encyclopedia indicates that BCL11A contains a degron. Using our biochemical HTRF assay, we screened our proprietary MGD molecule library to identify MGD molecules that promoted the association of BCL11A and cereblon. We then observed that these MGD molecules showed concentration-dependent ternary complex formation. These MGD molecules were highly selective over several known and novel neosubstrates, including GSPT1 and CK1a.

Identification of BCL11A-directed MGD molecules





Neosubstrate selectivity (Single-point HTRF)

Target	Z-score
BCL11A	15.5
CK1α	0.0
GSPT1	-0.4
NEK7	3.3
CDK2/CycE1	0.8
VAV1	-0.2

"Z-score" in the table above is a measure of statistical significance.

Current status and next steps of our discovery programs

We are currently optimizing chemical leads that are derived from multiple series of MGD molecules in the CDK2, NEK7, VAV1 and BCL11A programs. We anticipate advancing at least two of these programs into lead optimization in where the most promising MGD molecules will be profiled in a series of *in vitro* and *in vivo* assays before advancing them into toxicology studies.

Other programs

We are specifically focused on developing product candidates for targets that have been deemed undruggable or inadequately drugged. Our QuEEN platform was purpose-built to support the discovery and development of drugs that degrade a wide landscape of therapeutically-relevant proteins by (i) systematically identifying therapeutically-relevant target proteins that may be amenable to molecular glue-based degradation; and (ii) rationally designing molecules that can be optimized towards high potency and selectivity, with properties that we believe to be favorable. Our early pipeline includes programs in genetically defined oncology indications, as well as inflammatory, immunologic and genetic disease indications. We are further engaged in the discovery of additional targets in other indications, including, but not limited to, neurodegenerative and other neurological diseases. We are planning to develop our MGD molecules in succinct patient populations through biomarker-driven clinical trials.

Our services, collaboration and licenses agreements

Services agreement with Ridgeline

During our initial years of operation, we built and conducted our research and development activities pursuant to the Ridgeline Services Agreement, with Ridgeline, a wholly-owned subsidiary of Versant Ventures, our largest shareholder. Ridgeline is a company incubator and discovery engine of Versant Ventures, focused on providing drug discovery expertise and operational support. By leveraging Ridgeline's deep experience in the areas of discovery, drug design and medicinal chemistry, together with our biology expertise, we were able to accelerate the discovery and development of our molecular glue degraders. Alexander Mayweg, the chairman of our board of directors, is the president of Ridgeline and a Managing Director at Versant Ventures, Bradley Bolzon, a member of our board of directors, is the Chairman and Managing Director of Versant Ventures, and Markus Warmuth, our Chief Executive Officer and President and a member of our board of directors, is a Venture Partner at Versant Ventures.

Under the Ridgeline Services Agreement, all results, inventions and products and any related intellectual property arising from services provided by Ridgeline are owned by us. In consideration for the services provided under the Ridgeline Services Agreement, we pay Ridgeline an amount equal to actual costs incurred by Ridgeline in providing the services plus a specified markup on a quarterly basis. Certain executives and employees of Ridgeline have also received equity grants from us. No milestone or royalty payments are owed to Ridgeline. To date, we have paid Ridgeline $25.0 million in connection with the Ridgeline Services Agreement.

The term of the Ridgeline Services Agreement continues in effect unless either we or Ridgeline elect to terminate the agreement, which either party may do for any or no reason upon 30 days prior written notice.

During 2020, we continued to build our operations, internal chemistry, biology and preclinical development capabilities through key additional hires to assume activities conducted by Ridgeline on our behalf, and we expect to continue to reduce Ridgeline's services under the Ridgeline Services Agreement in 2021.

Agreements with Cancer Research Technology Limited and the Institute of Cancer Research

CRT and the ICR jointly own certain intellectual property generated at the ICR using funding from CRUK related to the field of protein degradation. In April 2018, we concurrently entered into a license agreement, or the

License Agreement, with CRT and the ICR, and a formation and investment agreement, or the Formation and Investment Agreement with CRT and the ICR, pursuant to which we agreed to issue an aggregate of 4,000,000 common shares to CRT, the ICR and affiliated founding scientists as consideration for the rights granted under the License Agreement at a price per share of CHF 0.01 for an aggregate purchase price of CHF 40,000.

Collaboration and option agreement

In April 2018, we entered into the Collaboration and Option Agreement, with CRT, a wholly-owned subsidiary of Cancer Research UK, or CRUK, and the ICR. Under the Collaboration and Option Agreement, the ICR was responsible for performing certain research and development activities through December 31, 2020, or the Collaboration Term, which included assembling a library of cereblon-binding compounds and identifying and validating new biological targets for drug discovery through phenotypic cell based screening. During the Collaboration Term, we paid the ICR certain amounts to cover the cost of employing eight full-time employees and certain research outsourcing costs.

Under the Collaboration and Option Agreement, we are obligated to exercise commercially reasonable efforts at all times to (i) develop one or more products for use in human clinical trials, including at least one product with an application in oncology indication, (ii) pursue regulatory authorization for each product and, where applicable, price approval in at least one major market, which include the United Kingdom, the United States, France, Italy, Spain, Germany and Japan and (iii) introduce and commercialize each product in the foregoing major markets where regulatory authorization and, where applicable, price approval for such product has been obtained. Further, if a product is launched or ready to be launched in the United Kingdom, we are obligated to use commercially reasonable efforts to cause such product to be made available throughout the United Kingdom at an affordable price as specified in the Collaboration and Option Agreement.

Pursuant to the Collaboration and Option Agreement, we are obligated to pay CRT milestone payments upon the achievement of certain milestones. The aggregate amount of milestone payments and royalties to be paid will depend on whether or not the development candidates that we identify are subject to the Collaboration and Option Agreement. Those milestone payments are in the single-digit millions for the first product we develop under the Collaboration and Option Agreement and a reduced amount in milestone payments for any additional product we develop in the single-digit millions. We are also obligated to pay CRT low-single digit royalties on net sales on a product-by-product and country-by-country basis. Our obligation to pay royalties will expire upon the later of (i) the expiration of the last patent which covers such product in such country; (ii) 10 years following the first commercial sale of such product in such country; and (iii) the expiration of any extended patent exclusivity period in the relevant country. To date we have paid $4.8 million under the Collaboration and Option Agreement.

All intellectual property developed or discovered pursuant to the research collaboration during the Collaboration term is owned by us, subject to the ICR's and CRT's rights in and to their pre-existing intellectual property and the ICR's and CRT's research rights; provided, however, any substrate list and target deconvolution data that is generated by or on behalf of the ICR in connection with its independent research and screening activities that result in a non-degradation program is jointly owned by CRT and the ICR under certain conditions. We are permitted to grant sub-licenses in respect of the rights granted under the Collaboration and Option Agreement, subject to certain limitations.

Even though the Collaboration Term under the Collaboration and Option Agreement expired on December 31, 2020, the term of the Collaboration and Option Agreement itself continues until it is otherwise terminated by (i) either party in the event of a material breach or upon an insolvency event, (ii) mutual agreement of the parties for any reason, (iii) us in the event that CRT and/or the ICR challenges the validity of any patent made or conceived pursuant to the research collaboration or if the joint steering committee determines that the continuation of the research collaboration would be commercially unreasonable, scientifically unviable, illegal

or impossible or (iv) CRT and the ICR (acting together) in the event that any person who develops, sells or manufactures tobacco or otherwise makes a majority of its profits in the tobacco business acquires more than 50% of our voting securities or if we permanently abandon all discovery, development and commercialization efforts for all products related to the research collaboration.

License agreement

Under the License Agreement, CRT and the ICR granted us a worldwide, exclusive, fully-paid, irrevocable, perpetual, sub-licensable license to (i) CRT and the ICR's intellectual property rights in its compound library to research, develop and commercialize products that (a) contain or comprise such compounds or (b) are discovered, developed or generated using or incorporating CRT and the ICR's existing intellectual property, or Licensed Products, and (ii) CRT and the ICR's certain specified know-how and other intellectual property rights unrelated to its compound library to research, develop and commercialize products designed or intended to have a primary mechanism of action through cereblon-mediated protein degradation, or Protein Degradation Products, in each case of (i) and (ii), for the treatment, prevention and/or diagnosis of any and all diseases, disorders or conditions. CRT and the ICR also granted us a worldwide, non-exclusive, fully-paid, irrevocable, perpetual and sub-licensable license to certain of CRT and the ICR's specified non-compound related intellectual property rights and know-how to research, develop and commercialize Licensed Products and Protein Degradation Products for the treatment, prevention and/or diagnosis of any and all diseases, disorders or conditions. The foregoing exclusive license is subject to CRT and the ICR's retained rights to practice certain specified licensed intellectual property rights to carry out noncommercial academic research and teaching.

In consideration for the rights granted under the License Agreement, we issued an aggregate of 4,000,000 common shares to CRT, the ICR and affiliated founding scientists pursuant to the Formation and Investment Agreement at a price per share of CHF 0.01 for an aggregate purchase price of CHF 40,000 and paid CRT a technology access fee equal to approximately $42,000. The License Agreement will remain effective until terminated by written agreement between us, CRT and the ICR.

Competition

The biotechnology industry is extremely competitive in the race to develop new products. While we believe we have significant competitive advantages due to our management team's years of expertise in protein degradation, molecular glues and clinical and preclinical development of precision medicines in general, we currently face and will continue to face competition for our development programs from other companies that develop heterobifunctional degraders, similar molecular glue degraders or have protein degradation development platforms. Our competition will also include companies focused on existing and novel therapeutic modalities such as small molecule inhibitors antibodies and gene therapies. The competition is likely to come from multiple sources, including large and specialty pharmaceutical companies, biotechnology companies and academic institutions that are in the business of research, development, manufacturing and commercialization

Competitors in our efforts to develop MGD therapeutics for patients, include, but are not limited to, BioTheryX Therapeutics, Inc., C4 Therapeutics, Inc., Nurix Therapeutics, Inc., Kymera Therapeutics, Inc., Arvinas, Inc. and Seed Therapeutics, Inc., all of whom currently have product candidates in preclinical or clinical development. In addition, lenalidomide and pomalidomide, which are both marketed by Bristol-Myers Squibb, are believed to function as MGDs. Further, several large pharmaceutical companies have disclosed investments in this field.

In addition to the competitors we face in developing small molecule protein degraders, we will also face competition in the indications we expect to pursue with our MGD programs. Many of these indications already have approved standards of care which may include existing therapeutic modalities. In order to compete effectively with these existing therapies, we will need to demonstrate that our MGDs perform favorably when compared to existing therapeutics.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates and currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently engage with third-party contract manufacturing organizations, or CMOs, for the manufacture of our product candidates and we intend to continue to do so in the future. We rely on and expect to continue to engage on third-party manufacturers for the production of both drug substance and finished drug product. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term supply arrangements in place. Should any of these manufacturers become unavailable to us for any reason, we believe that there are a number of potential replacements, although we may incur some delay in identifying and qualifying such replacements.

Intellectual property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and Patent Cooperation Treaty, or PCT, patent applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology in relation to the commercialization of our products.

As of April 19, 2021, we owned 10 Swiss pending patent applications, one U.S. pending patent application and one pending PCT application that has not entered national stage relating to our QuEEN platform and our GSPT1 program as further described below. Patent prosecution related to our pending patent applications is in the early stages and, as such, no patent examiner has yet fully scrutinized the merits of any of our pending patent applications. Additionally, we own three pending U.S. applications to register trademark for our marks “MONTE ROSA,” “MONTE ROSA THERAPEUTICS” and “GLUEOMICS.”

With respect to our GSPT1 program, as of April 19, 2021, we owned four Swiss priority patent applications and one PCT patent application (WO2021069705) that has not entered national stage that cover various GSPT1 degraders. Each of these patent applications includes composition of matter, pharmaceutical compositions, and methods of using the disclosed GSPT1 degraders. Any U.S. or foreign patent issuing from the PCT patent application, if such patent is issued, would be scheduled to expire in 2040, and any U.S. or foreign patents issuing from the four Swiss priority patent applications, if such patents are issued, would be scheduled to expire in 2042, excluding any additional term for patent term adjustment or patent term extension, and assuming national phase entries are timely made based upon the pending PCT application and timely payment of all applicable maintenance or annuity fees. We also own four Swiss priority patent applications that cover

biomarkers and one Swiss priority patent application directed to certain methods of reading through nonsense mutations, each of which relates to our GSPT1 program. Any U.S. or foreign patents issuing from these five Swiss priority patent applications, if such patents are issued, would be scheduled to expire in 2042, excluding any additional term for patent term adjustment or patent term extension, and assuming national phase entries are timely made based upon the pending PCT application and timely payment of all applicable maintenance or annuity fees.

With respect to our QuEEN platform, as of April 19, 2021, we owned one U.S. provisional patent application that covers our QuEEN platform and the use thereof in developing and applying therapeutics. We are continuing to assess whether we will convert this U.S. provisional patent application into a non-provisional patent application and ultimately seek patent protection for our QuEEN platform, or instead maintain the intellectual property described in this provisional patent application as a trade secret. Any U.S. or foreign patent issuing from this U.S. provisional patent application, if such patent is issued, would be scheduled to expire in 2042, excluding any additional term for patent term adjustment or patent term extension.

Government regulation

The FDA and other regulatory authorities at federal, state and local level, as well as in foreign countries and local jurisdictions, extensively regulate among other things, the research, development, testing, manufacture, quality control, sampling, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs. We, along with our vendors, contract research organizations and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidates. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the U.S., the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, as amended, its implementing regulations and other laws. If we fail to comply with applicable FDA or other requirements at any time with respect to product development, clinical testing, approval or any other legal requirements relating to product manufacture, processing, handling, storage, quality control, safety, marketing, advertising, promotion, packaging, labeling, export, import, distribution, or sale, we may become subject to administrative or judicial sanctions or other legal consequences. These sanctions or consequences could include, among other things, the FDA's refusal to approve pending applications, issuance of clinical holds for ongoing studies, withdrawal of approvals, warning or untitled letters, product withdrawals or recalls, product seizures, relabeling or repackaging, total or partial suspensions of manufacturing or distribution, injunctions, fines, civil penalties or criminal prosecution.

The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice, or GLP, requirements;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an IRB or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with applicable IND regulations, GCP requirements and other clinical trial-related regulations, to establish the safety and efficacy of the investigational product for each proposed indication;

- submission to the FDA of a NDA;
- a determination by the FDA within 60 days of its receipt of an NDA, to accept the filing for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the drug will be produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the U.S.

Preclinical studies and clinical trials for drugs

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of drug chemistry, formulation and stability, as well as in vitro and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety/toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before clinical trials may begin. Some long-term preclinical testing may continue after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research patients will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Submission of an IND may result in the FDA not allowing clinical trials to commence or not allowing clinical trials to commence on the terms originally specified in the IND.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. The FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public

registries. Information about applicable clinical trials, including clinical trial results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor must submit data from the clinical trial to the FDA in support of an NDA. The FDA will accept a well-designed and well-conducted foreign clinical trial not conducted under an IND if the trial was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap or be combined.

- Phase 1—Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, excretion the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2—Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.
- Phase 3—Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval and physician labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggest a significant risk for human volunteers and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor’s initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate

and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. marketing approval for drugs

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. An NDA must contain proof of the drug's safety and efficacy in order to be approved. The marketing application may include both negative and ambiguous results of preclinical studies and clinical trials, as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use 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 efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a drug may be marketed in the U.S.

The FDA reviews all submitted NDAs before it accepts them for filing and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of a new molecular entity NDA and respond to the applicant, and six months from the filing date of a new molecular entity NDA for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, program to ensure that the benefits of the drug outweigh its risks. The REMS program could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries or other risk-minimization tools.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which 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.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. 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, the FDA may inspect one or

more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter. A complete response letter generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed it may limit the approved indications for use of 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 a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a 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-marketing studies or surveillance programs. After approval, some 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.

Orphan drug designation and exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the U.S., or if it affects 200,000 or more individuals in the U.S., there is no reasonable expectation that the cost of developing and making the product available in the U.S. for the disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan products are eligible for certain incentives, including tax credits for qualified clinical testing and waiver of application fees.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to a seven-year period of marketing exclusivity during which the FDA may not approve any other applications to market the same therapeutic agent for the same indication, except in limited circumstances, such as a subsequent product's showing of clinical superiority over the product with orphan exclusivity or where the original applicant cannot produce sufficient quantities of product. Competitors, however, may receive approval of different therapeutic agents for the indication for which the orphan product has exclusivity or obtain approval for the same therapeutic agent but for a different indication than that for which the orphan product has exclusivity. Orphan product exclusivity could also block the approval of one of our products for seven years if a competitor obtains approval for the same therapeutic agent for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity. Further, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was

materially defective or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited development and review programs for drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval, and the purpose of these programs is to either expedite the development or review of important new drugs to get them to patients earlier than under standard FDA development and review procedures.

A new drug is eligible for Fast Track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the agency may review portions of the marketing application before the sponsor submits the complete application, as well as Priority Review, discussed below.

In addition, a new drug may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track designation in addition to intensive guidance on an efficient drug development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process including Priority Review designation and Accelerated Approval. A product is eligible for Priority Review if it has the potential to provide a significant improvement in safety or effectiveness in the treatment, diagnosis or prevention of a serious disease or condition. Under priority review, the FDA targets reviewing an application in six months after filing compared to ten months after filing for a standard review.

Additionally, products are eligible for Accelerated Approval if they can be shown to have an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality which 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. Accelerated Approval is usually contingent on a sponsor’s agreement to conduct additional post-approval studies to verify and describe the product’s clinical benefit. The FDA may withdraw approval of a drug or indication approved under Accelerated Approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for Accelerated Approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be

shortened. Furthermore, Fast Track designation, Breakthrough Therapy designation, Priority Review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

Pediatric information and pediatric exclusivity

Under the Pediatric Research Equity Act, or PREA, as amended, certain NDAs and certain supplements to an NDA must contain data to assess the safety and efficacy of the drug 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. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. The FD&C Act requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug can also obtain pediatric market exclusivity in the U.S. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial or of multiple pediatric trials in accordance with an FDA-issued “Written Request” for such trials.

U.S. post-approval requirements for drugs

Drugs 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, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers and individuals working on behalf of manufacturers may not market or promote such uses. 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, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization.

In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

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, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs or mandated modification of promotional materials and labeling and issuance of corrective information.

Marketing exclusivity

Market exclusivity provisions under the FD&C Act can delay the submission or the approval of certain marketing applications. The FD&C Act provides a five-year period of non-patent exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FD&C Act alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the U.S. in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of

the Department of Health and Human Services, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Current and future healthcare reform legislation

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes intended to broaden access to healthcare, improve the quality of healthcare, and contain or lower the cost of healthcare. For example, in the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or ACA, among other things, subjected products to potential competition by lower-cost products, expanded the types of entities eligible for the 340B drug discount program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a Medicare Part D coverage gap discount program for certain Medicare Part D beneficiaries, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

There have been executive, judicial and congressional challenges to certain aspects of the ACA Act as well as efforts to repeal or replace certain aspects of the ACA. For example, the U.S. Supreme Court is currently reviewing the constitutionality of the ACA, but it is unknown when a decision will be reached. Although the Supreme Court has not yet ruled 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 coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

Other federal health reform measures have been proposed and adopted in the U.S. since the ACA was enacted. By way of example, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. This reduction went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021. CMS has indicated that it is delaying the processing of claims in April to allow Congress to pass legislation that would extend the suspension. In addition, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Furthermore, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several congressional inquiries and proposed legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drug products. At the federal level, the previous administration used several

means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical 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 healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. It is difficult to predict the future legislative landscape in healthcare and the effect on our business, results of operations, financial condition and prospects. However, we expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Third-party payor coverage and reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we may receive regulatory marketing approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from third-party payors. Third-party payors include government healthcare programs (e.g., Medicare, Medicaid), managed care providers, private health insurers, health maintenance organizations and other organizations. These third-party payors decide which medications they will pay for and will establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and other third-party payors is essential for most patients to be able to afford treatments such as targeted protein degradation therapies.

In the United States, no uniform policy exists for coverage and reimbursement for products among third-party payors. Therefore, decisions regarding the extent of coverage and amount of reimbursement to be provided can differ significantly from payor to payor. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

One third-party payor’s decision to cover a particular product or service does not ensure that other payors will also provide coverage for the medical product or service . Third-party payors may limit coverage to specific products on an approved list or formulary, which may not include all FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded product on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors.

Moreover, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate a payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Despite our best efforts, our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover an approved product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition.

Finally, in some foreign countries, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, in the European Union, or EU, pricing and reimbursement of pharmaceutical products are regulated at a national level under the individual EU Member States' social security systems. Some foreign countries provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and can control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A country may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Even if approved for reimbursement, historically, product candidates launched in some foreign countries, such as some countries in the EU, do not follow price structures of the U.S. and prices generally tend to be significantly lower.

Other healthcare laws and regulations

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors may expose us to broadly applicable federal and state fraud and abuse laws, as well as other healthcare laws and regulations. These laws may impact, among other things, our proposed sales, marketing, and distribution strategies. In the U.S., these laws include, among others:

- The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or paying remuneration (a term interpreted broadly to include anything of value, including, for example, gifts, discounts and credits), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, or arranging for, an item, good, facility or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations can result in significant civil monetary and criminal penalties for each violation, plus up to three times the amount of remuneration, imprisonment, and exclusion from government healthcare programs.

- Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties, for each false claim and treble the amount of the government's damages. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Further, a violation of the federal Anti-Kickback Statute can also form the basis for False Claims Act liability.
- The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes additional criminal and civil liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private); and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, including the final omnibus rule published on January 25, 2013, imposes, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain, transmit, or obtain, protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.
- Federal transparency laws, including the federal Physician Payment Sunshine Act created under the ACA, and its implementing regulations, which requires manufacturers of certain drugs, devices, medical supplies, and biologics, among others, to track and disclose payments under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and other transfers of value they make to U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners. This information is subsequently made publicly available in a searchable format on a CMS website.

Analogous state law equivalents of each of the above U.S. federal laws and similar healthcare laws and regulations in the European Union and other jurisdictions, such, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state and local marketing and/or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require the reporting of information related to drug pricing; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; state and local laws that require the licensure and/or registration of pharmaceutical sales representatives; state laws that require pharmaceutical companies to comply with the pharmaceutical

industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal, state and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. 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, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource consuming and can divert a company's attention from the business.

Compliance with other federal and state laws or requirements; changing legal requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to we may be subject.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our products; or (iv) additional record-

keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. environmental, health and safety laws and regulations

We may be 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, but this insurance may not provide adequate coverage against potential liabilities. However, 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.

Government regulation of drugs outside of the United States

To market any product outside of the U.S., we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our products.

Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Non-clinical studies and clinical trials

Similarly to the U.S., the various phases of non-clinical and clinical research in the European Union, or EU, are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the safety and non-toxicity of new chemical (or biological) substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in the Directive 2004/10/EC. In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organisation for Economic Co-operation and Development requirements.

Certain countries outside of the United States have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. In the EU for

example, a clinical trial authorization, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved by the national health authority and the ethics committee has granted a positive opinion in relation to the conduct of the trial in the relevant member state(s), in accordance with a country's requirements, clinical study development may proceed.

Clinical trials of medicinal products in the European Union must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU member states govern the system for the approval of clinical trials in the EU. Under this system, and prior to commencing a clinical trial, the sponsor must obtain a CTA from the competent national authority of each EU member state in which the clinical trial is to be conducted. Furthermore, the sponsor may only start a clinical trial at a specific trial site after the relevant independent ethics committee has issued a favorable opinion. The CTA must be accompanied by, among other documents, a copy of the trial protocol and an investigational medicinal product dossier (the Common Technical Document) containing information about the manufacture and quality of the medicinal product under investigation and other supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU member states and further detailed in applicable guidance documents. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with GMP. Other national and EU-wide regulatory requirements may also apply.

In April 2014, the new Clinical Trials Regulation (EU) No 536/2014, or the Clinical Trials Regulation, was adopted. It is expected that the Clinical Trials Regulation will apply following confirmation of full functionality of the Clinical Trials Information System, or CTIS, the centralized EU portal and database for clinical trials foreseen by the regulation, through an independent audit. The regulation becomes applicable six months after the European Commission publishes notice of this confirmation. The Clinical Trials Regulation is currently expected to become applicable by early 2022. The Clinical Trials Regulation will be directly applicable in all EU member states, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the EU will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable, the Clinical Trials Regulation will apply to the clinical trial from the expiry of such three year period. The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the EU, for example by providing for a streamlined application procedure via a single entry point and simplifying reporting procedures for clinical trial sponsors.

Marketing authorizations

In the EU, medicinal products can only be placed on the market after obtaining a marketing authorization, or MA. To obtain regulatory approval of an investigational drug in the EU, a marketing authorization application, or MAA must be submitted. The process for doing this depends, among other things, on the nature of the

medicinal product. Medicinal products must be authorized for marketing by using either the centralized authorization procedure or a national authorization procedures.

- Centralized procedure—If pursuing a MA for a product candidate for a therapeutic indication under the centralized procedure, following the opinion of the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single MA valid across the EU as well as in the European Economic Area, or EEA, countries Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines derived from biotechnology processes, such as genetic engineering, or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized MA to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EU, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EU. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who makes the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for certain expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment, however this is not guaranteed. The benefits of a PRIME designation include the appointment of a CHMP rapporteur before submission of a MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.
- National authorization procedures—There are also two other possible routes to authorize products for therapeutic indications in several EU member states, which are available for products that fall outside the scope of the centralized procedure:
    - Decentralized procedure—Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU member state for medicinal products that have not yet been authorized in any EU member states.
    - Mutual recognition procedure—Under the mutual recognition procedure, a medicine is first authorized in one EU member state, in accordance with the national procedures of that country. Following this, the applicant may seek additional MAs from other EU member states in a procedure whereby the countries concerned agree to recognize the validity of the original, national MA.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the EU, Great Britain will no longer be covered by centralized MAs (under the Northern Irish Protocol, centralized MAs will continue to be recognized in Northern Ireland). All medicinal products with a current centralized MA were automatically converted to Great Britain MAs on January 1, 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new MA in the centralized procedure, in order to more quickly grant a new Great Britain MA. A separate application will, however, still be required.

Data and marketing exclusivity

In the EU, upon receiving a MA, innovative medicinal products, sometimes referred to as new chemical entities (i.e., reference products) generally qualify for eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the non-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic/biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed in the EU until the expiration of the market exclusivity period. The overall ten-year period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU or member state regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Orphan medicinal products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the U.S. In the EU a medicinal product may be designated as orphan if (i) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. The application for orphan drug designation must be submitted before the application for MA. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a MA, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten-year orphan market exclusivity period, no MAA shall be accepted by the EMA for the same indication in respect of a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, MA may be granted to a similar product for the same indication at any time if (i) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (ii) the applicant consents to a second orphan medicinal product application; or (iii) the applicant cannot supply enough orphan medicinal product.

Pediatric development

In the EU, MAAs for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO, unless a waiver or deferral applies. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which a MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for a six-months supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan pharmaceutical products, a two year extension of the orphan market exclusivity is granted.

Post-approval requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, authorization of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

For other countries outside of the European Union, such as countries in Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Should we utilize third-party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Brexit and the regulatory framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as “Brexit”. Thereafter, in March 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which European Union pharmaceutical law remains applicable to the United Kingdom. This transition period is due to end on December 31, 2020. This means that since January 1, 2021, the United Kingdom operates under a distinct regulatory regime. EU pharmaceutical laws now only apply to the United Kingdom in respect of Northern Ireland (as laid out in the Protocol on Ireland and Northern Ireland, including but not limited to MAAs). Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, MA, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

Employees and human capital resources

As of April 19, 2021, we had 60 full-time employees, of which 32 have M.D. or Ph.D. degrees. We also contract for the services of 3.2 full-time equivalent employees through our agreement with Ridgeline. Within our workforce, 47 employees are engaged in research and development and 12 are engaged in business development, finance, legal, and general management and administration. 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 new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Facilities

Our corporate headquarters is located in Boston, Massachusetts, where we will lease and occupy approximately 16,748 square feet of office space at 645 Summer Street, Boston, MA 02210. The current term of our Boston lease expires in March 2026. We have an additional location used for office and lab space that occupies approximately 2,110 square feet located at Hochbergerstrasse 60C, 4057 Basel, Basel-City, Switzerland.

We believe that our facilities are adequate for our current needs and for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space. We believe that suitable additional or

substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Legal proceedings

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

Management

The following table sets forth information about our executive officers and directors as of the date of this prospectus.

Name	Age	Position(s)
Executive Officers		
Markus Warmuth, M.D.	50	Chief Executive Officer, President and Director
Ajim Tamboli, CFA.	44	Chief Financial Officer
Owen B. Wallace, Ph.D.	52	Chief Scientific Officer
Sharon Townson, Ph.D.	46	Chief Technology Officer
John Castle, Ph.D.	50	Chief Data Scientist
Non-Employee Directors		
Alexander Mayweg, Ph.D.	46	Director and Non-Executive Chair of the Board of Directors
Bradley J. Bolzon, Ph.D.	61	Director
Ali Behbahani, M.D.	45	Director
Kimberly L. Blackwell, M.D.	52	Director
Andrew Schiff, M.D.	55	Director
Chandra P. Leo. M.D.	50	Director
Christine Siu, M.B.A.	44	Director

(1) Member of our audit committee

(2) Member of our compensation committee

(3) Member of our nominating and corporate governance committee

The following is a biographical summary of the experience of our executive officers and directors. There are no family relationships among any of our executive officers or directors.

Executive officers

Markus Warmuth, M.D. has served as our President and Chief Executive Officer and a member of our board of directors since January 2020. Dr. Warmuth has also served as a Venture Partner at Versant Venture Management, LLC, a healthcare investment firm, since September 2019. From July 2018 to August 2019, he worked as an Entrepreneur-in-Residence for Third Rock Ventures, LLC, a venture capital firm. From October 2011 to May 2018, Dr. Warmuth was the Chief Executive Officer and, previously from August 2011 to October 2011, Chief Scientific Officer of H3 Biomedicine Inc., a drug development company. Dr. Warmuth has served as a member of the board of directors of IMV Inc., a clinical stage biopharmaceutical company, since November 2018 and previously served as a member of the board of directors of Relay Therapeutics, Inc., a drug discovery company, from September 2018 to August 2019. He received an M.D. from Ludwig Maximilian University, Munich, Germany.

We believe that Dr. Warmuth is qualified to serve on our board of directors because of his extensive management and investment experience in the biopharmaceutical industry.

Ajim Tamboli, CFA has served as our Chief Financial Officer since September 2020. From 2019 to 2020, Mr. Tamboli served as Chief Financial Officer at Rodin Therapeutics Inc., a biopharmaceutical company. From

2018 to 2019, he served as a partner of Asymmetry Capital Management, L.P., an investment management firm. From 2013 until 2018, Mr. Tamboli was a founding partner of and investor at Endurant Capital Management LP, a healthcare-dedicated asset management firm. From 2010 until 2013, Mr. Tamboli was a life sciences investor with Columbia Management Group, an investment advisor and mutual fund sponsor. Mr. Tamboli was a biotechnology equity research analyst with Lehman Brothers from 2003 to 2008 and prior to that with Credit Suisse from 2000 to 2001. Mr. Tamboli received an M.S. in biotechnology and a B.S. in biomedical science from the University of Pennsylvania, where he was a Benjamin Franklin Scholar. He is a CFA® charterholder.

Owen B. Wallace, Ph.D. has served as our Chief Scientific Officer since February 2021. From April 2017 until February 2021, Dr. Wallace served as Chief Scientific Officer at Fulcrum Therapeutics, Inc., a biopharmaceutical company. From June 2013 until April 2017, Dr. Wallace served as Head, Global Discovery Chemistry at Novartis Institutes of BioMedical Research. From May 2000 until June 2013, Dr. Wallace served in various positions at Eli Lilly and Company, a global pharmaceutical company, including global leadership roles as Global Senior Director of Discovery Chemistry Research and Site Scientific Leader at the Lilly Research Centre in Surrey, UK. Dr. Wallace began his career as a Research Investigator at Bristol-Myers Squibb, a pharmaceutical company, where he worked on the HIV attachment program that led to the FDA's approval of Rukobia, a prescription medicine that is used with other antiretroviral medicines to treat HIV-1 infection, in 2020. Dr. Wallace received a Ph.D. and M.S. in chemistry from Yale University, and a B.Sc. (Hons) in chemistry and computer science from the University College Cork.

Sharon Townson, Ph.D. has served as our Chief Technology Officer since January 2021 and previously served as our Vice President of Biomolecular Sciences from July 2020 until December 2020. From April 2019 to June 2020, Dr. Townson served as Executive Director, Head of Platform Biology at Kymera Therapeutics, Inc., a biopharmaceutical company. From June 2013 until December 2018, Dr. Townson served in several roles at Warp Drive Bio, Inc,, a biotechnology company, including Scientific Director of Physical Biochemistry, Director of Physical Biochemistry and Associate Director of Biochemistry and Biophysics. Dr. Townson received a Ph.D. in molecular biology and biochemistry from the University of Manchester Institute of Science and Technology and a B.S. in biomolecular sciences from Salford University.

John Castle, Ph.D. has served as our Chief Data Scientist since May 2020. From October 2017 to April 2020, Dr. Castle served as Associate Vice President of Translational Medicine and Bioinformatics, and previously, from May 2017 to October 2017, Executive Director of Translational Medicine and, from November 2014 to May 2017, Senior Director of Bioinformatics at Agenus Inc, a drug development company. From October 2017 to January 2018, Dr. Castle served as Chief Scientific Officer for Achilles Therapeutics UK Limited, a drug development company. Dr. Castle served as Director of Computational Medicine at BioNTech SE, a biotechnology company, from 2009, when the company was started, until November 2014. Dr. Castle received a Ph.D. in geophysics from the University of Washington and a B.A. in physics from Rice University. Dr. Castle was also a Fulbright Scholar at the Australian National University at Canberra.

Non-employee directors

Alexander Mayweg, Ph.D. has served as a member of our board of directors since April 2018 and as our chairman since September 2020. Dr. Mayweg has served as a Managing Director at Versant Venture Management, LLC, a healthcare investment firm, since March 2020, and previously served as a Partner at Versant Venture Management, LLC from January 2018 to March 2020 and as a Venture Partner at Versant Venture Management, LLC from January 2017 to December 2017. Additionally, since April 2017, Dr. Mayweg has served as Chief Scientific Officer at Ridgeline Therapeutics, a discovery engine sponsored by Versant Ventures Management, LLC that creates and operates biotechnology companies in Basel, Switzerland. From 2013 to 2016, Dr. Mayweg served as Vice President and Global Head of Medicinal Chemistry at F. Hoffmann-La Roche AG, a

multinational healthcare company, where he held various leadership positions in pharmaceutical drug discovery and medicinal chemistry across Europe, the U.S. and Asia. Dr. Mayweg is currently a member of the board of directors of Black Diamond Therapeutics, Inc., a biopharmaceutical company. Dr. Mayweg received a D. Phil. in organic chemistry at Oxford University, followed by post-doctorate training in organic chemistry at Stanford University, and a B.S. in chemistry from the Imperial College of Science and Technology.

We believe that Dr. Mayweg is qualified to serve on our board of directors based on his knowledge of the healthcare sector across international markets and his extensive operational experience in the biopharmaceutical industry.

Bradley J. Bolzon, Ph.D. has been a member of our board of directors since April 2018 and served as the chairman of our board until September 2020. Dr. Bolzon has served as Chairman and Managing Director of Versant Venture Management, LLC, where he has been employed since May 2004. From February 2000 to May 2004, Dr. Bolzon served as Executive Vice President, Global Head of Business Development, Licensing & Alliances of F. Hoffman-La Roche AG., a multinational healthcare company. Dr. Bolzon also held executive roles at Eli Lilly and Company, a global pharmaceutical company, in drug discovery, clinical research, regulatory affairs and business development. Since April 2014, Dr. Bolzon has served as a member of the board of directors of CRISPR Therapeutics AG, a biotechnology company and, since December 2017, has served as a member of the board of directors of Black Diamond Therapeutics, Inc., a biopharmaceutical company. Dr. Bolzon previously served as a member of the board of directors of Flexion Therapeutics, Inc., a pharmaceutical company, from its inception in 2007 to June 2014. Dr. Bolzon received a Ph.D. in pharmacology, a M.S. in pharmacology from the University of Toronto and a B.S. from the University of Guelph College of Biological Science. He conducted post-doctoral work at the University of Ottawa Heart Institute.

We believe that Dr. Bolzon is qualified to serve on our board of directors because of his global pharmaceutical industry and venture capital experience.

Ali Behbahani, M.D. has been a member of our board of directors since April 2020. Dr. Behbahani joined New Enterprise Associates, Inc., a venture capital firm, in 2007 and is a General Partner on the healthcare team. Prior to joining New Enterprise Associates, Inc., Dr. Behbahani served as a consultant in business development at The Medicines Company, a pharmaceutical company, a Venture Associate at Morgan Stanley, a multinational investment bank and financial services company, and a Healthcare Investment Banking Analyst at Lehman Brothers, a global financial services firm. Dr. Behbahani currently serves as a member of the board of directors of Nkarta, Inc., a biotechnology company, Oyster Point Pharma, a clinical-stage pharmaceutical company, Black Diamond Therapeutics, Inc., a biopharmaceutical company, Adaptimmune Therapeutics, a biopharmaceutical company, Genocea Biosciences, Inc., a biopharmaceutical company and CRISPR Therapeutics AG, a biotechnology company. Dr. Behbahani formerly served as a member of the board of directors of Nevro Corp., a global medical device company. Dr. Behbahani received an M.D. from the University of Pennsylvania School of Medicine, an M.B.A. from the Wharton School of the University of Pennsylvania and a B.S. in biomedical engineering, electrical engineering and chemistry from Duke University.

We believe that Dr. Behbahani is qualified to serve on our board of directors because of his extensive experience as an investor in the life sciences industry and his service as a director of other publicly traded companies.

Kimberly L. Blackwell, M.D. has been a member of our board of directors since July 2020. Dr. Blackwell has served as Chief Medical Officer of Tempus Labs, Inc., a biotechnology company, since 2020. Dr. Blackwell formerly served as Vice President of Early Phase Oncology and Immuno-oncology at Eli Lilly and Company, a global pharmaceutical company, from 2018 to 2020. From 2012 to 2018, Dr. Blackwell served as Director of the Women’s Cancer Program, Professor of Medicine, and Associate Director for Strategic Relations at the Duke

Cancer Institute where she lead the clinical development teams for promising early stage therapeutics. Dr. Blackwell currently serves as a member of the board of directors of Zentalis Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company. Dr. Blackwell received an M.D. from the Mayo Clinic College of Medicine and Science and a B.A. in bioethics from Duke University.

We believe that Dr. Blackwell is qualified to serve on our board of directors because of her extensive experience in the field of medicine and experience serving in executive roles at companies in the life sciences industry.

Andrew Schiff, M.D. has been a member of our board of directors since September 2020. Dr. Schiff serves as a Managing Partner of Aisling Capital, a venture capital firm, that he has been affiliated with since 1999. Prior to joining Aisling Capital, Dr. Schiff practiced internal medicine at the New York Presbyterian Hospital, where he currently maintains his position as a Clinical Assistant Professor of Medicine. Dr. Schiff currently serves as a member of the board of directors of Aclaris Therapeutics, Inc., a pharmaceutical company. Dr. Schiff formerly served as a member of the board of directors of ZELTIQ Aesthetics, Inc., a medical services company acquired by Allergan PLC. Dr. Schiff received an M.D. from Cornell University Medical College, an M.B.A. from Columbia Business School, and a B.S. in neuroscience with honors from Brown University.

We believe that Dr. Schiff is qualified to serve on our board of directors because of his experience as a venture capitalist, a professor in the field of medicine and a board member of numerous companies in the life sciences industry.

Chandra P. Leo, M.D. has been a member of our board of directors since September 2020. Dr. Leo has served as an Investment Advisor in the private equity team at HBM Partners AG, a Swiss healthcare investment company, since 2007. Prior to joining HBM Partners AG, Dr. Leo worked as a postdoctoral scientist at Stanford University, as a physician at the University Hospital Leipzig and as a principal at Wellington Partners, a venture capital firm. Dr. Leo currently serves as a director on the boards of Fore Biotherapeutics Inc., River 2 Renal Corp. and River 3 Renal Corp., all of which are biotechnology companies, and Gynesonics Inc., a medical device company. He received an M.D. from the Freie Universität Berlin, an M.B.A from INSEAD and an M.A.S. in medicines development from the University of Basel.

We believe that Dr. Leo is qualified to serve on our board of directors because of his extensive experience in the field of medicine and in private equity.

Christine Siu, M.B.A. has been a member of our board of directors since December 2020. Ms. Siu has served as the Chief Operating Officer in Residence of BridgeBio Pharma Inc., a pharmaceutical company, since January 2020. She formerly served as the Chief Financial Officer of Eidos Therapeutics, Inc., a biopharmaceutical company, from December 2017 to December 2019 and, previously as Chief Operating Officer of Eidos Therapeutics, Inc. from April 2016 to December 2017. Ms. Siu served as the Chief Business Officer of The Bluefield Project to Cure Frontotemporal Dementia from 2014 to 2017, and previously from 2012 to 2014 as Senior Director of Corporate Development at Global Blood Therapeutics, Inc., a biopharmaceutical company. Previously, she held positions at various private equity and venture capital firms, including Third Rock Ventures, LLC, Warburg Pincus LLC and Thomas, McNerney & Partners, LLC, where she invested in life sciences companies. Ms. Siu received an M.B.A. from Harvard Business School and a B.S. with distinction in cellular molecular biology and economics from the University of Michigan.

We believe that Ms. Siu is qualified to serve on our board of directors because of her experience as a venture capitalist in the life sciences industry and serving as an executive in business, financial and operational roles.

Board composition

Our board of directors currently consists of eight members, each of whom is a member pursuant to the board composition provisions of our current certificate of incorporation and agreements with our stockholders, which

agreements are described in the section of this prospectus entitled “Certain relationships and related person transactions.” These board composition provisions will terminate upon the closing of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee’s and our board of directors’ priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until their earlier resignation or removal. Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least of the votes that all our stockholders would be entitled to cast in an annual election of directors, 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.

Staggered board

In accordance with the terms of our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three staggered classes of directors and each director will be assigned to one of the three classes. At each annual meeting of the stockholders, one class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2022 for Class I directors, 2023 for Class II directors and 2024 for Class III directors.

- Our Class I directors will be ;
- Our Class II directors will be ; and
- Our Class III directors will be .

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering will provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Director independence

We intend to apply to list our common stock on The Nasdaq Global Market. Under the Nasdaq listing rules, independent directors must comprise a majority of a listed company’s board of directors within twelve months from the date of listing. In addition, the Nasdaq listing rules require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Securities Exchange Act of 1934, 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 Nasdaq listing rules, a director will only qualify as an “independent director” if, in the opinion of that 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 under the Exchange Act, 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: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (ii) 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 of directors 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: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In , 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 background, employment and affiliations, including family relationships, our board of directors has determined that all members of our board of directors, except , are independent directors, including for purposes of Nasdaq and the SEC rules. In making that determination, our board of directors considered the relationships that each director has with us and all other facts and circumstances the board of directors deemed relevant in determining independence, including the potential deemed beneficial ownership of our capital stock by each director, including non-employee directors that are affiliated with certain of our major stockholders. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of Nasdaq and the rules and regulations of the SEC. There are no family relationships among any of our executive officers and directors.

We intend to adopt a policy, subject to and effective upon the effectiveness of the registration statement of which this prospectus forms a part, that outlines a process for our securityholders to send communications to the board of directors.

Board committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors and will be effective upon the effectiveness of the registration statement of which this prospectus forms a part. We believe that the composition and functioning of all of our committees will comply with the applicable requirements of Nasdaq, the Sarbanes-Oxley Act of 2002 and SEC rules and regulations that will be applicable to us. We intend to comply with future requirements to the extent they become applicable to us.

Following the consummation of this offering, the full text of our audit committee charter, compensation committee charter, and nominating and corporate governance charter will be posted on the investor relations portion of our website at https://www.monterosatx.com. We do not incorporate the information contained on, or accessible through, our corporate website into this prospectus, and you should not consider it a part of this prospectus.

Audit committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our audit committee will consist of and will be chaired by . The functions of the audit committee will include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending based upon the audit committee's review and discussions with management and our independent registered public accounting firm whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

All members of our audit committee will meet the requirements for financial literacy under the applicable rules and regulations of the SEC and the Nasdaq listing rules. Our board of directors has determined that qualifies as an "audit committee financial expert" within the meaning of applicable SEC regulations. In making this determination, our board of directors considered the nature and scope of experience that has previously had with public reporting companies, including service as . Our board of directors has determined that all of the directors that will become members of our audit committee upon the effectiveness of the registration statement of which this prospectus forms a part satisfy the relevant independence requirements for service on the audit committee set forth in the rules of the SEC and the Nasdaq listing rules. Both our independent registered public accounting firm and management will periodically meet privately with our audit committee.

Compensation committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our compensation committee will consist of , and will be chaired by . The functions of the compensation committee will include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;

- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation (i) reviewing and determining the cash compensation of our Chief Executive Officer and (ii) reviewing and approving grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq listing rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing our compensation committee report if and when required by SEC rules;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis," if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Each member of our compensation committee will be a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Code.

Nominating and corporate governance committee

Upon the effectiveness of the registration statement of which this prospectus forms a part, our nominating and corporate governance committee will consist of and will be chaired by . The functions of the nominating and corporate governance committee will include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

Our board of directors may from time to time establish other committees.

Compensation committee interlocks and insider participation

None of the members of our compensation committee is, or has at any time during the prior three years been, one of our officers or employees. None of our executive officers currently serve, or have in the past fiscal year served, as a member of the board of directors or compensation committee of any entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee.

Code of business conduct and ethics

Our board of directors intends to adopt, subject to and effective upon the effectiveness of the registration statement of which this prospectus forms a part, a Code of Business Conduct and Ethics in connection with this offering. The Code of Business Conduct and Ethics will apply to all of our employees, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions), agents and representatives, including directors and consultants.

We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics and our Code of Ethics on our website identified below. Upon the completion of this offering, the full text of our Code of Business Conduct and Ethics and our Code of Ethics will be posted on our website at https://www.monterosatx.com. The inclusion of our website address in this prospectus does not include or incorporate by reference the information on our website into this prospectus, and you should not consider that information a part of this prospectus.

Limitations on liability and indemnification agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws, both of which will become effective upon the closing of this offering, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder’s rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director’s liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective upon the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective upon the consummation of this offering will provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;

- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Executive compensation

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

As an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act. The compensation provided to our named executive officers for the fiscal year ended December 31, 2020 is detailed in the 2020 Summary Compensation Table and accompanying footnotes and narrative that follow. Our named executive officers are:

- Markus Warmuth, M.D., our Chief Executive Officer;
- Ajim Tamboli, our Chief Financial Officer; and
- Min Wang, J.D., Ph.D., our former Chief Operating Officer.

To date, the compensation of our named executive officers has consisted of a combination of base salary, bonuses and long-term incentive compensation in the form of stock options and restricted stock. Our named executive officers, like all full-time employees, are eligible to participate in our health and welfare benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

2020 Summary compensation table

The following table presents information regarding the compensation awarded to, earned by, and paid to each individual who served as one of our named executive officers for services rendered to us in all capacities during the fiscal year ended December 31, 2020.

Name and principal position	Year	Salary ($)	Bonus ($)(1)	Stock awards(2)	Option awards ($)(2)	Total ($)
Markus Warmuth, M.D.	2020	465,000	434,170	191,029	1,130,569	2,220,768
Chief Executive Officer						
Ajim Tamboli(3)	2020	91,146	131,250		489,637	712,033
Chief Financial Officer						
Min Wang, J.D., Ph.D.(4)	2020	130,170	188,125		586,835	905,130
Former Chief Operating Officer						

(1) The amount represent discretionary bonuses paid for company performance in 2020 and a $62,170 signing bonus paid to Dr. Warmuth and a $25,000 signing bonus paid to Dr. Wang.

(2) The amounts reported represent the aggregate grant date fair value of the stock options and restricted stock awarded to the named executive officers during fiscal year 2020, calculated in accordance with Financial Accounting Standards Board, or FASB Accounting Standards Codification, or ASC Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and does not correspond to the actual economic value that may be received upon exercise of the stock option or any sale of any of the underlying shares of common stock.

(3) Mr. Tamboli joined the Company in September 2020 as our Chief Financial Officer. Mr. Tamboli's base salary was pro-rated for his partial year of service during fiscal year 2020.

(4) Dr. Wang joined the Company in September 2020, as our Chief Operating Officer and her base salary was pro-rated for her partial year of service during fiscal year 2020. Dr. Wang resigned from the Company in February 2021.

Narrative disclosure to summary compensation table

Base salaries

Base salaries for our named executive officers are reviewed periodically and adjusted from time to time based on factors including market-competitive compensation levels, job responsibilities, individual performance and experience. The 2020 base salaries for Dr. Warmuth, Mr. Tamboli and Dr. Wang were $465,000, $350,000, and $435,000, respectively. On December 4, 2020, the Board increased the base salaries of Mr. Warmuth, Mr. Tamboli and Dr. Wang for 2021 to $481,275, $358,750 and $445,875, respectively.

Annual cash bonuses

We do not sponsor or maintain a formal annual bonus plan. However, subject to the attainment of certain company and individual-performance goals, the board of directors may approve discretionary bonuses based on a percentage of the executive's base salary, as they did for 2020 for our named executive officers. Neither Mr. Tamboli's nor Dr. Wang's annual bonus was pro-rated for their partial year of service.

Employment arrangements with our named executive officers

Markus Warmuth, M.D. On November 15, 2019, and as revised as of February 13, 2020, we entered into an offer letter with Dr. Warmuth for the position of President and Chief Executive Officer, or the Warmuth Employment Agreement, pursuant to which Dr. Warmuth is entitled to a base salary of $465,000 and an annual target bonus equal to 40% of his base salary. His salary is subject to periodic review at the discretion of the board of directors. Pursuant to the Warmuth Employment Agreement, Dr. Warmuth was eligible to receive an equity award of 1,470,588 shares of restricted stock to be subject to time-based vesting. In the event that Dr. Warmuth ceases to provide services to us as an employee, officer, consultant, advisor or director, the Company may repurchase all unvested restricted shares at the original purchase price within the 120 day period following the cessation of such services. The restricted stock granted to Dr. Warmuth is further described below in the "Outstanding equity awards at 2020 fiscal year-end" table below. Dr. Warmuth was also entitled to a signing bonus of $62,189.86 to be paid no later than March 15, 2020.

Dr. Warmuth's employment has no specified term and can be terminated at will by either party. In the event of his termination without cause or for good reason (as such terms are defined in the Warmuth Employment Agreement), or a qualifying termination, Dr. Warmuth shall be entitled to (i) the sum of 12 months of his then-current base salary plus 100% of his target bonus, less any applicable withholding and any amounts payable pursuant to that certain restrictive covenant agreement by and between the Company and Dr. Warmuth, payable in substantially equal installments in accordance with our payroll practices over 12 months, (ii) subject to Dr. Warmuth's election to receive benefits pursuant to the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended, or COBRA, a monthly amount equal to the monthly employer contribution, based on the premiums as of the date of termination, that we would have made to provide health insurance for Dr. Warmuth if he had remained employed by us until the earliest of (x) the date that is 12 months following his termination, (y) the date he becomes eligible for group health benefits under any other group medical plan or (z) the cessation of his continuation rights under COBRA and (iii) accelerated vesting of the portion(s) of any outstanding equity awards subject to time-based vesting that would have vested in the one year period following such termination. The post-termination exercise period of all of Dr. Warmuth's then-outstanding stock option will be extended to the earlier of (i) the expiration date of the applicable option and (ii) one year from the date of termination unless the awards agreements provide for earlier termination in connection with a liquidation or sale of the Company. The foregoing severance benefits are conditioned upon Dr. Warmuth's execution of a separation agreement, including a release of claims and compliance with certain restrictive

covenants. In the event of a qualifying termination that occurs within the period beginning three (3) months prior to a change in control (as such term is defined the Warmuth Employment Agreement) and ending on the first anniversary of such change in control, Dr. Warmuth will be entitled to the foregoing benefits, except that the equity acceleration will be applied to 100% of Dr. Warmuth's outstanding and unvested equity awards (irrespective of whether such awards are subject to time-based vesting or performance-based vesting) and the salary and bonus amounts due will be paid in lump sum. In both of the aforementioned instances, the equity acceleration terms apply notwithstanding any contrary provisions included in the applicable award agreement.

Ajim Tamboli. On September 18, 2020, we entered into an offer letter with Mr. Tamboli for the position of Chief Financial Officer, or the Tamboli Employment Agreement, pursuant to which Mr. Tamboli is entitled to a base salary of $350,000 and an annual target bonus equal to 37.5% of his base salary. His salary is subject to periodic review at the discretion of the board of directors. Pursuant to the Tamboli Employment Agreement, Mr. Tamboli was eligible to receive an equity award of stock options to purchase 1,215,169 of our common stock. The stock option granted to Mr. Tamboli is further described below in the "Outstanding Equity Awards at 2020 Fiscal Year-End" table below.

Mr. Tamboli's employment has no specified term and can be terminated at will by either party. In the event of his termination without cause or for good reason (as such terms are defined in the Tamboli Employment Agreement), or a qualifying termination, Mr. Tamboli shall be entitled to (i) an amount equal to 12 months of his then-current base salary, less any applicable withholding, and any amounts payable pursuant to the Restrictive Covenant Agreement by and between the Company and Mr. Tamboli, payable in substantially equal installments in accordance with our payroll practices over six months, (ii) subject to Mr. Tamboli's election to receive benefits pursuant to COBRA, a monthly amount equal to the monthly employer contribution, based on the premiums as of the date of termination, that we would have made to provide health insurance for Mr. Tamboli if he had remained employed by us until the earliest of (x) the date that is 12 months following his termination, (y) the date he becomes eligible for group health benefits under any other group medical plan or (z) the cessation of his continuation rights under COBRA, and (iii) accelerated vesting of the portion(s) of any outstanding equity awards subject to time-based vesting that would have vested in the one year period following such termination. The foregoing severance benefits are conditioned upon Mr. Tamboli's execution of a separation agreement, including a release of claims and compliance with certain restrictive covenants. In the event of a qualifying termination that occurs within the period the one year period following a change in control (as such term is defined the Tamboli Employment Agreement), Mr. Tamboli will be entitled to the foregoing benefits, except that the equity acceleration will be applied to 100% of Mr. Tamboli's then-outstanding and unvested time-based equity awards and the salary and bonus amounts due will be paid in lump sum. In addition, if Mr. Tamboli remains employed on the date that is six months following a change in control, then any outstanding equity awards subject to time-based vesting shall become fully exercisable or nonforfeitable as of such date. In the aforementioned instances, the equity acceleration terms apply notwithstanding any contrary provisions included the applicable award agreement.

Min Wang, J.D., Ph.D. On September 2, 2020, we entered into an offer letter with Dr. Wang for the position of Chief Operating Officer, or the Wang Employment Agreement, pursuant to which Dr. Wang is entitled to a base salary of $435,000 and an annual target bonus equal to 37.5% of her base salary. Her salary is subject to periodic review at the discretion of the board of directors. Pursuant to the Wang Employment Agreement, Dr. Wang was eligible to receive a stock option award to purchase 1,458,203 shares of our common stock to be subject to time-based vesting, or the Wang Option. The stock option granted to Dr. Wang is further described below in the "Outstanding equity awards at 2020 fiscal year-end" table below. Dr. Wang was also entitled to a $25,000 sign-on bonus, subject to 100% repayment in the event she resigns for any reason other than Good Reason within the twelve (12) month period following her start date, or a Repayment Event.

Dr. Wang's employment had no specified term and was terminable at will by either party. On February 6, 2021, and as revised February 11, 2021, Dr. Wang entered into a separation agreement that provided for a termination of employment effective February 12, 2021 and certain separation benefits in exchange for a release of claims, or the Separation Agreement. Pursuant to the terms of the Separation Agreement and subject to execution and non-revocation of a release of claims, Dr. Wang was entitled to accrued base salary, accelerated vesting of 136,706 shares of our common stock underlying the Wang Option and a reduction in the amount of sign-on bonus she was required to remit upon a Repayment Event from $25,000 to $15,625. The remaining outstanding portion of the Wang Option was not vested as of the date of her termination of employment and was terminated and cancelled for no consideration.

Outstanding equity awards at 2020 fiscal year-end

The following table sets forth information concerning outstanding equity awards held by our named executive officers as of December 31, 2020.

	Option award				Stock awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($) (5)
Markus Warmuth	—	2,777,644(1)	0.62	12/04/2030	1,011,030(4)	
Ajim Tamboli	—	1,215,169(2)	0.62	12/04/2030		
Min Wang	—	1,458,203(3)	0.62	12/04/2030		

(1) Subject to the executive's continuous service, the shares subject to this option vest 25% on December 4, 2021 and in 1/48th increments monthly thereafter. In the event the executive's employment is terminated without cause or he or she resigns for good reason, this award shall accelerate and vest as if he had provided an additional 12 months of service. In the event a change in control occurs and subject to executive's continuous service, on the earlier of (i) the 6 month anniversary of such change in control or (ii) the date the Company terminates his employment without cause or he resigns for good reason, 100% of the then-outstanding unvested shares underlying this option will immediately accelerate, vest and become exercisable.

(2) Subject to the executive's continuous service, the shares subject to this option vest 25% on September 28, 2021 and in 36 equal monthly installments thereafter. installments thereafter. In the event the executive's employment is terminated without cause or he resigns for good reason, this award shall accelerate and vest as if he had provided an additional 12 months of service. Subject to the executive's continuous service following a change in control, on the 6 month anniversary of such change in control 100% of the then-outstanding unvested shares underlying this option will immediately accelerate, vest and become exercisable.

(3) Subject to the executive's continuous service, the shares subject to this option vest 25% on September 14, 2021 and in 36 equal monthly installments thereafter. In the event the executive's employment is terminated without cause or she resigns for good reason, this award shall accelerate and vest as if she had provided an additional 12 months of service. Subject to the executive's continuous service following a change in control, on the 6 month anniversary of such change in control 100% of the then-outstanding unvested shares underlying this option will immediately accelerate, vest and become exercisable.

(4) Reflects a restricted stock grant that vested 25% on September 1, 2020 and in 36 equal monthly installments thereafter, subject to Dr. Warmuth's continuous service. In the event Dr. Warmuth's employment is terminated without cause or he resigns for good reason, these shares shall accelerate and vest as if he had provided an additional 12 months of service. In the event such termination occurs within 3 months prior to or 12 months following a change in control, 100% of the then-outstanding shares will immediately accelerate and vest.

(5) Calculated based on $ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus.

Employee benefit and equity compensation plans

2020 Stock Option and Grant Plan

Our 2020 Plan was approved by our board of directors and stockholders in April 2020, and amended by our board of directors and stockholders in September 2020. Under the 2020 Plan, we have reserved for issuance an aggregate of 13,111,444 shares of our common stock. The number of shares of common stock reserved for

issuance is subject to adjustment in the event of any merger, consolidation, sale of all or substantially all of our assets, reorganization, recapitalization, reclassification, stock split, stock dividend, reverse stock split or other similar transaction.

The shares of common stock underlying awards that are forfeited, canceled, reacquired by us prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) and shares of common stock that are withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding are currently added back to the shares of common stock available for issuance under the 2020 Plan. Upon completion of this offering, such shares will be added to the shares of common stock available under the 2021 Plan.

Our board of directors has acted as administrator of the 2020 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan. Persons eligible to participate in the 2020 Plan are those employees, officers and directors of, and consultants and advisors to, our company as selected from time to time by the administrator in its discretion.

The 2020 Plan permits the granting of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code of 1986, as amended, or the Code, and (ii) options that do not so qualify. The per share exercise price of each option is determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each option is fixed by the administrator but may not exceed 10 years from the date of grant. The administrator determines at what time or times each option may be exercised. In addition, the 2020 Plan permits the granting of restricted shares of common stock, unrestricted shares of common stock, and restricted stock units.

The 2020 Plan provides that upon the occurrence of a “sale event,” as defined in the 2020 Plan, all outstanding stock options will terminate at the effective time of such sale event, unless the parties to the sale event agree that such awards will be assumed or continued by the successor entity. In the event of a termination of the 2020 Plan and all options issued thereunder in connection with a sale event, optionees will be provided an opportunity to exercise options that are then exercisable or will become exercisable as of the effective time of the sale event within a specified period of time prior to the consummation of the sale event. In addition, we have the right to provide for cash payment to holders of options, in exchange for the cancellation thereof, in an amount per share equal to the difference between the value of the consideration payable per share of common stock in the sale event and the per share exercise price of such options. In the event of, and subject to the consummation of, a sale event, restricted stock and restricted stock units (other than those becoming vested as a result of the sale event) will be forfeited immediately prior to the effective time of a sale event unless such awards are assumed or continued by the successor entity. In the event that shares of restricted stock are forfeited in connection with a sale event, such shares of restricted stock shall be repurchased at a price per share equal to the original per share purchase price of such shares. We have the right to provide for cash payment to holders of restricted stock or restricted stock units, in exchange for the cancellation thereof, in an amount per share equal to the value of the consideration payable per share of common stock in the sale event.

Additionally, the 2020 Plan provides for certain drag along rights pursuant to which grantees may be obligated to, on the request of the Company or the accepting requisite holder, sell, transfer and deliver, or cause to be sold, transferred and delivered, to a buyer, their shares in the event the Company or the accepting requisite holder determine to enter into a sale event with a buyer.

The board of directors may amend or discontinue the 2020 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The administrator of the 2020 Plan may also amend or cancel any outstanding award, provided that no amendment to an award may adversely affect a participant’s

rights without his or her consent. The administrator of the 2020 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options or effect the repricing of such awards through cancellation and re-grants.

The 2020 Plan will automatically terminate upon the earlier of 10 years from the date on which the 2020 Plan was initially adopted by our board of directors or 10 years from the date the 2020 Plan was initially approved by our stockholders. As of , options to purchase shares of common stock were outstanding under the 2020 Plan. Our board of directors has determined not to make any further awards under the 2020 Plan following the closing of this offering.

2021 Stock Option and Incentive Plan

Our 2021 Plan was adopted by our board of directors on , 2021, approved by our stockholders on , 2021 and will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The 2021 Plan will replace the 2020 Plan as our board of directors has determined not to make additional awards under the 2020 Plan following the closing of our initial public offering. However, the 2020 Plan will continue to govern outstanding equity awards granted thereunder. The 2021 Plan allows us to make equity-based and cash-based incentive awards to our officers, employees, directors and consultants.

We have initially reserved shares of our common stock for the issuance of awards under the 2021 Plan, or the Initial Limit. The 2021 Plan provides that the number of shares reserved and available for issuance under the 2021 Plan will automatically increase on January 1, 2022 and each January 1 thereafter, by % of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. These limits are subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2021 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards under the 2021 Plan and the 2020 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2021 Plan (provided that any such shares of common stock will first be converted into shares of common stock).

The maximum number of shares of common stock that may be issued in the form of incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2022 and on each January 1 thereafter by the lesser of the Annual Increase for such year or shares of common stock.

The grant date fair value of all awards made under our 2021 Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed $; provided, however, that such amount shall be $ for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

The 2021 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Plan. Persons eligible to participate in the 2021 Plan will be those full or part-time officers, employees, non-employee directors and consultants as selected from time to time by our compensation committee in its discretion.

The 2021 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code, and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option is granted (i) pursuant to a transaction described in, and in a manner consistent with Section 424(a) of the Code or (ii) to individuals who are not subject to U.S. income tax. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights under the 2021 Plan subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2021 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Our compensation committee may grant cash bonuses under the 2021 Plan to participants, subject to the achievement of certain performance goals.

The 2021 Plan provides that upon the effectiveness of a “sale event,” as defined in the 2021 Plan, an acquirer or successor entity may assume, continue or substitute for the outstanding awards under the 2021 Plan. To the extent that awards granted under the 2021 Plan are not assumed or continued or substituted for by the successor entity, upon the effective time of the sale event, such awards shall terminate. In such case, except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting, conditions or restrictions shall become fully vested and nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the administrator’s discretion or to the extent specified in the relevant award certificate. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. In addition, in connection with the termination of the 2021 Plan upon a sale event, we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors may amend or discontinue the 2021 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such

action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2021 Plan require the approval of our stockholders. The administrator of the 2021 Plan is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent. No awards may be granted under the 2021 Plan after the date that is 10 years from the effective date of the 2021 Plan. No awards under the 2021 Plan have been made prior to the date of this prospectus.

2021 Employee Stock Purchase Plan

Our Employee Stock Purchase Plan, or the ESPP, was adopted by our board of directors on 2021, approved by our stockholders on 2021 and will become effective on the date immediately preceding the date on which the registration statement of which this prospectus forms a part is declared effective by the SEC. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. The ESPP initially reserves and authorizes the issuance of up to a total of shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) shares of our common stock, (ii) % of the outstanding number of shares of common stock on the immediately preceding December 31, 2020 or (iii) such lesser number of shares of common stock as determined by the plan administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All employees who are customarily employed by us or one of our designated subsidiaries for more than 20 hours per week and who we have employed for at least days/months are eligible to participate in the ESPP. However, any employee who owns 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of our common stock under the ESPP.

We may make one or more offerings each year to our employees to purchase shares under the ESPP. Offerings will usually begin on each and and will continue for six-month periods, referred to as offering periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the applicable offering date.

Each employee who is a participant in the ESPP may purchase shares of our common stock by authorizing payroll deductions of up to % of his or her eligible compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of our common stock on the last business day of the offering period at a price equal to % of the fair market value of the shares of our common stock on the first business day or the last business day of the offering period, whichever is lower, provided that no more $25,000 worth of common stock (or such other lesser maximum number of shares as may be established by the administrator) may be purchased by any one employee during any offering period. Under applicable tax rules, an employee may purchase no more than $25,000 worth of shares of our common stock, valued at the start of the purchase period, under the ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

401(k) Plan

Commencing in 2021, we maintain a tax-qualified retirement plan that provides all regular U.S. employees with an opportunity to save for retirement on a tax-advantaged basis. Under our 401(k) plan, participants may elect to defer a portion of their compensation on a pre-tax basis or after tax (Roth) basis subject to applicable annual limits under the Code. Pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employee elective deferrals are 100% vested at all times. As a U.S. tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan and all contributions are deductible by us when made and earnings on Roth contributions are not taxable when distributed from the 401(k) Plan. We make safe-harbor match contributions of 100% of the first 4% of each participant's eligible compensation.

Nonqualified deferred compensation

Our named executive officers did not participate in, or earn any benefits under, a nonqualified deferred compensation plan sponsored by us during fiscal year 2020.

Other benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

Director compensation

2020 Director compensation table

The following table presents the total compensation paid by the Company to members of our board of directors during the fiscal year ended December 31, 2020. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the members of our board of directors in 2020 for their services as members of the board of directors. Markus Warmuth, our Chief Executive Officer, does not receive any compensation from the Company for his service on our board of directors. See the section entitled “Executive compensation” for more information on the compensation paid to or earned by Dr. Warmuth as an employee for year ended December 31, 2020. The following table presents the total compensation for each person who served as a non-employee director during the fiscal year ended December 31, 2020.

Name	Fees earned or paid in cash ($)(1)	Option awards ($)(2)(3)	Total ($)
Ali Behbahani, M.D.			
Kimberly L. Blackwell, M.D.(4)	8,750	21,337	30,087
Bradley J. Bolzon, Ph.D.			
Chandra P. Leo. M.D.			
Alexander Mayweg, Ph.D.			
Andrew Schiff, M.D.			
Christine Siu(4)	8,750	41,494	50,244

(1) Each of Dr. Blackwell and Ms. Siu are entitled to receive an annual retainer equal to $35,000. The amounts reported reflect a prorated amount of board fees paid to each director for their service on our board of directors in 2020.

(2) The amounts reflect the grant date fair value of stock options granted in 2020 in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting conditions. The assumptions used in calculating the grant date fair value of the stock awards reported in this column are set forth in Note 9 of our consolidated financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by our non-employee directors upon the exercise of such options.

(3) Each of Dr. Blackwell and Ms. Siu were entitled to receive an option to purchase 101,857 shares of our common stock upon her appointment to the board of directors. Subject to the director’s continuous service on our board of directors, these stock options vest 25% on the applicable vesting commencement date and in 36 equal monthly installments monthly thereafter. The then-outstanding unvested shares underlying the stock options will immediately accelerate, vest and become exercisable upon a change of control.

(4) As of December 31, 2020, each of Dr. Blackwell and Ms. Siu held an option to purchase 101,857 shares of our common stock.

Non-employee director compensation policy

In connection with this offering, we intend to amend our non-employee director compensation program that will become effective upon the date immediately preceding the date on which the registration statement of which this prospectus is a part is declared effective. The program will be designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors.

Certain relationships and related person transactions

The following is a description of transactions or series of transactions since our inception in November 2019, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, $120,000; and
- in which any of our executive officers, directors or holder of five percent or more of any class of our capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under "Management—Non-employee director compensation" and "Executive compensation."

Series A preferred stock financing

In 2019, Monte Rosa Therapeutics AG sold an aggregate of 19,250,000 Series A convertible preferred shares in multiple closings at a purchase price of $1.00 per share for an aggregate amount of $19.25 million. The following table summarizes purchases of Series A convertible preferred shares of Monte Rosa Therapeutics AG by related persons:

Stockholder	Shares of Series A preferred shares		Total purchase price
Entities affiliated with Versant Ventures(1)	19,250,000	$	19,250,000.00

(1) Represents 19,250,000 Series A convertible preferred shares purchased by Versant Venture Capital VI, L.P. Each of Markus Warmuth, Bradley J. Bolzon and Alexander Mayweg serves as an officer of the Company and/or on our board of directors and is an affiliate of Versant Venture Capital, of which Versant Venture Capital VI, L.P. is an affiliated fund. Entities affiliated with Versant Ventures collectively hold more than 5% of our voting securities.

Convertible note financing

In December 2019, we issued a convertible promissory note to Versant Venture Capital VI, L.P. in the principal amount of $750,000.

Each of Markus Warmuth, Bradley J. Bolzon and Alexander Mayweg serves as an officer of the Company and/or on our board of directors and is an affiliate of Versant Ventures, of which Versant Venture Capital VI, L.P. is an affiliated fund. Entities affiliated with Versant Ventures collectively hold more than 5% of our voting securities.

Contribution and exchange agreements

In April 2020 and September 2020, we entered into two separate Contribution and Exchange Agreements with the shareholders of record of Monte Rosa Therapeutics AG, whereby all such shareholders contributed, and we acquired, all of such shareholders' right, title and interest in and to their shares of Monte Rosa Therapeutics AG, and, in consideration therefor, such shareholders received shares of our common stock and/or Series A convertible preferred stock. See the section entitled "Prospectus summary—Corporate information" for more information on the contribution and exchange transaction. In connection with the closing of the April 2020 Contribution and Exchange Agreement, all of the outstanding convertible promissory notes issued by us to Versant Venture Capital VI, L.P. in 2019 were automatically converted into 754,280 shares of our Series A convertible preferred stock. The following table summarizes the acquisition of shares of our common stock and

Series A convertible preferred stock in connection with the Contribution and Exchanges Agreements by related persons:

Stockholder	Shares of common stock	Shares of Series A preferred stock
Entities affiliated with Versant Ventures(1)	1,000,000	20,004,280
Markus Warmuth(2)	1,470,588	

(1) Represents 1,000,000 shares of common stock acquired by Versant Venture Capital VI, L.P. Each of Markus Warmuth, Bradley J. Bolzon and Alexander Mayweg serves as an officer of the Company and/or on our board of directors and is an affiliate of Versant Ventures, of which Versant Venture Capital VI, L.P. is an affiliated fund. Entities affiliated with Versant Ventures collectively hold more than 5% of our voting securities.

(2) Markus Warmuth currently serves on our board of directors and as our Chief Executive Officer and President.

Series A-2 preferred stock financing

In April 2020, we sold an aggregate of 9,627,234 shares of our Series A-2 convertible preferred stock at a purchase price of $1.2984 per share for an aggregate amount of approximately $12.5 million. The following table summarizes purchases of our Series A-2 convertible preferred stock by related persons:

Stockholder	Shares of Series A-2 preferred stock		Total purchase price
Entities affiliated with New Enterprise Associates(1)	9,627,234	$	12,500,000.62

(1) Represents 9,588,725 shares of Series A-2 convertible preferred stock purchased by New Enterprise Associates 17, L.P. and 38,509 shares of Series A-2 preferred stock purchased by NEA Ventures 2019, L.P. Ali Behbahani serves on our board of directors and is an affiliate of New Enterprise Associates, of which New Enterprise Associates 17, L.P. and NEA Ventures 2019, L.P. are affiliated funds. Entities affiliated with New Enterprise Associates collectively hold more than 5% of our voting securities.

Series B preferred stocking financing

In September 2020, with a subsequent closing in February 2021, we sold an aggregate of 48,000,000 shares of our Series B preferred stock at a purchase price of $2.00 per share for an aggregate amount of $96.0 million. The following table summarizes purchases of our Series B convertible preferred stock by related persons:

Stockholder	Shares of Series B preferred stock	Total purchase price
Entities affiliated with Versant Ventures(1)	7,150,000	$14,300,000.00
Entities affiliated New Enterprise Associates(2)	11,500,000	$23,000,000.00

(1) Represents 3,000,000 shares of Series B convertible preferred stock purchased by Versant Venture Capital VI, L.P. and 4,150,000 shares of Series B convertible preferred stock purchased by Versant Vantage I, L.P. Each of Markus Warmuth, Bradley Bolzon and Alexander Mayweg serves as an officer of the Company and/or on our board of directors and is an affiliate of Versant Ventures, of which Versant Venture Capital VI, L.P. and Versant Vantage I, L.P. are affiliated funds. Entities affiliated with Versant Ventures collectively hold more than 5% of our voting securities.

(2) Represents 11,500,000 shares of Series B convertible preferred stock purchased by New Enterprise Associates 17, L.P. Ali Behbahani serves on our board of directors and is an affiliate of New Enterprise Associates, of which F New Enterprise Associates 17, L.P. is an affiliated fund. Entities affiliated with New Enterprise Associates collectively hold more than 5% of our voting securities.

Series C preferred stocking financing

In March 2021, we sold an aggregate of 32,054,521 shares of our Series C convertible preferred stock at a purchase price of $2.9637 per share for an aggregate amount of approximately $95.0 million. The following table summarizes purchases of our Series C convertible preferred stock by related persons:

Stockholder	Shares of Series B preferred stock	Total purchase price
Entities affiliated with Versant Ventures(1)	2,699,328	$7,999,998.40
Entities affiliated New Enterprise Associates(2)	2,361,912	$6,999,998.60

(1) Represents 2,699,328 shares of Series C convertible preferred stock purchased by Versant Vantage I, L.P. Each of Markus Warmuth, Bradley J. Bolzon and Alexander Mayweg serves as an officer and/or on our board of directors and is an affiliate of Versant Ventures, of which Versant Vantage I, L.P. is an affiliated fund. Entities affiliated with Versant Ventures collectively hold more than 5% of our voting securities.

(2) Represents 2,361,912 shares of Series C convertible preferred stock purchased by New Enterprise Associates 17, L.P. Ali Behbahani serves on our board of directors and is an affiliate of New Enterprise Associates, of which F New Enterprise Associates 17, L.P. is an affiliated fund. Entities affiliated with New Enterprise Associates collectively hold more than 5% of our voting securities.

Agreement with Ridgeline

Our subsidiary, Monte Rosa Therapeutics AG, entered into a services agreement with Ridgeline, in April 2018. Ridgeline is a discovery engine owned by Versant Ventures Capital. Pursuant to the services agreement, Ridgeline provides Monte Rosa Therapeutics AG with certain services, including research and development and management and administration. Ridgeline also provides us with the services of a team of scientists. In connection with the services provided, Monte Rosa Therapeutics AG pays Ridgeline approximately $2.2 million on a quarterly basis, which represents actual costs incurred by Ridgeline in providing the services plus a specified markup. Monte Rosa Therapeutics AG paid Ridgeline $13.4 million and $4.0 million in the years ended December 31, 2020 and 2019.

Each of Bradley J. Bolzon, Alexander Mayweg and Markus Warmuth serves as an officer and/or on our board of directors and is an affiliate of Versant Ventures, of which Versant Ventures VI, L.P. and Versant Vantage I, L.P. are affiliated funds. Entities affiliated with Versant Ventures collectively hold more than 5% of our voting securities. See “Business—Services agreement with Ridgeline.”

Agreements with stockholders

In connection with our Series A preferred stock financing, Series A-2 preferred stock financing, Series B preferred stock financing and Series C preferred stock financing, we entered into investors’ rights, voting and right of first refusal and co-sale agreements containing registration rights, information rights, voting rights and rights of first refusal, among other things, with certain holders of our preferred stock and certain holders of our common stock. These stockholder agreements will terminate upon the closing of this offering, except for the registration rights granted under our investors’ rights agreement, as more fully described in “Description of capital stock—Registration rights.”

Stock option grants to executive officers

We have granted stock options to our named executive officers as more fully described in the section entitled “Executive compensation.”

Restricted stock grants to chief executive officer

We have granted restricted stock to our Chief Executive Officer as more fully described in the section entitled “Executive compensation.”

Indemnification agreements

In connection with this offering, we intend to enter into new agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Policies for approval of related party transactions

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction were disclosed to our board of directors prior to their consideration of such transaction, and the transaction was not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approved the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction were disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we expect to adopt a written related party transactions policy that will provide that such transactions must be approved by our audit committee. This policy will become effective on the date on which the registration statement of which this prospectus forms a part is declared effective by the SEC. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed $120,000 and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

Principal stockholders

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

- each person, or group of affiliated persons, who is known by us to be the beneficial owner of five percent or more of our outstanding common stock (on an as-converted to common stock basis);
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

The information in the following table is calculated based on shares of common stock deemed to be outstanding before this offering and shares of common stock outstanding after this offering, assuming no exercise by the underwriters of their option to purchase additional shares of common stock. The number of shares outstanding is based on the number of shares of common stock outstanding as of March 31, 2021 as adjusted to give effect to:

- the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 109,686,035 shares of common stock upon the completion of this offering; and
- the sale of shares of common stock in this offering (assuming no exercise of the underwriters' option to purchase additional shares).

Each individual or entity shown on the table has furnished information with respect to beneficial ownership. Except as otherwise indicated below, the address of each officer, director and five percent stockholder listed below is c/o Monte Rosa Therapeutics, Inc., 645 Summer Street, Suite 102, Boston, MA 02210.

We have determined beneficial ownership in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities as well as any shares of common stock that the person has the right to acquire within 60 days of March 31, 2021 through the exercise of stock options or other rights. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them.

	Shares of common stock beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
5% or Greater Stockholders			
Entities affiliated with Versant Ventures(1)	30,853,608	26.23%	
Entities affiliated with New Enterprise Associates(2)	23,489,146	19.97%	
Entities affiliated with Cormorant Asset Management, LLC(3)	9,187,080	7.81%	
Avoro Life Sciences Fund LLC	6,748,321	5.74%	
Entities affiliated with FMR LLC(4)	6,748,321	5.74%	
HBM Healthcare Investments (Cayman) Ltd.(5)	6,349,664	5.40%	

	Shares of common stock beneficially owned	Percentage of shares beneficially owned	
		Before offering	After offering
Directors, Named Executive Officers and Other Executive Officers			
Alexander Mayweg	—	—%	
Bradley J. Bolzon	—	—%	
Ali Behbahani	—	—%	
Kimberly L. Blackwell	—	—%	
Andrew Schiff	—	—%	
Chandra P. Leo	—	—%	
Christine Siu	—	—%	
Markus Warmuth	1,470,588	1.25%	
Ajim Tamboli	—	—%	
Owen Wallace	—	—%	
Sharon Townson	—	—%	
John Castle	61,114(6)	*	
All executive officers and directors as a group (12 persons)	1,531,702	1.30%	

* Less than one percent.

(1) Consists of: (a) 1,000,000 shares of common stock purchased by Versant Venture Capital VI, L.P., (b) 20,004,280 shares of common stock issuable upon conversion of the Series A convertible preferred stock purchased by Versant Venture Capital VI, L.P., (c) 3,000,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by Versant Venture Capital VI, L.P., (d) 4,150,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by Versant Vantage I, L.P. and (e) 2,699,328 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by Versant Vantage I, L.P. Versant Ventures VI GP, L.P. ("VV VI GP") is the general partner of Versant Venture Capital VI, L.P. ("VVC VI") and Versant Ventures VI GP-GP, LLC ("VV VI GP-GP") is the general partner of VV VI GP. Each of Bradley J. Bolzon, a member of our board of directors, Jerel C. Davis, Kirk G. Nielsen, Clare Ozawa, Robin L. Praeger and Tom Woiwode Ph.D., as managing directors of VV VI GP-GP, may be deemed to share voting and dispositive power over the shares held by VVC VI. Versant Vantage I GP, L.P. ("VV I GP") is the general partner of Versant Vantage I, L.P. ("VV I"), and Versant Vantage I GP-GP, LLC ("VV I GP-GP") is the general partner of VV I GP. Each of Bradley J. Bolzon, a member of our board of directors, Jerel C. Davis, Clare Ozawa, Robin L. Praeger and Dr. Woiwode, as managing directors of VV I GP-GP, may be deemed to share voting and dispositive power over the shares held by VV I. Bradley J. Bolzon may be deemed to have voting or dispositive power with respect to any of the above referenced shares and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. Additionally, all indirect holders of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their respective pecuniary interest therein. The address for VVC VI and VV I is One Sansome Street, Suite 3630, San Francisco, CA 94104.

(2) Consists of: (a) 9,588,725 shares of common stock issuable upon conversion of the Series A convertible preferred stock purchased by New Enterprise Associates 17, L.P. (NEA 17), (b) 38,509 shares of common stock issuable upon conversion of the Series A convertible preferred stock purchased by NEA Ventures 2019, L.P. (NEA Ventures), (c) 11,500,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by NEA 17 and (d) 2,361,912 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by NEA 17. The shares directly held by NEA 17 are indirectly held by NEA Partners 17, L.P. (NEA Partners 17) the sole general partner of NEA 17, NEA 17 GP, LLC (NEA 17 LLC) the sole general partner of NEA Partners 17 and each of the individual managers of NEA 17 LLC. The individual managers, or collectively, the managers, of NEA 17 LLC are Forest Baskett, Ali Behbahani, Carmen Chang, Anthony A. Florence, Jr., Edward Mathers, Mohamad Makhzoumi, Joshua Makower, Scott D. Sandell, Paul Walker, Rick Yang, Liza Landsman, and Peter Sonsini. The managers share voting and dispositive power with regard to the shares held by NEA 17. Karen P. Welsh, the general partner of NEA Ventures, has sole voting and dispositive power with regard to the shares held by NEA Ventures. Ali Behbahani, a member of our board of directors, is employed as a General Partner at New Enterprise Associates, Inc., has no voting or investment power over the shares owned of record by NEA Ventures, and disclaims beneficial ownership of all shares except to the extent of his actual pecuniary interest in such shares. All indirect owners of the above referenced shares disclaim beneficial ownership of all applicable shares except to the extent of their actual pecuniary interest in such shares. The address of New Enterprise Associates 17, L.P. and its affiliated entity is c/o New Enterprise Associates, 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

(3) Consists of: (a) 3,723,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by Cormorant Private Healthcare Fund III, LP, (b) 2,978,250 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by Cormorant Private Healthcare Fund II, LP, (c) 798,750 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by Cormorant Global Healthcare Master Fund, LP, (d) 1,287,664 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by Cormorant Private Healthcare Fund III, LP., (e) 369,470 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by Cormorant Global Healthcare Master Fund, LP and (f) 29,946 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by CRMA SPV, L.P. Cormorant Asset Management LP ("Cormorant Management") serves as the investment manager to the Cormorant funds listed above ("Cormorant Funds"), and Bihua Chen serves as the managing member of Cormorant Management. Ms. Chen may be deemed to beneficially own the shares held by the Cormorant Funds. The business address of the Cormorant Funds, Cormorant Management, and Ms. Chen is 200 Clarendon Street, 52nd Floor, Boston, MA 02116.

(4) Consists of: (a) 5,061,241 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by Fidelity Select Portfolios: Biotechnology Portfolio and (b) 1,687,080 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by Fidelity Advisor Series VII: Fidelity Advisor Biotechnology Fund. These accounts are managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman, the Chief Executive Officer and the President of FMR LLC. Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the investment Company Act, to form a controlling group with respect to FMR LLC. Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act ("Fidelity Funds") advised by Fidelity Management & Research Company LLC ("FMR Co"), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. FMR Co carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees. The principal business address of all entities and persons listed in this footnote is 245 Summer Street, Boston, Massachusetts 02210.

(5) Consists of: (a) 5,000,000 shares of common stock issuable upon conversion of the Series B convertible preferred stock purchased by HBM Healthcare Investments (Cayman) Ltd. and (b) 1,349,664 shares of common stock issuable upon conversion of the Series C convertible preferred stock purchased by HBM Healthcare Investments (Cayman) Ltd. The board of directors of HBM Healthcare Investments (Cayman) Ltd. has sole voting and investment power with respect to the shares by held by such entity. The board of directors of HBM Healthcare Investments (Cayman) Ltd. is comprised of Jean-Marc Lesieur, Richard Coles, Sophia Harris, Dr. Andreas Wicki, Paul Woodhouse and Mark Kronenfeld, none of whom has individual voting or investment power with respect to such shares, and each disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address for HBM Healthcare Investments (Cayman) Ltd. is Governor's Square, Suite #4-212-2, 23 Lime Tree Bay Avenue, PO Box 30852, Grand Cayman, KY1-1204, Cayman Islands.

(6) Consists of shares of common stock that the person has the right to acquire within 60 days of March 31, 2021 through the exercise of stock options.

Description of capital stock

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective immediately upon the closing of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately upon the closing of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Upon completion of this offering, our authorized capital stock will consist of shares of common stock, par value $0.0001 per share, and shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock will be undesignated.

As of March 31, 2021, shares of our common stock (of which shares are subject to a right of repurchase by us pursuant to a stock restriction agreement between us and the holders of such shares) were outstanding and held of record by 30 stockholders, and 20,004,280 shares of Series A convertible preferred stock, 9,627,234 shares of Series A-2 convertible preferred stock and 24,000,000 shares of Series B convertible preferred stock were outstanding and held of record by 18 stockholders. This amount does not take into account the conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

Common stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the common stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred stock

Upon the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the closing of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of March 31, 2021, options to purchase shares of common stock at a weighted-average exercise price of $ per share were outstanding under our 2020 Stock Option and Grant Plan, as amended, or the 2020 Plan.

Registration rights

Upon the completion of this offering, the holders of shares of our preferred stock, including those issuable upon the conversion of preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of a second amended and restated investors' rights agreement between us, certain holders of our common stock and holders of our preferred stock. The second amended and restated investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand registration rights

Beginning 180 days after the effective date of this registration statement, the holders of shares of our common stock, including those issuable upon the conversion of shares of our preferred stock upon closing of this offering, are entitled to demand registration rights. Under the terms of the second amended and restated investors' rights agreement, we will be required, upon the written request of holders of at least a majority of the securities eligible for registration then outstanding to file a registration statement with respect to at least a majority of the securities eligible for registration then outstanding, we will be required to file a registration statement covering all securities eligible for registration that our stockholders request to be included in such registration. We are required to effect only one registration pursuant to this provision of the second amended and restated investors' rights agreement in any twelve-month period.

Short-form registration rights

Pursuant to the second amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of stockholders holding at least thirty percent of the securities eligible for registration then outstanding we will be required to file a Form S-3 registration restatement with respect to outstanding securities of such stockholders having an anticipated aggregate offering, net of related fees and expenses, of at least $5.0 million. We are required to effect only two registrations in any twelve month period pursuant to this provision of the second amended and restated investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback registration rights

Pursuant to the second amended and restated investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of our common stock, including those issuable upon the conversion of our preferred stock, are entitled to include their shares in the registration. Subject to certain exceptions contained in the second amended and restated investors' rights agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our second amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of registration rights

The demand registration rights and short form registration rights granted under the second amended and restated investors' rights agreement will terminate on the fifth anniversary of the completion of this offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 under the Securities Act within a three month period.

Expenses

Ordinarily, other than underwriting discounts and commissions, we are generally required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue-sky fees and expenses.

Anti-takeover effects of Delaware law and certain provisions of our certificate of incorporation and amended and restated bylaws

Some provisions of Delaware law, our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board composition and filling vacancies

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No written consent of stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice

of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance notice requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to certificate of incorporation and bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our bylaws and certificate of incorporation must be approved by not less than of the outstanding shares entitled to vote on the amendment, and not less than of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated preferred stock

Our certificate of incorporation provides for authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Delaware anti-takeover statute

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed

manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, exchange, mortgage or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Choice of forum

Our bylaws that will be in effect upon the effectiveness of this registration statement provide that the Court of Chancery of the State of Delaware will be the exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty by one or more of our directors, officers or employees, (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision; provided, however, that this forum provision will not apply to any causes of action arising under the Exchange Act or the Securities Act. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision. We recognize that the Delaware Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware. Additionally, the Delaware Forum Provision may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Stock exchange listing

We intend to apply to list our common stock on The Nasdaq Global Market under the proposed trading symbol “GLUE”.

Transfer agent and registrar

The Transfer Agent and Registrar for our common stock will be .

Shares eligible for future sale

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. 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. Nevertheless, sales of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of March 31, 2021, upon the completion of this offering, shares of our common stock will be outstanding, assuming the issuance of shares offered by us in this offering, no exercise of the underwriters’ option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below, and restricted shares of common stock are subject to time-based vesting terms. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be “restricted securities” as such term is defined in Rule 144 under the Securities Act. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately shares immediately after this offering, assuming no exercise of the underwriters’ option to purchase additional shares, based on the number of shares outstanding as of March 31, 2021; or
- the average weekly trading volume of our common stock on The Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the periodic reporting requirements of the Exchange Act for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares.

However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriting” included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-up agreements

We, all of our directors and officers and substantially all of our stockholders have agreed not to sell or otherwise transfer or dispose of any of our securities for a period of 180 days from the date of this prospectus, subject to certain exceptions. The representatives of the underwriters in this offering may, in their sole discretion, permit early release of shares subject to the lock-up agreements. See the section entitled “Underwriting,” appearing elsewhere in this prospectus for more information.

Registration rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section entitled “Description of capital stock—Registration rights” appearing elsewhere in this prospectus for more information.

Equity incentive plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. As of the date of this prospectus, we estimate that such registration statement on Form S-8 will cover approximately shares.

Material U.S. federal income tax considerations for non-U.S. holders

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust the income of which is not subject to U.S. federal income tax on a net income basis and that (i) is not subject to the primary supervision of a court within the United States or over which no U.S. persons have authority to control all substantial decisions and (ii) has not made an election to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all 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 differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds 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 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 any U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare contribution tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, or any other aspect of any U.S. federal tax other than income and estate 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 or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;

- pension plans;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- “qualified foreign pension funds,” or entities wholly owned by a “qualified foreign pension fund”;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on our common stock

Distributions, if any, on our common stock 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 holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on sale or other taxable disposition of our common stock.” Any such distributions will also be subject to the discussions below under the sections entitled “Backup withholding and information reporting” and “Withholding and information reporting requirements—FATCA.”

Subject to the discussion in the following two paragraphs in this section, 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 a reduced rate specified by an applicable income tax treaty between the United States and such holder’s country of residence.

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 requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated 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 a reduced rate 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 holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or a successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. 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 a U.S. tax return with the IRS.

Gain on sale or other taxable disposition of our common stock

Subject to the discussions below under “Backup withholding and information reporting” and “Withholding and information reporting requirements —FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income or withholding tax on any gain realized upon such holder’s sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the graduated 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, the branch profits tax described above in “Distributions on our common stock” also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions 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 between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that 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 sale of other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” as described below, unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation if the fair market value of its U.S. real property interests, as defined in the Code and applicable Treasury regulations, 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 do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup withholding and information reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on our common stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally 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 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 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. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can 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 filed with the IRS in a timely manner.

Withholding and information reporting requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act (FATCA), generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on, or, subject to the discussion of certain proposed U.S. Treasury regulations below, gross proceeds from the sale or other disposition of, our common stock paid to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. However, the U.S. Treasury released proposed regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a sale or other disposition of our common stock. In the preamble to such proposed regulations, the U.S. Treasury stated that taxpayers may generally rely on the proposed regulations until final regulations are issued. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Federal estate tax

Individual Non-U.S. Holders and entities the property of which is potentially includible in such an individual's gross estate for U.S. federal estate tax purposes (for example, a trust funded by such an individual and with respect to which the individual has retained certain interests or powers), should note that, absent an applicable treaty exemption, our common stock will be treated as U.S.-situs property subject to U.S. federal estate tax.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Cowen and Company, LLC and Piper Sandler & Co. are acting as joint book-running managers of the offering and as representatives of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of shares of common stock listed next to its name in the following table:

Name	Number of shares
J.P. Morgan Securities LLC	
Cowen and Company, LLC	
Piper Sandler & Co.	
Guggenheim Securities, LLC	
Total	

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $ per share. Any such dealers may resell shares to certain other brokers or dealers at a discount of up to $ per share from the initial public offering price. After the initial offering of the shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is $ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	$	$
Total	$	$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately $. We have also agreed to reimburse the underwriters for certain of their expenses
related to the Financial Industry Regulatory Authority, Inc., in an amount up to $.

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that we will not (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, or submit to, or file with, the SEC a registration statement under the Securities Act relating to, any shares of our common stock or securities convertible into or exercisable or exchangeable for any shares of our common stock, or publicly disclose the intention to make any offer, sale, pledge, loan, disposition or filing, or (ii) enter into any swap or other arrangement that transfers all or a portion of the economic consequences associated with the ownership of any shares of common stock or any such other securities (regardless of whether any of these transactions are to be settled by the delivery of shares of common stock or such other securities, in cash or otherwise), in each case without the prior written consent of J.P. Morgan Securities LLC, Cowen and Company, LLC and Piper Sandler & Co. for a period of 180 days after the date of this prospectus, other than the shares of our common stock to be sold in this offering.

The restrictions on our actions, as described above, do not apply to certain transactions, including (i) the issuance of shares of common stock or securities convertible into or exercisable for shares of our common stock pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of warrants or options (including net exercise) or the settlement of RSUs (including net settlement), in each case outstanding on the date of the underwriting agreement and described in this prospectus; (ii) grants of stock options, stock awards, restricted stock, RSUs, or other equity awards and the issuance of shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock (whether upon the exercise of stock options or otherwise) to our employees, officers, directors, advisors, or consultants pursuant to the terms of an equity compensation plan in effect as of the closing of this offering and described in this prospectus, provided that such recipients enter into a lock-up agreement with the underwriters; or (iii) our filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any plan in effect on the date of the underwriting agreement and described in this prospectus or any assumed benefit plan pursuant to an acquisition or similar strategic transaction.

Our directors and executive officers, and substantially all of our shareholders (such persons, the “lock-up parties”) have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each lock-up party, with limited exceptions, for a period of 180 days after the date of this prospectus (such period, the “restricted period”), may not (and may not cause any of their direct or indirect affiliates to), without the prior written consent of J.P. Morgan Securities LLC, Cowen and Company, LLC and Piper Sandler & Co. (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock (including, without limitation, common stock or such other securities which may be deemed to be beneficially owned by such lock-up parties in accordance with the rules and regulations of the SEC and securities which may be issued upon exercise of a stock option or warrant (collectively with the
common stock, the “lock-up securities”)), (ii) enter into any hedging, swap or other agreement or transaction that transfers, in whole or in part, any of the economic consequences of ownership of the lock-up securities,

whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of lock-up securities, in cash or otherwise, (iii) make any demand for, or exercise any right with respect to, the registration of any lock-up securities, or (iv) publicly disclose the intention to do any of the foregoing. Such persons or entities have further acknowledged that these undertakings preclude them from engaging in any hedging or other transactions or arrangements (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) designed or intended, or which could reasonably be expected to lead to or result in, a sale or disposition or transfer (by any person or entity, whether or not a signatory to such agreement) of any economic consequences of ownership, in whole or in part, directly or indirectly, of any lock-up securities, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of lock-up securities, in cash or otherwise.

The restrictions described in the immediately preceding paragraph and contained in the lock-up agreements between the underwriters and the lock-up parties do not apply, subject in certain cases to various conditions, to certain transactions, including (a) transfers or dispositions of lock-up securities: (i) as bona fide gifts, or for bona fide estate planning purposes, (ii) by will or intestacy or other testamentary document, (iii) to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, (iv) to a corporation, partnership, limited liability company, investment fund or other entity (A) of which the lock-up party and/or its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests or (B) controlled by, or under common control with, the lock-up party or the immediate family member of the lock-up party, (v) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (iv), (vi) in the case of a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control or common investment management with the lock-up party or its affiliates or (B) as part of a distribution to limited partners, members or stockholders of the lock-up party; (vii) by operation of law, (viii) to us from an employee upon death, disability or termination of employment of such employee, (ix) as part of a sale of lock-up securities acquired in this offering (other than, in the case of an officer or director of the Company, any lock-up securities such officer or director may purchase in this offering) or in open market transactions after the completion of this offering, (x) to us in connection with the vesting, settlement or exercise of restricted stock units, options, warrants or other rights to purchase shares of our common stock (including “net” or “cashless” exercise), including for the payment of exercise price and tax and remittance payments, or (xi) pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by our board of directors and made to all shareholders involving a change in control, provided that if such transaction is not completed, all such lock-up securities would remain subject to the restrictions in the immediately preceding paragraph; (b) exercise of the options, settlement of RSUs or other equity awards, or the exercise of warrants granted pursuant to plans described in this prospectus, provided that any lock-up securities received upon such exercise, vesting or settlement would be subject to restrictions similar to those in the immediately preceding paragraph; (c) the conversion of outstanding preferred stock, warrants to acquire preferred stock, or convertible securities into shares of our common stock or warrants to acquire shares of our common stock, provided that any common stock or warrant received upon such conversion would be subject to restrictions similar to those in the immediately preceding paragraph; and (d) the establishment by lock-up parties of trading plans under Rule 10b5-1 under the Exchange Act, provided that such plan does not provide for the transfer of lock-up securities during the restricted period.

J.P. Morgan Securities LLC, Cowen and Company, LLC and Piper Sandler & Co., in their sole discretion, may release the securities subject to any of the lock-up agreements with the underwriters described above, in whole or in part at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

We will apply to have our common stock approved for listing/quotation on The Nasdaq Global Market under the symbol “GLUE.”

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. 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 common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common stock in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on The Nasdaq Global Market, in the over-the-counter market or otherwise.

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. In determining the initial public offering price, we and the representatives of the underwriters expect to consider a number of factors including:

- the information set forth in this prospectus and otherwise available to the representatives;
- our prospects and the history and prospects for the industry in which we compete;
- an assessment of our management;
- our prospects for future earnings;
- the general condition of the securities markets at the time of this offering;

- the recent market prices of, and demand for, publicly traded common stock of generally comparable companies; and
- other factors deemed relevant by the underwriters and us.

Neither we nor the underwriters can assure investors that an active trading market will develop for our common shares, or that the shares will trade in the public market at or above the initial public offering price.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

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 has 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 offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(ii) 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 the Representatives for any such offer; or

(iii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Issuer or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the underwriters and the Issuer that it is a "qualified investor" within the meaning of Article 2(e) of the Prospectus Regulation. In the case of any shares being offered to a financial intermediary as that term is used in the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Relevant State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

For the purposes of this provision, the expression an "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.

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:

(i) to any legal entity which is a qualified investor as defined under Article 2 of the U.K. Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the U.K. Prospectus Regulation), subject to obtaining the prior consent of the Representatives for any such offer; or

(iii) in any other circumstances falling within Section 86 of the FSMA;

provided that no such offer of the shares shall require the Issuer or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the U.K. 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 shares and the expression "U.K. Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, in the United Kingdom, this document is being distributed only to, and is directed only at, and any offer subsequently made may only be directed at persons who are "qualified investors" (as defined in the U.K. Prospectus Regulation) (i) who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended, or

the “Order,” and/or (ii) who are high net worth companies (or persons to whom it may otherwise be lawfully communicated) falling within Article 49(2)(a) to (e) of the Order (all such persons together being referred to as “relevant persons”) or otherwise in circumstances which have not resulted and will not result in an offer to the public of the shares in the United Kingdom within the meaning of the Financial Services and Markets Act 2000. In the United Kingdom, any investment or investment activity to which this document relates is only available to, and will be engaged in with, relevant persons. Any person in the UK who is not a relevant person must not act on or rely upon this document or any of its contents.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) 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 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.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and 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 document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

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

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (i) to “professional investors” as defined in the Securities and Futures Ordinance

(Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (ii) in other circumstances which do not result in the document being a "prospectus" (as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, 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 to do so under the securities laws of Hong Kong) other than with respect to shares 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 thereunder.

Notice to prospective investors in Singapore

Each representative has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each representative has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

(i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;

(ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, 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 are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(i) 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

(ii) 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 or securities-based derivatives contracts (each term as defined in Section 2(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 pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, 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 a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to prospective investors in the Dubai international financial centre

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus supplement nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the Dubai International Financial Centre, or DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Legal matters

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters relating to this offering will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York.

Experts

The combined and consolidated financial statements as of December 31, 2020 and 2019 and for the years then ended 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 combined and consolidated 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 (File Number 333-) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the 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 https://www.monterosatx.com and upon completion of the 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 in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

Index to combined and consolidated financial statements

Report of independent registered public accounting firm

To the Stockholders and Board of Directors of Monte Rosa Therapeutics, Inc.

Opinion on the financial statements

We have audited the accompanying combined and consolidated balance sheets of Monte Rosa Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, the related combined and consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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 and in accordance with auditing standards generally accepted in the United States of America. 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
April 19, 2021

We have served as the Company's auditor since 2021.

Monte Rosa Therapeutics, Inc.
Combined and consolidated balance sheets

(in thousands, except share and per share amounts)	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 41,699	$ 5,995
Restricted cash	—	3,250
Prepaid expenses and other current assets	1,892	514
Total current assets	43,591	9,759
Property and equipment, net	4,623	1,335
Restricted cash	1,164	—
Total assets	$ 49,378	$ 11,094
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 7,066	$ 3,195
Accrued expenses and other current liabilities	2,529	347
Preferred stock tranche obligations	19,680	—
Convertible note payable	—	750
Total current liabilities	29,275	4,292
Defined benefit plan liability	1,067	—
Total liabilities	30,342	4,292
Commitments and contingencies (Note 6)		
Convertible preferred stock, $0.0001 par value; 77,631,514 shares authorized and 53,631,514 shares issued and outstanding as of December 31, 2020; and 19,250,000 shares authorized, issued and outstanding as of December 31, 2019; aggregate liquidation value of $80.5 million as of December 31, 2020	67,764	18,950
Stockholders' deficit		
Common stock, $0.0001 par value; 97,500,000 shares authorized, 7,699,359 shares issued and 5,950,779 shares outstanding as of December 31, 2020; and $0.01 par value; 5,000,000 authorized, issued and outstanding as of December 31, 2019	1	50
Additional paid-in capital	404	—
Accumulated other comprehensive loss	(1,056)	—
Accumulated deficit	(48,077)	(12,198)
Total stockholders' deficit	(48,728)	(12,148)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 49,378	$ 11,094

See accompanying notes to the combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Combined and consolidated statements of operations and comprehensive loss

(in thousands, except share and per share amounts)	Year ended December 31, 2020	2019
Operating expenses:		
Research and development	$ 24,005	$ 7,350
General and administrative	4,005	644
Total operating expenses	28,010	7,994
Loss from operations	(28,010)	(7,994)
Other income (expense):		
Interest income (expense), net	9	(1)
Foreign currency exchange loss, net	(198)	(21)
Changes in fair value of preferred stock tranche obligations, net	(7,680)	276
Total other (expense) income	(7,869)	254
Net loss	$ (35,879)	$ (7,740)
Provision for pension benefit obligation	(1,056)	—
Comprehensive loss	$ (36,935)	$ (7,740)
Reconciliation of net loss to net loss attributable to common stockholders		
Net loss	$ (35,879)	$ (7,740)
Net loss per share attributable to common stockholders—basic and diluted	$ (6.70)	$ (1.55)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	5,355,459	5,000,000

See accompanying notes to the combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Combined and consolidated statements of convertible preferred stock and stockholders' deficit

(in thousands, except share amounts)	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total Stockholders' deficit
	Shares	Amount	Shares	Amount				
Balance—January 1, 2019	5,000,000	$ 4,370	5,000,000	$ 50	$ —	$ —	$ (4,458)	$ (4,408)
Issuance of Series A convertible preferred stock, net of issuance costs of $0	14,250,000	14,580	—	—	—	—	—	—
Net Loss	—	—	—	—	—	—	(7,740)	(7,740)
Balance—December 31, 2019	19,250,000	18,950	5,000,000	50	—	—	(12,198)	(12,148)
Vesting of restricted common stock	—	—	950,779	1	—	—	—	1
Change in par value of common stock due to the Contribution and Exchange agreement	—	—	—	(50)	50	—	—	—
Conversion of convertible note and accrued interest to Series A convertible preferred stock	754,280	754	—	—	—	—	—	—
Issuance of Series A-2 convertible preferred stock, net of issuance costs of $178	9,627,234	12,322	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $262 and discount on allocation of proceeds to preferred stock tranche obligation of $12,000	24,000,000	35,738	—	—	—	—	—	—
Provision for pension benefit obligation	—	—	—	—	—	(1,056)	—	(1,056)
Stock-based compensation expense	—	—	—	—	354	—	—	354
Net Loss	—	—	—	—	—	—	(35,879)	(35,879)
Balance—December 31, 2020	53,631,514	$67,764	5,950,779	$ 1	404	$ (1,056)	$ (48,077)	$ (48,728)

See accompanying notes to the combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Combined and consolidated statements of cash flows

(in thousands)	Year ended December 31, 2020	2019
Cash flows from operating activities:		
Net loss	$ (35,879)	$ (7,740)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	354	—
Depreciation	537	72
Changes in fair value of preferred stock tranche obligations	7,680	(276)
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(1,377)	(346)
Accounts payable	3,435	2,860
Accrued expenses and other current liabilities	2,197	(743)
Net cash used in operating activities	(23,053)	(6,173)
Cash flows from investing activities:		
Purchases of property and equipment	(3,389)	(1,385)
Net cash used in investing activities	(3,389)	(1,385)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock	60,500	14,250
Payment of convertible preferred stock issuance costs	(440)	—
Proceeds from issuance of convertible note payable	—	750
Net cash provided by financing activities	60,060	15,000
Net increase in cash, cash equivalents and restricted cash	33,618	7,442
Cash, cash equivalents and restricted cash—beginning of year	9,245	1,803
Cash, cash equivalents and restricted cash—end of year	$ 42,863	$ 9,245
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 41,699	$ 5,995
Restricted cash	1,164	3,250
Total cash, cash equivalents and restricted cash	$ 42,863	$ 9,245
Supplemental disclosure of noncash items		
Conversion of convertible note payable and accrued interest into Series A convertible preferred stock	$ 754	$ —
Purchases of property and equipment in accounts payable	$ 458	$ 23

See accompanying notes to the combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Notes to the combined and consolidated financial statements

1. Description of business, contribution and exchange, and liquidity

Business

Monte Rosa Therapeutics, Inc. is a biopharmaceutical company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. As used in these combined and consolidated financial statements, unless the context otherwise requires, references to the Company or Monte Rosa refer to Monte Rosa Therapeutics, Inc. and its wholly owned subsidiaries Monte Rosa Therapeutics AG and Monte Rosa Therapeutics Securities Corp. The Company was incorporated in Delaware in November 2019 and is headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland.

Contribution and exchange

Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated in April 2018. Monte Rosa Therapeutics, Inc. was incorporated in November 2019. In 2020, Monte Rosa Therapeutics, Inc. and Monte Rosa Therapeutics AG, entities under common control since the incorporation of Monte Rosa Therapeutics, Inc., consummated a contribution and exchange agreement, or the Contribution and Exchange, whereby Monte Rosa Therapeutics, Inc. acquired the net assets and shareholdings of Monte Rosa Therapeutics AG via a one-for-one exchange of equity between Monte Rosa Therapeutics, Inc. and the shareholders of Monte Rosa Therapeutics AG in a common control reorganization. Accordingly, the historical financial information has been retrospectively adjusted to include the historical results and financial position of Monte Rosa Therapeutics, Inc. combined with Monte Rosa Therapeutics AG's historical results and financial position, after the elimination of all intercompany accounts and transactions.

Risks and uncertainties

The Company is subject to risks common to companies in the biopharmaceutical industry including, but not limited to, the successful discovery and development of its product candidates, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing.

Liquidity considerations

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff, and raising capital and has financed its operations primarily through the issuance of convertible preferred shares.

The Company's continued discovery and development of its product candidates will require significant additional 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 and extensive compliance-reporting capabilities. Even if product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

As of December 31, 2020, the Company had an accumulated deficit of $48.1 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $35.9 million and $7.7 million for the years ended December 31, 2020 and 2019, respectively. The Company expects that its

operating losses and negative cash flows will continue for the foreseeable future as the Company continues to develop its product candidates. The Company currently expects that its cash and cash equivalents of $41.7 million as of December 31, 2020 together with the milestone closing of the Series B convertible preferred stock, or Series B Preferred, for gross proceeds of $48.0 million in February 2021 and the closing of the Series C convertible preferred stock, or Series C Preferred, for gross proceeds of $95.0 million in March 2021 will be sufficient to fund operating expenses and capital requirements for at least 12 months from the date the combined and consolidated financial statements are issued. However, additional funding will be necessary to fund future discovery research, pre-clinical and clinical activities. The Company will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although it has been successful in raising capital in the past, there is no assurance that the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and the Company may not be able to enter into collaborations or other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect the Company's business prospects, even the ability to continue operations.

Coronavirus pandemic

The coronavirus, or COVID-19, pandemic has spread worldwide, and has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on the Company's business and operations are uncertain. To date, our operations have not been significantly impacted by the COVID-19 pandemic.

The actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on the Company cannot be predicted. As a result, there can be no assurance that the Company will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact the Company's business, financial condition and results of operations causing interruptions or delays in the Company's programs and services.

2. Summary of significant accounting policies

Basis of presentation

The accompanying combined and consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and are stated in U.S. dollars. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification and Accounting Standards Updates, or ASUs, of the Financial Accounting Standards Board, or FASB. All intercompany balances and transactions have been eliminated in combination or consolidation.

Use of estimates

The preparation of the combined and consolidated financial statements in conformity with GAAP requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and reported amounts of

expenses during the reporting periods. Actual results could differ from those estimates. On an ongoing basis, the Company evaluates its estimates, including those related to accrued research and development expenses, other long-lived assets, the fair values of the Company's preferred stock tranche obligations, or Preferred Stock Tranche Obligations, common stock, stock- based compensation and the valuation of deferred tax assets. The Company bases its estimates using historical experience, Company forecasts and future plans, current economic conditions, and information from third-party professionals that management believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources and adjusts those estimates and assumptions when facts and circumstances dictate.

The Company utilizes estimates and assumptions in determining the fair value of its common stock, including stock-based awards. The Company has granted stock options at exercise prices that represent the fair value of its common stock on the specific grant dates. The Company utilized various valuation 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*, or AICPA TPA, to estimate the fair value of its common stock. Each valuation methodology includes estimates and assumptions that require the Company's judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of convertible preferred stock, the superior rights and preferences of the convertible preferred stock senior to the Company's common stock at the time, and a probability analysis of various liquidity events, such as a public offering or sale of the Company, under differing scenarios. Changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

Currency and currency translation

The combined and consolidated financial statements are presented in U.S. dollars, the Company's reporting currency. The functional currency of the Company's wholly owned subsidiary, Monte Rosa Therapeutics AG, is the U.S. dollar. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in foreign currency exchange loss, net in the combined and consolidated statements of operations.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid investments with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents are stated at fair value and may include money market funds, U.S. Treasury and U.S. government-sponsored agency securities, corporate debt, commercial paper and certificates of deposit. The Company's cash equivalents at December 31, 2020 and 2019 consist of bank demand deposits and money market fund investments.

The Company had restricted cash of $1.2 million as of December 31, 2020, primarily related to a security deposit on its operating lease for its office in Boston, Massachusetts and funds reserved for a corporate credit card facility in Switzerland, which is presented as a noncurrent asset on the Company's combined and consolidated balance sheet. The Company had restricted cash of $3.3 million as of December 31, 2019, primarily related to restriction from the Swiss government pending recording of capital funds in the commercial registry. This restricted cash is presented as a current asset on the Company's combined and consolidated balance sheet.

Concentrations of credit risk and off-balance sheet risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist primarily of cash and cash equivalents. The Company has invested in cash and cash equivalents at December 31, 2020 and 2019, held in a financial institution that management believes is creditworthy. These deposits may exceed

federally insured limits. The Company has not experienced any losses historically in these accounts and believes it in not exposed to significant credit risk in its 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.

Fair value of financial instruments

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value instrument.

Deferred initial public offering costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' deficit as a reduction of proceeds generated as a result of the offering.

Should a planned equity financing be abandoned, the deferred initial public offering costs would be expensed immediately as a charge to operating expenses in the combined and consolidated statement of operations. The Company recorded no deferred initial public offering costs as of December 31, 2020 and 2019.

Property and equipment

Property and equipment are stated at cost, subject to adjustments for impairments, less accumulated depreciation. Depreciation is calculated using the straight-line method over the useful life of the asset as follows:

Asset	Estimated useful life
Laboratory equipment	Five years
Computer hardware	Three years

Maintenance and repairs that do not improve or extend the life of the respective asset are expensed as incurred. Upon disposal of an asset, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Leasehold improvements are amortized over the shorter of the useful life or remaining term of the lease.

Impairment of long-lived assets

The Company evaluates whether current facts or circumstances indicate that the carrying values of its long-lived assets may not be recoverable. If such facts or circumstances are determined to exist, an estimate of the undiscounted future cash flows of these assets is compared to the carrying value the assets to determine whether impairment exists. If the assets are determined to be impaired, the loss is measured based on the difference between the fair value and carrying value of the assets. No impairment losses were recorded during the years ended December 31, 2020 or 2019.

Research and development expenses

Research and development costs are expensed as incurred. The Company's research and development expenses consist primarily of costs incurred for the research and development of its product candidates and include expenses incurred under agreements with consultants to conduct preclinical and non-clinical studies, costs to acquire supplies for preclinical studies, salaries and related personnel costs, including stock-based compensation, depreciation and other allocated facility-related and overhead expenses.

Accrued research and development costs

The Company records accruals for estimated costs of discovery research activities and preclinical studies. A portion of the Company's research and development activities are conducted by third-party service providers. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. The Company accrues the costs incurred under the agreements based on an estimate of actual work completed in accordance with the agreements. In the event the Company makes advance payments for goods or services that will be used or rendered for future research and development activities, the payments are deferred and capitalized as a prepaid expense and recognized as expense as the goods are received or the related services are rendered. Such payments are evaluated for current or long-term classification based on when they are expected to be realized. If the Company does not identify costs that have begun to be incurred or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from the Company's estimates.

Convertible preferred stock

The Company classifies convertible preferred stock outside of stockholders' deficit on the accompanying combined and consolidated balance sheets as the requirements of triggering a deemed liquidation event are not within the Company's control. In the event of a deemed liquidation event, the proceeds from the event are distributed in accordance with liquidation preferences (see Note 8).

Preferred stock tranche obligations

Included in the terms of the Series A and Series B Preferred Stock Purchase Agreements were certain rights, or Tranche Rights, granted to the investors who purchased the Series A and Series B Preferred. The Series A Tranche Rights gave the investor the option to purchase up to an aggregate of 15,000,000 additional shares of Series A Preferred at $1.00 per share. The Series B Tranche Rights gave investors the option to purchase up to an aggregate of 24,000,000 shares of Series B Preferred at $2.00 per share. The Company concluded that both the Series A and the Series B Tranche Rights met the definition of a freestanding financial instrument, as the

Series A and Series B Tranche Rights were legally detachable and separately exercisable from the Series A and Series B Preferred. At initial recognition, the Company recorded these Series A and Series B Tranche Rights as a liability on the balance sheets at its estimated fair value. The Series A and Series B Preferred Stock Tranche Obligations are subject to remeasurement at each balance sheet date, with changes in fair value recognized in changes in fair value of Preferred Stock Tranche Obligations on the Company's combined and consolidated statements of operations.

Stock-based compensation

Stock-based compensation expense related to stock options granted to employees, directors and non-employees is recognized based on the grant-date estimated fair values of the awards using the Black-Scholes option pricing model, or Black-Scholes. Stock-based compensation expense related to restricted stock granted to employees and non-employees is recognized based on the grant-date fair value of the Company's common stock. The value is recognized as expense ratably over the requisite service period, which is generally the vesting term of the award. The Company adjusts the expense for actual forfeitures as they occur. Stock-based compensation expense is classified in the accompanying combined and consolidated statements of operations based on the function to which the related services are provided.

The grant date fair value of the Company's common stock utilized in Black-Scholes is determined by the Company's board of directors with the assistance of management. The grant date fair value of the Company's common stock is determined using valuation methodologies which utilizes certain assumptions including probability weighting of events, volatility, time to liquidation, a risk-free interest rate and an assumption for a discount for lack of marketability. In determining the fair value of the Company's common stock, the methodologies used to estimate the enterprise value of the Company were performed using methodologies, approaches, and assumptions consistent with the AICPA TPA.

Income taxes

The Company uses the liability method to account for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using enacted tax rates applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company assesses the likelihood of deferred tax assets being realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible.

The Company files U.S. federal and state income tax returns, as well as Swiss income tax returns. The Company's tax positions are subject to audit. Financial statement effects of uncertain tax positions are recognized when it is more likely than not, based on the technical merits of the position, that it will be sustained upon examination. The Company evaluates uncertain tax positions on a regular basis. The evaluations are based on a number of factors, including changes in facts and circumstances, changes in tax law, correspondence with tax authorities during the course of the audit, and effective settlement of audit issues. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax. To date, the Company has not been subject to any interest and penalties.

Defined pension benefit obligation

The Company maintains a mandatory pension for its employees in Switzerland through affiliation with the Swiss Life Collective BVG Foundation. All benefits in accordance with the regulations are reinsured in their entirety with Swiss Life Ltd within the framework of the corresponding contract. This plan is considered to be a defined benefit plan under GAAP.

The Company recognizes an asset for the plan's overfunded status or a liability for the plan's underfunded status in its combined and consolidated balance sheets. Additionally, the Company measures the plan's assets and obligations that determine its funded status as of the end of the year and recognizes the change in the funded status within the combined and consolidated statements of comprehensive loss.

The Company uses an actuarial valuation to determine its pension benefit costs and credits. The amounts calculated depend on a variety of key assumptions, including discount rates and expected return on plan assets. Details of the assumptions used to determine the net funded status are described in Note 12. The Company's pension plan assets are assigned to their respective levels in the fair value hierarchy in accordance with the valuation principles described in the Fair Value of Financial Instruments section above.

Net loss per share

The Company calculates basic and diluted net loss per share attributable to common stockholders in conformity with the two-class method required for participating securities. The Company considers its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock and unvested shares of common stock would be entitled to receive dividends on a basis consistent with the common stockholders. The net loss attributable to common stockholders is not allocated to the convertible preferred stock as the holders of those securities do not have a contractual obligation to share in losses.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is calculated by dividing net loss by the weighted average number of shares of common stock and potential dilutive common stock equivalents outstanding during the period if the effect is dilutive. Potentially dilutive securities include stock options, restricted common stock, and convertible preferred stock. The calculation of diluted loss per share also requires that, to the extent issuance of additional shares from the Preferred Stock Tranche Obligation is dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the Preferred Stock Tranche Obligation for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares. In all periods presented, the Company's outstanding stock options, restricted common stock, convertible preferred stock, and issuance of additional preferred stock from the Tranche Rights were excluded from the calculation of diluted net loss per share because their effects were antidilutive.

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the chief operating decision maker, or CODM, in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its chief executive officer. The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Comprehensive loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. The Company's other comprehensive loss includes adjustments to unrecognized pension benefit costs for Monte Rosa Therapeutics AG. For the years ended December 31, 2020 and 2019, the Company incurred other comprehensive loss of $1.1 million and $0, respectively.

Recently adopted accounting pronouncements

Effective January 1, 2019, the Company adopted ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. Prior to the adoption of ASU 2018-07, the measurement date for non-employee awards was generally the date the services are completed, resulting in financial reporting period adjustments to equity-based compensation during the vesting terms for changes in the fair value of the awards. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without subsequent changes in the fair value of the award. The impact of adopting ASU 2018-07 was immaterial to the combined and consolidated financial statements.

Recently issued accounting pronouncements

The Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act (JOBS Act).

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, as amended, or ASU 2016-02, with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize the liabilities related all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This standard is effective for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and financial statement disclosures.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging*, *and Topic 825, Financial Instruments*, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and financial statement disclosures.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This guidance is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the impact adoption of ASU 2019-12 will have on the financial statements and disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 will simplify the accounting for

convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (i) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for the Company beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently assessing the impact adoption of ASU 2020-06 will have on the financial statements and disclosures.

3. Fair value measurements

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

	As of December 31, 2020			
	Level 1	Level 2	Level 3	Total
Current assets				
Money market funds	$38,712	$ —	$ —	$38,712
Pension plan assets(1)	—	1,217	—	1,217
Total assets measured at fair value	$38,712	$ 1,217	$ —	$39,929
Current liabilities				
Preferred stock tranche obligation	$ —	$ —	$19,680	$19,680
Total liabilities measured at fair value	$ —	$ —	$19,680	$19,680

(1) The fair value of pension plan assets has been determined as the surrender value of the portfolio of active insured members held within the Swiss Life Collective BVG Foundation collective investment fund.

There were no assets or liabilities measured at fair value as of December 31, 2019.

Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds are based on quoted prices in active markets for identical securities. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company's Series B Preferred Stock Tranche Obligation is measured at fair value using a Black-Scholes option pricing valuation methodology. The fair value of Series B Preferred Stock Tranche Obligation includes inputs not observable in the market and thus represents a Level 3 measurement. The option pricing valuation methodology utilized requires inputs based on certain subjective assumptions, including (i) expected stock price volatility, (ii) calculation of an expected term, (iii) a risk-free interest rate, and (iv) expected dividends. The assumptions utilized to value the Series B Preferred Stock Tranche Obligation on issuance were (i) expected stock price volatility of 76%; (ii) remaining term 2.0 years; (iii) a risk-free rate of 0.14%; and (iv) an expectation of no dividends. The assumptions utilized to value the Series B Preferred Stock Tranche Obligation as of December 31, 2020 were (i) expected stock price volatility of 93%; (ii) remaining term of 1.7 years; (iii) a risk-free interest rate of 0.12%; and (iv) an expectation of no dividends.

The following table provides a reconciliation of assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Amount
Balance at January 1, 2019	$ 606
Change in fair value	(276)
Settlement of Preferred Stock Tranche Obligation	(330)
Balance at December 31, 2019	—
Issuance of Preferred Stock Tranche Obligation	12,000
Change in fair value	7,680
Balance at December 31, 2020	$ 19,680

There were no transfers among Level 1, Level 2 or Level 3 categories in the years ended December 31, 2020 or 2019.

4. Property and equipment, net

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

	December 31,	
	2020	2019
Laboratory equipment	$5,205	$1,393
Computer hardware	27	14
Total property and equipment, at cost	5,232	1,407
Less: accumulated depreciation	(609)	(72)
Property and equipment, net	$4,623	$1,335

Depreciation expense for the years ended December 31, 2020 and 2019 was $537,000 and $72,000, respectively.

5. Accrued expenses and other current liabilities

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

	December 31,	
	2020	2019
Compensation and benefits	$ 1,129	$ —
Other	1,400	347
Total other current liabilities	$ 2,529	$ 347

6. Commitments and contingencies

Operating lease agreements

The Company leases facilities in Boston, Massachusetts under an operating lease through April 2021, and Basel, Switzerland under an operating lease through April 2024. Rent expense for the years ended December 31, 2020 and 2019 was $1.1 million and $60,000, respectively. In 2020, the Company entered into an agreement to lease a new facility in Boston commencing in March 2021 and moved into the new facility in April 2021.

Future minimum lease payments under the Company's non–cancelable operating leases as of December 31, 2020 were as follows (in thousands):

2021	$1,886
2022	1,663
2023	1,707
2024	1,626
2025	1,609
Thereafter	405
Total future minimum lease payments	$8,896

License, collaboration and investment agreements

In April 2018, the Company entered into license, collaboration and investment agreements with Cancer Research Technology Limited, or CRT, and The Institute of Cancer Research, or the ICR, for the purpose of development in the field of cereblon-mediated protein degradation (the "License and Collaboration"). Pursuant to the License and Collaboration, CRT and the ICR granted the Company an exclusive and non-exclusive, worldwide, and sublicensable licenses under CRT's and the ICR's intellection property rights in the field of cereblon mediated protein degradation to discover, research, develop, have developed, use, keep, make, have made, market, import, offer for sale, and sell products in the field of cereblon-mediated protein degradation.

In consideration for the rights granted under the License Agreement, the Company issued an aggregate of 4,000,000 common shares to CRT, the ICR and affiliated founding scientists pursuant to the Formation and Investment Agreement and paid CRT a technology access fee. The License Agreement will remain effective until terminated by written agreement between the Company, CRT and the ICR.

Upon execution of the License and Collaboration, the Company paid an immaterial access fee which was expensed to research and development in 2018. The research program conducted with the ICR with respect to cereblon-mediated protein degradation was completed as of December 31, 2020. However, the License and Collaboration Agreement continues until it is otherwise terminated under the terms and conditions stated within the agreement. The Company's research and development expenses under the License and Collaboration Agreement for activities conducted by the ICR were $1.2 million and $1.8 million in the years ended December 31, 2020 and 2019, respectively. Accounts payable in the combined and consolidated balance sheets for research services and external costs under the License and Collaboration Agreement due to the ICR were $639,000 and $15,000 as of December 31, 2020 and 2019, respectively.

The Company is further obligated to make milestone payments for achieving certain clinical progression events, aggregating up to $7 million for the first product candidate and $3.5 million for each subsequent product candidate. In addition, the Company is further required to pay low single-digit royalties on net sales for each product successfully developed and commercialized in the field of cereblon-mediated protein degradation under the terms of the License and Collaboration on a country by country basis until the later of (i) the date when the manufacture, use, offer for sale, sale or importation of a product is no longer covered by a valid claim in the country of sale, use or manufacture; (ii) ten years from the first commercial sale of such product in the relevant country; and (iii) the expiry of any extended exclusivity period granted with respect to an orphan drug designation, pediatric designation or other exclusivity in the relevant country.

The License and Collaboration will remain effective until (i) the termination by either the Company or the ICR and CRT upon the bankruptcy or uncured breach of the other party, (ii) by the ICR and CRT if the Company should abandon all discovery, development and commercialization efforts for all products covered under the License and Collaboration; (iii) by the Company if it is determined the continued development of products

covered under the License and Collaboration would be commercially unreasonable, scientifically unviable, illegal, unethical or impossible, with a 90-day notification period; or (iv) for any/no reason by written agreement of the Company and the ICR and CRT.

Indemnification

The Company, as permitted under Delaware law and in accordance with its certification of incorporation and bylaws and pursuant to indemnification agreements with certain of its officers and directors, indemnifies its officers and directors for certain events or occurrences, subject to certain limits, which the officer or director is or was serving at the Company's request in such capacity.

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's bylaws, under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, and (iii) procurement, service or license agreements under which the Company may be required to indemnify vendors, service providers or licensees for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the Company's products, technology, intellectual property or services.

From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may cause a material adverse effect on the Company's future business, operating results or financial condition. As of December 31, 2020, the Company was not aware of any claims under indemnification arrangements and does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible. Therefore, no related reserves have been established.

7. Convertible note payable

On December 12, 2019, the Company entered into a Convertible Promissory Note Agreement with an investor for a total principal amount of $750,000. The Convertible Note Payable accrued an annual interest rate of 1.68% with a maturity date of 12 months from the issuance date. The terms of the agreement provided that the Convertible Note Payable would automatically convert upon either (i) the occurrence of a qualified financing of at least $5.0 million in gross proceeds including the conversion of the note, in which the outstanding principal and all accrued and unpaid interest shall convert into shares of the equity financing at a conversion price equal to the price paid per share, or (ii) the Company enters into a Contribution and Exchange agreement with Monte Rosa Therapeutics AG, in which upon the consummation of such transaction, the outstanding principal and all accrued and unpaid interest shall convert into shares of Series A Preferred at a conversion price equal to $1.00 per share. The agreement also included terms for an optional conversion upon a change in control or upon maturity.

On April 14, 2020, the Company completed the Contribution and Exchange transaction (see Note 1), and the Convertible Note Payable plus accrued interest of $754,000 converted into 754,280 shares of Series A Preferred based on a conversion price of $1.00 per share.

8. Convertible preferred stock

As of December 31, 2020, the Company had 77,631,514 shares of $0.0001 par value convertible preferred stock, or Convertible Preferred Stock, authorized, of which 20,004,280 shares are designated as Series A Preferred;

9,627,234 shares are designated as Series A-2 convertible preferred stock, or Series A-2 Preferred; and 48,000,000 shares are designated as Series B Preferred.

The following table summarizes outstanding Convertible Preferred Stock (in thousands, except share and per share amounts):

	Series A preferred		Series A-2 preferred		Series B preferred		Total convertible preferred stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance—January 1, 2019	5,000,000	$ 4,370	—	$ —	—	$ —	5,000,000	$ 4,370
Issuance of Series A convertible preferred stock	14,250,000	14,580	—	—	—	—	14,250,000	14,580
Balance—December 31, 2019	19,250,000	18,950	—	—	—	—	19,250,000	18,950
Conversion of convertible note to convertible preferred stock	754,280	754	—	—	—	—	754,280	754
Issuance of convertible preferred stock, net of issuance costs of $440 and discount on allocation of proceeds to preferred stock tranche obligation of $12,000	—	—	9,627,234	12,322	24,000,000	35,738	33,627,234	48,060
Balance—December 31, 2020	20,004,280	$ 19,704	9,627,234	$ 12,322	24,000,000	$ 35,738	53,631,514	$ 67,764
Original issue price, or Original Issue Price, per share		$ 1.00		$ 1.2984		$ 2.00		
Liquidation value		$ 20,004		$ 12,500		$ 48,000		$ 80,504

In 2019, the Company issued 14,250,000 shares of Series A Preferred at a price of $1.00 per share to an existing investor for gross proceeds of $14.2 million pursuant to the terms of the Formation and Investment Agreement. The Formation and Investment agreement provided the purchaser of the Series A Preferred (i) a call option for the purchase of 5,000,000 Series A Preferred at a price per share of $1.00, and (ii) a call option for the purchase of up to 10,000,000 Series A Preferred at a price per share of $1.00, together the Series A Preferred Stock Tranche Obligation, both contingent on the achievement of certain research milestones.

The Company concluded that the Series A Preferred Stock Tranche Obligation met the definition of a freestanding financial instrument, as it is legally detachable and separately exercisable from the Series A Preferred. Therefore, the Company allocated the proceeds received from the initial 2018 issuance of Series A Preferred between the Series A Preferred Stock Tranche Obligation and the Series A Preferred. The fair value of the Series A Preferred Stock Tranche Obligation of $606,000 on issuance was allocated from the $5.0 million proceeds of the Series A Preferred financing. The board of directors approved or waived the milestones for the Preferred Stock Tranche Obligations and the Company issued an additional 14,250,000 shares of Series A Preferred during the year ended December 31, 2019.

In April 2020, the Company authorized the sale of up to 9,635,000 shares of its Series A-2 Preferred at a price of $1.2984 per share and issued 9,627,234 shares of Series A-2 Preferred to a single investor for aggregate gross proceeds of $12.4 million.

In September 2020, the Company authorized the sale of up to 48,000,000 shares of its Series B Preferred at a price of $2.00 per share, or Series B Financing. In an initial closing in September 2020, the Company issued 24,000,000 shares of Series B Preferred to several new and existing investors for aggregate gross proceeds of $48.0 million. The Series B Financing further allowed certain purchasers of Series B Preferred the option, or the Series B Preferred Stock Tranche Obligation, to purchase up to an additional 24,000,000 shares of Series B Preferred at a price per share of $2.00 at such time prior to the earlier of (i) September 2022, (ii) the IPO (as defined under Conversion Rights below), and (iii) a Deemed Liquidation Event (as defined under “Liquidation Rights” below), the Company’s cash balance minus current liabilities is less than $5.0 million and on notice of approval by a majority of the board of directors, including the approval of a majority of the preferred directors, for potential aggregate gross proceeds of up to $48.0 million.

The Company concluded that the Preferred Stock Tranche Obligation met the definition of a freestanding financial instrument, as it is legally detachable and separately exercisable from the Series B Preferred. Therefore, the Company allocated the proceeds received from the issuance of shares under the Series B Preferred Stock Purchase Agreement between the Preferred Stock Tranche Obligation and the Series B Preferred. The fair value of the Preferred Stock Tranche Obligation of $12.0 million on issuance was allocated from the $48.0 million proceeds of the Series B Preferred financing and is classified as a current liability on the combined and consolidated balance sheets as of December 31, 2020 as the Series B Preferred would become redeemable upon a Deemed Liquidation Event, the occurrence of which is not within the Company's control.

The rights and preferences and privileges of Convertible Preferred Stock are described below:

Dividend rights

Holders of Convertible Preferred Stock, on a *pari passu* basis but in preference to the holders of common stock, shall be entitled to receive, when, as and if declared by the board of directors, but only out of funds that are legally available therefor, cash dividends at the rate of eight percent of the respective series Original Issue Price per annum on each outstanding share of Convertible Preferred Stock, collectively the Preferred Dividend. All such Preferred Dividends shall be payable only when, as and if declared by the board of directors and shall be non-cumulative, and, if and when declared, shall be declared on each series of Convertible Preferred Stock and not on individual series of the Convertible Preferred Stock.

Further, the Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock unless the holders of the Convertible Preferred Stock then outstanding shall first receive, or simultaneously receive, both the applicable Preferred Dividend and a dividend on each outstanding share of Convertible Preferred Stock in an amount at least equal to that dividend per share of Convertible Preferred Stock as would equal the product of (i) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (ii) the number of shares of common stock issuable upon conversion of a share of Convertible Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend. The board of directors has not declared any dividends to-date.

Conversion rights

Each share of Convertible Preferred Stock is convertible at the option of the holder, at any time after the date of issuance, into a fully paid and non-assessable share of common stock. Each share of Convertible Preferred Stock is convertible into that number of common shares as is determined by dividing the applicable original purchase price of such share by the applicable conversion price. The conversion rate is subject to adjustment upon the occurrence of certain events, including diluting issues of shares, stock splits, stock combinations, certain dividends and distributions, a merger and a reorganization. The conversion rates for each series of Convertible Preferred Stock as of December 31, 2020 is 1:1.

All shares of the Convertible Preferred Stock automatically convert upon (i) the closing of a firm commitment underwritten initial public offering of common stock, in which the price per share is at least $3.00 per share, subject to adjustment in the event of stock dividend, stock split, combination or other similar recapitalization with respect to the common stock, resulting in gross proceeds of at least $50.0 million, or the IPO; or (ii) as specified by vote or written consent of a majority of the outstanding shares of Series B Preferred and at least a majority of the outstanding shares of Convertible Preferred Stock.

Liquidation preference

With first priority to the holders of Series B Preferred and second priority to the holders Series A-2 and Series A, as a single class on a *pari passu* basis, before any payment shall be made to the holders of common stock by

reason of their ownership thereof, the holders of Convertible Preferred Stock then outstanding shall be entitled to be paid (i) in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, out of the assets of the Company available for distribution to its stockholders, or (ii) in the event of a merger or consolidation involving the Company or a subsidiary or on the sale, lease, transfer, exclusive license or other disposition by the Company or a subsidiary of all or substantially all assets of the Company not elected otherwise by holders of 70% of the outstanding shares of Convertible Preferred Stock, voting together as a single class on an as-if converted basis, or a Deemed Liquidation Event, out of the consideration available for distribution to stockholders from the consideration received by the Company for such Deemed Liquidation Event, net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the board of directors, together with any other assets of the Company available for distribution.

The amount payable per share to the holders of Series B Preferred shall be equal to the greater of (i) the Series B Preferred Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had the shares of Series B Preferred been converted into common stock immediately prior to such event. The amount payable per share to the holders of Series A-2 Preferred and Series A, as a single class on a *pari passu* basis, shall be equal to the greater of (i) the Original Issue Price of each respective Series A-2 Preferred and Series A Preferred, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had the shares of respective Series A-2 Preferred and Series A Preferred converted into common stock immediately prior to such event.

If upon any such event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of the outstanding shares of Series B Preferred the full amount to which they shall be entitled, the holders of shares of Series B Preferred shall share ratably, on a *pari passu* basis, in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. If the remaining assets of the Company available for distribution to its remaining stockholders shall be insufficient to pay the holders of the outstanding shares of Series A-2 Preferred and Series A Preferred, as a single class on a *pari passu* basis, the full amount to which they shall be entitled, the holders of shares of Series A-2 Preferred and Series A shall share ratably, on a *pari passu* basis, in any distribution of the remaining assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Voting rights

Each share of Convertible Preferred has voting rights equal to the number of shares of common stock into which the Convertible Preferred Stock can be converted.

The holders of Series B Preferred are entitled to elect two directors of the Company; the holders of Series A-2 Preferred are entitled to elect one director of the Company; and the holders of Series A Preferred, are entitled to elect two directors; altogether the Preferred Directors. The Company's board of directors is further comprised of one director elected by the holders of common stock, one director who is mutually acceptable to a Series B Preferred investor and Company management, and one director who is not an affiliate of the Company or of any investor who shall be approved by the board, including a majority of the Preferred Directors.

Redemption rights

Shares of Convertible Preferred Stock are not redeemable except in the case of a Deemed Liquidation Event.

9. Common stock

The Company had 97,500,000 shares of common stock authorized, of which 7,699,359 were issued and 5,950,779 were outstanding at December 31, 2020.

The holders of common stock are entitled to dividends when and if declared by the board of directors, subject to the preferences applicable to outstanding shares of Convertible Preferred Stock. The board of directors has not declared any dividends and the Company has not paid any dividends.

The holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders.

The Company has issued restricted stock to founders, employees and consultants, and expense for this restricted stock is recognized on a straight-line basis (see Note 10). The restricted stock generally vests monthly over 4 years.

As of December 31, 2020 and 2019, the Company has reserved the following shares of common stock for potential conversion of outstanding Preferred Stock, the vesting of restricted stock and exercise of stock options:

	Year ended December 31,	
	2020	2019
Convertible preferred stock	53,631,514	19,250,000
Options to purchase common stock	7,786,146	—
Unvested restricted common stock	1,748,580	—
	63,166,240	19,250,000

10. Stock-based compensation

Stock incentive plan

In April 2020, the Company adopted the 2020 Stock Option and Grant Plan, or Plan. Under the terms of the Plan, the Company may issue stock options, restricted stock and other stock awards, to employees, non-employee directors, and consultants. As of December 31, 2020, there were 5,396,349 shares of common stock reserved for future issuance under the Plan. Awards granted under the Plan expire no later than 10 years from the date of grant. For incentive stock options and non-statutory stock options, the option exercise price will not be less than 100% of the estimated fair value on the date of grant. Options and restricted stock granted to employees typically vest over a four-year period but may be granted with different vesting terms.

Stock option activity

The following summarizes stock option activity:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding—December 31, 2019	—	$ —	0.0	$ —
Granted	7,786,146	0.58	—	—
Outstanding—December 31, 2020	7,786,146	$ 0.58	9.9	$ 312
Options Exercisable—December 31, 2020	—	$ —	0.0	$ —

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock. No options were exercised during the years ended December 31, 2020 and 2019.

The weighted-average grant date fair value of options granted during the year ended December 31, 2020 was $0.38. No options were granted during the year ended December 31, 2019.

Fair value of stock option awards

The Company estimates the fair value of stock option awards on the grant date using Black-Scholes. The fair value of each award is estimated using the following assumptions:

	Year ended December 31, 2020
Expected term (years)	6.0
Expected volatility	75.9%
Risk-free interest rate	0.53%
Expected dividend yield	—%

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected term: The Company's expected term represents the period that options are expected to be outstanding and is determined using the simplified method, based on the mid-point between the vesting date and the end of the contractual term as the Company does not have sufficient historical data to use any other method to estimate expected term.

Expected volatility: The Company is a private company without any trading history in its common stock.

The expected volatility the Company uses in Black-Scholes is estimated based on the average volatility for comparable publicly-traded biopharmaceutical companies over a period equal to the expected term of the stock option grants. The comparable companies are chosen based on their similarities to the Company, including life cycle stage, therapeutic focus and size.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the stock option grants.

Expected dividend: The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Restricted stock award activity

The following summarizes restricted stock activity:

	Number of shares	Weighted average grant date fair value
Unvested as of December 31, 2019	—	$ —
Granted	2,721,034	$ 0.28
Vested	(950,779)	$ 0.25
Forfeited	(21,675)	$ 0.45
Unvested as of December 31, 2020	1,748,580	$ 0.29

The aggregate fair value of restricted stock that vested during the year ended December 31, 2020 was $242,000. The weighted average grant date fair value of restricted stock that vested during the year ended December 31, 2020 was $0.25.

Stock-based compensation expense

Stock-based compensation expense is classified as follows (in thousands):

	Year ended December 31, 2020
Research and development	$ 189
General and administrative	165
Total stock-based compensation expense	$ 354

As of December 31, 2020, total unrecognized stock–based compensation cost related to unvested stock options and restricted stock awards was $2.3 million and $0.5 million, respectively. The Company expects to recognize this remaining cost over a weighted average period of 3.7 and 2.8 years, respectively.

11. Income Taxes

The Company has incurred net operating losses for all the periods presented. The Company has not reflected the benefit of any such net operating loss carryforwards in the accompanying combined and consolidated financial statements. Domestic and foreign components of net loss are as follows (in thousands):

	Year ended December 31,	
	2020	2019
United States	$ (10,107)	$ (276)
Foreign	(25,772)	(7,464)
Net loss	$ (35,879)	$ (7,740)

The effective tax rate for the years ended December 31, 2020 and 2019 is different from the federal statutory rate primarily due to the valuation allowance against deferred tax assets as a result of insufficient sources of income. The reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended December 31,	
	2020	2019
Income tax benefit at the federal statutory rate	21.0%	21.0%
State income taxes, net of federal benefit	6.3%	6.3%
Research and development tax credits	0.8%	0.0%
Foreign rate differential	(5.7%)	(7.7%)
Adjustment related to Preferred Stock Tranche Obligation	(4.5%)	0.0%
Other	(0.1%)	0.0%
Change in valuation allowance	(17.8%)	(19.6%)
Total	0.0%	0.0%

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The principal components of the Company's deferred tax assets consisted of the following (in thousands):

	December 31,	
	2020	2019
Deferred tax assets		
Federal and state net operating loss carryforwards	$ 5,810	$ 1,683
Research and development tax credits	413	—
Other	52	—
Total deferred tax assets	6,275	1,683
Less: valuation allowance	(6,040)	(1,683)
Total net deferred tax assets	235	—
Deferred tax liabilities		
Defined benefit plan adjustment	(137)	—
Depreciation	(98)	—
Total deferred tax liabilities	(235)	—
Net deferred tax assets	$ —	$ —

The Company has incurred annual net operating losses in each year since inception. The Company has not reflected the benefit of any such net operating loss carryforwards in the financial statements. Due to the Company's history of losses, and lack of other positive evidence, the Company has determined that it is more likely than not that its net deferred tax assets will not be realized, and therefore, the net deferred tax assets are fully offset by a valuation allowance at December 31, 2020 and 2019. The Company increased its valuation allowance by $4.4 million for the year ended December 31, 2020 in order to maintain a full valuation allowance against its deferred tax assets.

As of December 31, 2020, the Company had federal net operating loss carryforwards, or NOLs, of $2.8 million and federal tax credits of $286,000 available to offset tax liabilities. The Company's federal NOLs have an indefinite life and federal tax credit carryforwards begin to expire in 2039. The Company also had gross foreign NOLs of $38.5 million that expire in 2026. The Company also had gross state NOLs of $2.8 million and state tax credits of $128,000 which are available to offset state tax liabilities. The state NOLs begin to expire in 2039 and the state tax credit carryforwards begin to expire in 2034. Federal and state NOLs and tax credit carryforwards are also subject to annual limitations in the event that cumulative changes in the ownership interests of significant stockholders exceed 50% over a three-year period, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986. The Company has not completed an analysis to determine if the NOLs and tax credits are limited due to a change in ownership. Should there be ownership changes that occurred, the Company's ability to utilize existing carryforwards could be substantially restricted.

The Company determines its uncertain tax positions based on whether and how much of a tax benefit taken by the Company in its tax filings is more likely than not to be sustained upon examination by the relevant income tax authorities.

There were no unrecognized tax benefits recorded as of December 31, 2020 and 2019.

The Company files income tax returns in the U.S., Switzerland and Massachusetts. The Company is not currently under examination by any taxing authority for any open tax year. Due to net operating loss carryforwards, all years remain open for income tax examination. To the extent the Company has tax attribute carryforwards, the

tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or IRS, foreign, or state tax authorities to the extent utilized in a future period. No federal, foreign, or state tax audits are currently in process.

12. Defined benefit plan

The Company, in compliance with Swiss Law, is contracted with the Swiss Life Collective BVG Foundation for the provision of pension benefits. All benefits are reinsured in their entirety with Swiss Life Ltd within the framework of the contract.

The technical administration and management of the savings account are guaranteed by Swiss Life on behalf of the collective foundation. Insurance benefits due are paid directly to the entitled persons by Swiss Life in the name of and for the account of the collective foundation. The pension plan is financed by contributions of both employees and employer.

The contract between the Company and the collective foundation can be terminated by either side. In the event of a termination, the Company would have an obligation to find alternative pension arrangements for its employees. Because there is no guarantee that the employee pension arrangements would be continued under the same conditions, there is a risk, albeit remote, that a pension obligation may fall on the Company.

The pension assets are pooled for all affiliated companies; the investment of assets is done by the governing bodies of the collective foundation or by mandated parties. The risks of disability, death and longevity are reinsured in their entirety with Swiss Life Ltd.

The Company had no defined benefit plan in 2019 as there were no full-time employees in Switzerland.

The following table represents the changes in benefit obligations and plan assets and the net amount recognized on the combined and consolidated balance sheets (in thousands):

	Year ended December 31, 2020
Change in benefit obligation:	
Benefit obligation—beginning of period	$ —
Service cost employer	63
Contributions paid by employees	26
Contributions paid by plan participants	1,154
Benefits paid	(15)
Actuarial loss	1,056
Benefit obligation—end of period	$ 2,284
Change in plan assets:	
Fair value of plan assets—beginning of period	$ —
Actual return on plan assets	1
Contributions paid by employer	51
Contributions paid by employees	26
Contributions paid by plan participants	1,154
Benefits paid	(15)
Fair value of plan assets—end of period	1,217
Defined benefit plan liability	$ 1,067

The net pension costs for the year ended December 31, 2020 was as follows (in thousands):

	Year ended December 31, 2020
Service cost	$ 63
Net pension cost	$ 63

The provision for pension benefit obligation recognized in other comprehensive loss for the year ended December 31, 2020 was as follows (in thousands):

	Year ended December 31, 2020
Actuarial loss arising from experience adjustments	$ 1,056
Defined benefit cost for the year recognized in other comprehensive loss	$ 1,056

The assumptions used to measure the projected benefit obligation and net pension costs were as follows:

	Year ended December 31, 2020
Inflation rate	0.50%
Discount rate	0.20%
Interest rate on savings accounts	0.45%
Expected rate of return on assets	0.45%
Salary increase	1.00%
Social Security increase	0.50%
Pension increase	0.00%
Retirement age	100% Male 65 Female 64
Mortality and disability rates	BVG 2015 GT

Estimated benefit payments, which reflect future expected service, are expected to be paid as follows (in thousands):

	December 31
2021	$ 149
2022	$ 141
2023	$ 134
2024	$ 128
2025	$ 123
2026-2030	$ 559

13. Net loss per common share

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Year ended December 31,	
	2020	2019
Net loss	$ (35,879)	$ (7,740)
Net loss per share attributable to common stockholders—basic and diluted	$ (6.70)	$ (1.55)
Weighted-average number of common shares used in computing net loss per share—basic and diluted	5,355,459	5,000,000

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per common share, as their effect is anti-dilutive:

	December 31,	
	2020	2019
Convertible Preferred Stock	53,631,514	19,250,000
Stock options to purchase common stock	7,786,146	—
Restricted common stock	1,748,580	—

Under the Series B Financing, up to 24,000,000 shares of Convertible Preferred may be contingently issued as described in Note 8.

14. Related parties

Versant Ventures has been a related party since inception of the Company as an investor and member of the board of directors. The Company has a service agreement with a Versant Ventures portfolio company, Ridgeline Therapeutics GmbH, or Ridgeline. Ridgeline provided management and administrative support to facilitate start-up of the Company and provided and continues to provide research and development services. Expenses attributable to Ridgeline were recognized primarily in research and development expenses in the Company's combined and consolidated statements of operations and comprehensive loss. The Company paid $13.4 million and $4.0 million to Ridgeline during the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020 and 2019, the Company had $4.8 million and $2.5 million, respectively, in accounts payable in the combined and consolidated balance sheets associated with Ridgeline.

The Company also has a cost sharing agreement with Versant Ventures for the Company's Chief Executive Officer. Amounts recognized as a result of this agreement are recognized in general and administrative expenses in the Company's combined and consolidated statements of operations and comprehensive loss. The Company paid $0 and $55,000 to Versant Ventures during the years ended December 31, 2020 and 2019, respectively, related to this agreement. As of December 31, 2020, the Company had $79,000 in prepaid expenses and other current assets in the combined and consolidated balance sheets related to this agreement. As of December 31, 2019, the Company had $173,000 in accounts payable and $51,000 in prepaids and other current assets in the combined and consolidated balance sheets related to this agreement.

The ICR has been a related party since inception of the Company. The Company has a license, collaboration and investment agreement with the ICR (Note 6).

During the year ended December 31, 2020, the Company reimbursed Aisling Capital Management LP, an affiliate of an investor, and New Enterprise Associates, an affiliate of an investor and member of the board of directors,

$92,000 and $22,000, respectively, for costs associated with investing in the Company. These amounts were recorded as issuance costs netted against convertible preferred stock in the combined and consolidated balance sheets.

15. Subsequent events

The Company has evaluated subsequent events through April 19, 2021, the date these financial statements were issued, and has determined that there have been no events that have occurred that would require adjustments to the Company's disclosures in the combined and consolidated financial statements, except as referenced below.

Financings

In February 2021, the Company issued 24,000,000 shares of Series B Preferred pursuant to the Preferred Stock Tranche Obligation for aggregate gross proceeds of $48.0 million.

In March 2021, the Company authorized the sale of up to 32,054,521 shares of its Series C convertible preferred stock at a price of $2.9637 per share, or Series C Preferred, and issued the authorized shares of Series C Preferred to several new and existing investors for aggregate gross proceeds of $95.0 million. The Series C Preferred carries first priority over the Series B Preferred and the Series A Preferred in liquidation, but otherwise maintains consistent rights, preferences and privileges of the Convertible Preferred Stock outstanding as of December 31, 2020.

Employee retirement plan

In February 2021, the Company adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible U.S. based employees of the Company. All employees are eligible to become participants of the plan immediately upon hire. Each active employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right, but is not obligated, to make additional contributions to this plan.

******

Monte Rosa Therapeutics, Inc.
Condensed consolidated balance sheets

(in thousands, except share and per share amounts) (unaudited)	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 168,436	$ 41,699
Prepaid expenses and other current assets	3,271	1,892
Total current assets	171,707	43,591
Property and equipment, net	7,732	4,623
Restricted cash	1,164	1,164
Total assets	$ 180,603	$ 49,378
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 7,326	$ 7,066
Accrued expenses and other current liabilities	1,765	2,529
Preferred stock tranche obligations	—	19,680
Total current liabilities	9,091	29,275
Defined benefit plan liability	956	1,067
Total liabilities	10,047	30,342
Commitments and Contingencies		
Convertible preferred stock, $0.0001 par value; 109,686,035 shares authorized, issued and outstanding as of March 31, 2021; and 77,631,514 shares authorized and 53,631,514 shares issued and outstanding as of December 31, 2020; aggregate liquidation value of $223.5 million as of March 31, 2021	231,172	67,764
Stockholders' deficit		
Common stock, $0.0001 par value; 136,654,851 shares authorized, 7,699,359 shares issued and 6,079,905 shares outstanding as of March 31, 2021; and 97,500,000 shares authorized, 7,699,359 shares issued and 5,950,779 shares outstanding as of December 31, 2020	1	1
Additional paid-in capital	656	404
Accumulated other comprehensive loss	(920)	(1,056)
Accumulated deficit	(60,353)	(48,077)
Total stockholders' deficit	(60,616)	(48,728)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 180,603	$ 49,378

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Condensed combined and consolidated statements of operations and comprehensive loss

(in thousands, except share and per share amounts) (unaudited)	Three months ended March 31, 2021	2020
Operating expenses:		
Research and development	$ 9,273	$ 3,815
General and administrative	2,231	478
Total operating expenses	11,504	4,293
Loss from operations	(11,504)	(4,293)
Other income (expense):		
Interest income, net	6	(3)
Foreign currency exchange gain (loss), net	182	(6)
Changes in fair value of preferred stock tranche obligations, net	(960)	—
Total other (expense) income	(772)	(9)
Net loss	$ (12,276)	$ (4,302)
Provision for pension benefit obligation	136	—
Comprehensive loss	$ (12,140)	$ (4,302)
Reconciliation of net loss to net loss attributable to common stockholders		
Net loss	$ (12,276)	$ (4,302)
Net loss per share attributable to common stockholders—basic and diluted	$ (2.03)	$ (0.86)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	6,034,427	5,000,000

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Condensed combined and consolidated statements of convertible preferred stock and stockholders' deficit

(in thousands, except share amounts)	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total Stockholders' deficit
	Shares	Amount	Shares	Amount				
Balance—January 1, 2020	19,250,000	18,950	5,000,000	50	—	—	(12,198)	(12,148)
Stock-based compensation expense	—	—	—	—	11	—	—	11
Net Loss	—	—	—	—	—	—	(4,302)	(4,302)
Balance—March 31, 2020	19,250,000	$ 18,950	5,000,000	$ 50	11	$ —	$ (16,500)	$ (16,439)
Balance—January 1, 2021	53,631,514	$ 67,764	5,950,779	$ 1	$ 404	$ (1,056)	$ (48,077)	$ (48,728)
Vesting of restricted common stock	—	—	129,126	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $69	24,000,000	68,571	—	—	—	—	—	—
Issuance of Series C convertible preferred stock, net of issuance costs of $163	32,054,521	94,837	—	—	—	—	—	—
Provision for pension benefit obligation	—	—	—	—	—	136	—	136
Stock-based compensation expense	—	—	—	—	252	—	—	252
Net Loss	—	—	—	—	—	—	(12,276)	(12,276)
Balance—March 31, 2021	109,686,035	$231,172	6,079,905	$ 1	656	$ (920)	$ (60,353)	$ (60,616)

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Condensed combined and consolidated statements of cash flows

(in thousands) (unaudited)	Three months ended March 31, 2021	2020
Cash flows from operating activities:		
Net loss	$ (12,276)	$ (4,302)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	252	11
Depreciation	274	71
Changes in fair value of preferred stock tranche obligations	960	—
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(1,381)	2
Accounts payable	(906)	174
Accrued expenses and other current liabilities	(738)	668
Net cash used in operating activities	(13,815)	(3,376)
Cash flows from investing activities:		
Purchases of property and equipment	(2,217)	(13)
Net cash used in investing activities	(2,217)	(13)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock	143,000	—
Payment of convertible preferred stock issuance costs	(231)	—
Net cash provided by financing activities	142,769	—
Net increase (decrease) in cash, cash equivalents and restricted cash	126,737	(3,389)
Cash, cash equivalents and restricted cash—beginning of period	42,863	9,245
Cash, cash equivalents and restricted cash—end of period	$169,600	$ 5,856
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$168,436	$ 5,856
Restricted cash	1,164	—
Total cash, cash equivalents and restricted cash	$169,600	$ 5,856
Supplemental disclosure of noncash items		
Settlement of preferred stock tranche obligation	$ 20,640	$ 0
Purchases of property and equipment in accounts payable	$ 1,166	$ 6

See accompanying notes to the condensed combined and consolidated financial statements.

Monte Rosa Therapeutics, Inc.
Notes to the condensed combined and consolidated financial statements
(unaudited)

1. Description of business, contribution and exchange, and liquidity

Business

Monte Rosa Therapeutics, Inc. is a biopharmaceutical company developing a portfolio of novel small molecule precision medicines that employ the body's natural mechanisms to selectively degrade therapeutically-relevant proteins. As used in these condensed combined and consolidated financial statements, unless the context otherwise requires, references to the Company or Monte Rosa refer to Monte Rosa Therapeutics, Inc. and its wholly owned subsidiaries Monte Rosa Therapeutics AG and Monte Rosa Therapeutics Securities Corp. The Company was incorporated in Delaware in November 2019 and is headquartered in Boston, Massachusetts with research operations in both Boston and Basel, Switzerland.

Contribution and exchange

Monte Rosa Therapeutics AG, a Swiss operating company, was incorporated in April 2018. Monte Rosa Therapeutics, Inc. was incorporated in November 2019. In 2020, Monte Rosa Therapeutics, Inc. and Monte Rosa Therapeutics AG, entities under common control since the incorporation of Monte Rosa Therapeutics, Inc., consummated a contribution and exchange agreement, or the Contribution and Exchange, whereby Monte Rosa Therapeutics, Inc. acquired the net assets and shareholdings of Monte Rosa Therapeutics AG via a one-for-one exchange of equity between Monte Rosa Therapeutics, Inc. and the shareholders of Monte Rosa Therapeutics AG in a common control reorganization. Accordingly, the historical financial information has been retrospectively adjusted to include the historical results and financial position of Monte Rosa Therapeutics, Inc. combined with Monte Rosa Therapeutics AG's historical results and financial position, after the elimination of all intercompany accounts and transactions.

Liquidity considerations

Since inception, the Company has devoted substantially all its efforts to business planning, research and development, recruiting management and technical staff, and raising capital and has financed its operations primarily through the issuance of convertible preferred shares.

The Company's continued discovery and development of its product candidates will require significant additional 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 and extensive compliance-reporting capabilities. Even if product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

As of March 31, 2021, the Company had an accumulated deficit of $60.4 million. The Company has incurred losses and negative cash flows from operations since inception, including net losses of $12.3 million and $4.3 million for the three months ended March 31, 2021 and 2020, respectively. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as the Company continues to develop its product candidates. The Company currently expects that its cash and cash equivalents of $168.4 million as of March 31, 2021 will be sufficient to fund operating expenses and capital requirements for at least 12 months from the date the condensed combined and consolidated financial statements are issued. However, additional funding will be

necessary to fund future discovery research, pre-clinical and clinical activities. The Company will seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements. Although it has been successful in raising capital in the past, there is no assurance that the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and the Company may not be able to enter into collaborations or other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect the Company's business prospects, even the ability to continue operations.

Coronavirus pandemic

The coronavirus, or COVID-19, pandemic has spread worldwide, and has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny and other measures. The outbreak and government measures taken in response have also had a significant impact, both directly and indirectly, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on the Company's business and operations are uncertain. To date, our operations have not been significantly impacted by the COVID-19 pandemic.

The actual and perceived impact of the COVID-19 pandemic is changing daily, and its ultimate effect on the Company cannot be predicted. As a result, there can be no assurance that the Company will not experience additional negative impacts associated with COVID-19, which could be significant. The COVID-19 pandemic may negatively impact the Company's business, financial condition and results of operations causing interruptions or delays in the Company's programs and services.

2. Summary of significant accounting policies

There have been no changes to the significant accounting policies as disclosed in Note 2 to the Company's annual combined and consolidated financial statements for the years ended December 31, 2020 and 2019 included in this Form S-1.

Unaudited Financial Information

The Company's condensed combined and consolidated financial statements included herein have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP, and pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC. In the Company's opinion, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the financial position and results of operations for the reported interim periods. The Company consider events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

Recently issued accounting pronouncements

The Company has elected to use the extended transition period for complying with new or revised accounting standards as available under the Jumpstart Our Business Startups Act (JOBS Act).

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, as amended, or ASU 2016-02, with guidance regarding the accounting for and disclosure of leases. The update requires lessees to recognize the

liabilities related all leases, including operating leases, with a term greater than 12 months on the balance sheet. This update also requires lessees and lessors to disclose key information about their leasing transactions. This standard is effective for annual reporting periods beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and financial statement disclosures.

In June 2016, the FASB issued Accounting Standards Update No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging*, *and Topic 825, Financial Instruments*, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and financial statement disclosures.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12. ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. This guidance is effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted. The Company is currently assessing the impact adoption of ASU 2019-12 will have on the financial statements and disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. ASU 2020-06 will simplify the accounting for convertible instruments by reducing the number of accounting models for convertible debt instruments and convertible preferred stock. Limiting the accounting models results in fewer embedded conversion features being separately recognized from the host contract as compared with current GAAP. Convertible instruments that continue to be subject to separation models are (i) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in capital. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity to reduce form-over-substance-based accounting conclusions. ASU 2020-06 will be effective for the Company beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently assessing the impact adoption of ASU 2020-06 will have on the financial statements and disclosures.

3. Fair value measurements

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

	As of March 31, 2021			
	Level 1	Level 2	Level 3	Total
Current assets				
Money market funds	$ 160,818	$ —	$ —	$ 160,818
Pension plan assets(1)	—	1,212	—	1,212
Total assets measured at fair value	$ 160,818	$ 1,212	$ —	$ 162,030
Current assets				As of December 31, 2020
Money market funds	$ 38,712	$ —	$ —	$ 38,712
Pension plan assets(1)	—	1,217	—	1,217
Total assets measured at fair value	$ 38,712	$ 1,217	$ —	$ 39,929
Current liabilities				
Preferred stock tranche obligation	$ —	$ —	$ 19,680	$ 19,680
Total liabilities measured at fair value	$ —	$ —	$ 19,680	$ 19,680

(1) The fair value of pension plan assets has been determined as the surrender value of the portfolio of active insured members held within the Swiss Life Collective BVG Foundation collective investment fund.

Money market funds are highly liquid investments and are actively traded. The pricing information on the Company's money market funds are based on quoted prices in active markets for identical securities. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

The Company's Series B Preferred Stock Tranche Obligation is measured at fair value using a Black-Scholes option pricing valuation methodology. The fair value of Series B Preferred Stock Tranche Obligation includes inputs not observable in the market and thus represents a Level 3 measurement. The option pricing valuation methodology utilized requires inputs based on certain subjective assumptions, including (i) expected stock price volatility, (ii) calculation of an expected term, (iii) a risk-free interest rate, and (iv) expected dividends. The assumptions utilized to value the Series B Preferred Stock Tranche Obligation as of December 31, 2020 were (i) expected stock price volatility of 93%; (ii) remaining term of 1.7 years; (iii) a risk-free interest rate of 0.12%; and (iv) an expectation of no dividends. The assumptions utilized to value the Series B Preferred Stock Tranche Obligation just prior to settlement were (i) expected stock price volatility of 26%; (ii) remaining term 0.003 years; (iii) a risk-free rate of 0.04%; and (iv) an expectation of no dividends. The Series B Preferred Stock Tranche Obligation was extinguished in February 2021 upon the issuance of the Series B Preferred Stock. Immediately prior to the issuance of the Series B Preferred Stock in February 2021, the Company adjusted the carrying value of the liability to its estimated fair value of $20.6 million.

The following table provides a reconciliation of assets and liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) (in thousands):

	Three months ended March 31,
	2021
Balance at beginning of period	$ 19,680
Change in fair value	960
Settlement of Preferred Stock Tranche Obligation	(20,640)
Balance at end of period	$ —

There were no transfers among Level 1, Level 2 or Level 3 categories in the three months ended March 31, 2021 or 2020.

4. Property and Equipment, net

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

	March 31, 2021	December 31, 2020
Laboratory equipment	$ 8,277	$ 5,205
Furniture and fixtures	277	—
Computer hardware and software	37	27
Leasehold improvements	24	—
Total property and equipment, at cost	$ 8,615	5,232
Less: accumulated depreciation	(883)	(609)
Property and equipment, net	$ 7,732	$ 4,623

Depreciation expense for the three months ended March 31, 2021 and 2020, was $274,000 and $71,000, respectively.

5. Convertible preferred stock

As of March 31, 2021, the Company had 109,686,035 shares of $0.0001 par value convertible preferred stock, or Convertible Preferred Stock, authorized, of which 20,004,280 shares are designated as Series A Preferred; 9,627,234 shares are designated as Series A-2 Preferred; 48,000,000 shares are designated as Series B Preferred; and 32,054,521 are designated as Series C convertible preferred stock, or Series C Preferred.

The following table summarizes outstanding Convertible Preferred Stock (in thousands, except share and per share amounts):

	Series A preferred		Series A-2 preferred		Series B preferred		Series C preferred		Total convertible preferred stock	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance—January 1, 2021	20,004,280	19,704	9,627,234	12,322	24,000,000	35,738	—	—	53,631,514	67,764
Issuance of Series B convertible preferred stock, net of issuance costs of $69	—	—	—	—	24,000,000	68,571	—	—	24,000,000	68,571
Issuance of Series C convertible preferred stock, net of issuance costs of $163	—	—	—	—	—	—	32,054,521	94,837	32,054,521	94,837
Balance—March 31, 2021	20,004,280	$ 19,704	9,627,234	$ 12,322	48,000,000	$ 104,309	32,054,521	$ 94,837	109,686,035	$ 231,172
Original issue price, or Original Issue Price, per share		$ 1.00		$ 1.2984		$ 2.00		$ 2.9637		
Liquidation value		$ 20,004		$ 12,500		$ 96,000		$ 95,000		$ 223,504

	Series A preferred		Total convertible preferred stock	
	Shares	Amount	Shares	Amount
Balance—January 1, 2020	19,250,000	$ 18,950	19,250,000	$ 18,950
Balance—March 31, 2020	19,250,000	$ 18,950	19,250,000	$ 18,950
Original issue price, or Original Issue Price, per share		$ 1.00		
Liquidation value		$ 19,250		$ 19,250

In February 2021, the Company issued 24,000,000 shares of Series B Preferred pursuant to the Preferred Stock Tranche Obligation for aggregate gross proceeds of $48.0 million.

In March 2021, the Company authorized the sale of up to 32,054,521 shares of its Series C Preferred Stock at a price of $2.9637 per share, and issued the authorized shares of Series C Preferred to several new and existing investors for aggregate gross proceeds of $95.0 million.

The rights and preferences and privileges of Convertible Preferred Stock are described below:

Dividend rights

Holders of Convertible Preferred Stock, on a *pari passu* basis but in preference to the holders of common stock, shall be entitled to receive, when, as and if declared by the board of directors, but only out of funds that are legally available therefor, cash dividends at the rate of eight percent of the respective series Original Issue Price per annum on each outstanding share of Convertible Preferred Stock, collectively the Preferred Dividend. All such Preferred Dividends shall be payable only when, as and if declared by the board of directors and shall be non-cumulative, and, if and when declared, shall be declared on each series of Convertible Preferred Stock and not on individual series of the Convertible Preferred Stock.

Further, the Company shall not declare, pay or set aside any dividends on shares of any other class or series of capital stock unless the holders of the Convertible Preferred Stock then outstanding shall first receive, or simultaneously receive, both the applicable Preferred Dividend and a dividend on each outstanding share of Convertible Preferred Stock in an amount at least equal to that dividend per share of Convertible Preferred Stock as would equal the product of (i) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (ii) the number of shares of common stock issuable upon conversion of a share of Convertible Preferred Stock, in each case calculated on the record date for determination of holders entitled to receive such dividend. The board of directors has not declared any dividends to-date.

Conversion rights

Each share of Convertible Preferred Stock is convertible at the option of the holder, at any time after the date of issuance, into a fully paid and non-assessable share of common stock. Each share of Convertible Preferred Stock is convertible into that number of common shares as is determined by dividing the applicable original purchase price of such share by the applicable conversion price. The conversion rate is subject to adjustment upon the occurrence of certain events, including diluting issues of shares, stock splits, stock combinations, certain dividends and distributions, a merger and a reorganization. The conversion rates for each series of Convertible Preferred Stock as of March 31, 2021 is 1:1.

All shares of the Convertible Preferred Stock automatically convert upon (i) the closing of a firm commitment underwritten initial public offering of common stock, in which the price per share is at least $3.00 per share, subject to adjustment in the event of stock dividend, stock split, combination or other similar recapitalization

with respect to the common stock, resulting in gross proceeds of at least $50.0 million, or the IPO; (ii) the closing of a transaction with a special purpose acquisition corporation, or SPAC Transaction having a value of at least $3.00 per share, subject to adjustment in the event of stock dividend, stock split, combination or other similar recapitalization with respect to the Preferred Stock and/or common stock, as applicable, of Preferred Stock and common stock as of the date of consummation of the SPAC Transaction based on the implied “pre-money” valuation of the Company immediately prior to the consummation of the SPAC Transaction and the aggregate cash proceeds available to the continuing operating entity in such SPAC Transaction, including the proceeds from any private placement or other financing conducted concurrently or in connection therewith, are at least $50.0 million gross proceeds; (iii) immediately prior to the closing of the Company’s initial listing of its common stock for trading on the Nasdaq Stock Market’s National Market, the New York Stock Exchange or another exchange or marketplace approved by the board, including approval of a majority of the Preferred Directors (as defined below), by means of an effective registration statement on Form S-1 under the Securities Act of 1933, as amended; or (iv) as specified by vote or written consent of a majority of the outstanding shares of Series C Preferred, Series B Preferred and at least a majority of the outstanding shares of Convertible Preferred Stock.

Liquidation preference

With first priority to the holders of Series C Preferred and the holders of Series B Preferred, as a single class on a *pari passu* basis, and second priority to the holders Series A-2 and Series A, as a single class on a *pari passu* basis, before any payment shall be made to the holders of common stock by reason of their ownership thereof, the holders of Convertible Preferred Stock then outstanding shall be entitled to be paid (i) in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, out of the assets of the Company available for distribution to its stockholders, or (ii) in the event of a merger or consolidation involving the Company or a subsidiary or on the sale, lease, transfer, exclusive license or other disposition by the Company or a subsidiary of all or substantially all assets of the Company not elected otherwise by holders of 70% of the outstanding shares of Convertible Preferred Stock, voting together as a single class on an as-if converted basis, or a Deemed Liquidation Event, out of the consideration available for distribution to stockholders from the consideration received by the Company for such Deemed Liquidation Event, net of any retained liabilities associated with the assets sold or technology licensed, as determined in good faith by the board of directors, together with any other assets of the Company available for distribution.

The amount payable per share to the holders of Series C Preferred and Series B Preferred, as a single class on a *pari passu* basis, shall be equal to the greater of (i) the Original Issue Price of each respective Series C Preferred and Series B Preferred, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had the shares of Series C Preferred and Series B Preferred been converted into common stock immediately prior to such event. The amount payable per share to the holders of Series A-2 Preferred and Series A, as a single class on a *pari passu* basis, shall be equal to the greater of (i) the Original Issue Price of each respective Series A-2 Preferred and Series A Preferred, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had the shares of respective Series A-2 Preferred and Series A Preferred converted into common stock immediately prior to such event.

If upon any such event, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of the outstanding shares of Series C Preferred and Series B Preferred, as a single class on a *pari passu* basis, the full amount to which they shall be entitled, the holders of shares of Series C Preferred and Series B Preferred shall share ratably, on a *pari passu* basis, in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. If the remaining assets of the Company available for distribution to its remaining stockholders shall

be insufficient to pay the holders of the outstanding shares of Series A-2 Preferred and Series A Preferred, as a single class on a *pari passu* basis, the full amount to which they shall be entitled, the holders of shares of Series A-2 Preferred and Series A shall share ratably, on a *pari passu* basis, in any distribution of the remaining assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Voting rights

Each share of Convertible Preferred has voting rights equal to the number of shares of common stock into which the Convertible Preferred Stock can be converted.

The holders of Series B Preferred are entitled to elect two directors of the Company; the holders of Series A-2 Preferred are entitled to elect one director of the Company; and the holders of Series A Preferred, are entitled to elect two directors; altogether the Preferred Directors. The Company's board of directors is further comprised of one director elected by the holders of common stock, one director who is mutually acceptable to a Series B Preferred investor and Company management, and one director who is not an affiliate of the Company or of any investor who shall be approved by the board, including a majority of the Preferred Directors.

Redemption rights

Shares of Convertible Preferred Stock are not redeemable except in the case of a Deemed Liquidation Event.

6. Common stock

As of March 31, 2021 and December 31, 2020, the Company has reserved the following shares of common stock for potential conversion of outstanding Preferred Stock, the vesting of restricted stock and exercise of stock options:

	March 31, 2021	December 30, 2020
Convertible preferred stock	109,686,035	53,631,514
Options to purchase common stock	6,464,649	7,786,146
Unvested restricted common stock	1,619,454	1,748,580
	117,770,138	63,166,240

7. Stock-based compensation

Stock incentive plan

In April 2020, the Company adopted the 2020 Stock Option and Grant Plan, or Plan. Under the terms of the Plan, the Company may issue stock options, restricted stock and other stock awards, to employees, non-employee directors, and consultants. As of March 31, 2021, there were 4,074,852 shares of common stock reserved for future issuance under the Plan. Awards granted under the Plan expire no later than 10 years from the date of grant. For incentive stock options and non-statutory stock options, the option exercise price will not be less than 100% of the estimated fair value on the date of grant. Options and restricted stock granted to employees typically vest over a four-year period but may be granted with different vesting terms.

Stock option activity

The following summarizes stock option activity:

	Number of options	Weighted average exercise price	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding—December 31, 2020	7,786,146	$ 0.58	9.9	$ 312
Forfeited	(1,321,497)	0.62	—	—
Outstanding—March 31, 2021	6,464,649	$ 0.57	9.6	$ 7,552
Vested or expected to vest—March 31, 2021	6,464,649	$ 0.57	9.6	$ 10,370
Exercisable—March 31, 2021	206,454	$ 0.52	9.6	$ 252

The aggregate intrinsic value of options granted is calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock. No options were exercised during the three months ended March 31, 2021 and 2020.

No options were granted during the three months ended March 31, 2021 and 2020.

Restricted stock award activity

The following summarizes restricted stock activity:

	Number of shares	Weighted average grant date fair value
Unvested as of December 31, 2020	1,748,580	$ 0.29
Vested	(129,126)	$ 0.17
Unvested as of March 31, 2021	1,619,454	$ 0.30

The aggregate fair value of restricted stock that vested during the three months ended March 31, 2021 was $22,000. The weighted average grant date fair value of restricted stock that vested during the three months ended March 31, 2021 was $0.17.

Stock-based compensation expense

Stock-based compensation expense is classified as follows (in thousands):

	Three months ended March 31,	
	2021	2020
Research and development	$ 60	$ 0
General and administrative	192	11
Total stock-based compensation expense	$ 252	$ 11

As of March 31, 2021, total unrecognized stock–based compensation cost related to unvested stock options and restricted stock awards was $2.1 million and $443,000, respectively. The Company expects to recognize this remaining cost over a weighted average period of 3.5 and 2.6 years, respectively.

8. Income taxes

The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2021 or 2020. The Company continues to maintain a full valuation allowance against all of its deferred tax assets.

The Company has evaluated the positive and negative evidence involving its ability to realize our deferred tax assets. The Company has considered its history of cumulative net losses incurred since inception and its lack of any commercial products. The Company has concluded that it is more likely than not that it will not realize the benefits of its deferred tax assets. The Company reevaluates the positive and negative evidence at each reporting period.

9. Net loss per common share

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands except share and per share amounts):

	Three months ended March 31,	
	2021	2020
Net loss	$ (12,276)	$ (4,302)
Net loss per share attributable to common stockholders—basic and diluted	$ (2.03)	$ (0.86)
Weighted-average number of common shares used in computing net loss per share—basic and diluted	6,034,427	5,000,000

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per common share, as their effect is anti-dilutive:

	March 31, 2021	March 31, 2020
Convertible Preferred Stock	109,686,035	19,250,000
Stock options to purchase common stock	6,464,649	—
Restricted common stock	1,619,454	1,470,588

10. Related parties

Versant Ventures has been a related party since inception of the Company as an investor and member of the board of directors. The Company has a service agreement with a Versant Ventures portfolio company, Ridgeline Therapeutics GmbH, or Ridgeline. Ridgeline provided management and administrative support to facilitate start-up of the Company and provided and continues to provide research and development services. Expenses attributable to Ridgeline were recognized primarily in research and development expenses in the Company's condensed combined and consolidated statements of operations and comprehensive loss. The Company paid $4.7 million and $2.5 million to Ridgeline during the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021 and December 31, 2020, the Company had $2.6 million and $4.8 million, respectively, in accounts payable in the condensed consolidated balance sheets associated with Ridgeline.

The Company also has a cost sharing agreement with Versant Ventures for the Company's Chief Executive Officer. Amounts recognized as a result of this agreement are recognized in general and administrative expenses in the Company's condensed combined and consolidated statements of operations and comprehensive loss. The Company received $79,000 and paid $15,000 to Versant Ventures during the three months ended

March 31, 2021 and 2020, respectively, related to this agreement. As of March 31, 2021 and December 31, 2020, the Company had $40,000 and $79,000, respectively, in prepaids and other current assets in the condensed consolidated balance sheets related to this agreement.

The ICR has been a related party since inception of the Company. The Company had a license, collaboration and investment agreement with the ICR as described in Note 6 of the Company's annual combined and consolidated financial statements. The Company paid $0 and $609,000 to ICR during the three months ended March 31, 2021 and 2020, respectively. As of March 31, 2021 and December 31, 2020, no amounts were owed by the Company to ICR.

11. Employee retirement plan

In February 2021, the Company adopted a defined contribution plan intended to qualify under Section 401(k) of the Internal Revenue Code covering all eligible U.S. based employees of the Company. All employees are eligible to become participants of the plan immediately upon hire. Each active employee may elect, voluntarily, to contribute a percentage of their compensation to the plan each year, subject to certain limitations. The Company reserves the right, but is not obligated, to make additional contributions to this plan. The Company makes safe-harbor match contributions of 100% of the first 4% of each participant's eligible compensation. The Company recorded $33,000 and $0 matching 401(k) contribution related expense during the three months ended March 31, 2021 and March 31, 2020, respectively.

12. Subsequent events

The Company has evaluated subsequent events through May 21, 2021, the date these financial statements were issued, and has determined that there have been no events that have occurred that would require adjustments to the Company's disclosures in the condensed combined and consolidated financial statements, except as referenced below.

In April 2021, the Company entered into a lease agreement for laboratory and office space in Basel, Switzerland. The lease is in effect for five years ending March 31, 2026 with a base rent for the facility is $416,000 per year. The rent is subject to an annual increase based on Swiss inflation on the anniversary date.

In April and May 2021, the Company granted 9,470,232 options to purchase the Company's common stock at a weighted average exercise price of $1.76 and a weighted average grant date fair value of $1.21.

Table of Contents

shares

Common Stock

Prospectus

J.P Morgan **Cowen** **Piper Sandler** **Guggenheim Securities**

Until , 2021, all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

, 2021

Part II

Information not required in prospectus

Item 13. Other expenses of issuance and distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, to be paid by us in connection with the sale of the shares of common stock being registered hereby. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee and the Nasdaq Global Market initial listing fee.

SEC registration fee	$	*
FINRA filing fee		*
Nasdaq listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Blue Sky fees and expenses (including legal fees)		*
Transfer agent and registrar fees and expenses		*
Miscellaneous		*
Total	$	*

* To be provided by amendment.

Item 14. Indemnification of directors and officers

Section 145 of the Delaware General Corporation Law (the DGCL) authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws to be in effect upon the effectiveness of this registration statement that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws to be in effect upon the effectiveness of this registration statement provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We intend to enter into indemnification agreements with each of our directors and executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines and settlement amounts), to each indemnified director or executive officer in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Exchange Act.

Item 15. Recent sales of unregistered securities

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act:

(a) Issuance of convertible promissory notes

In December 2019, we issued a convertible promissory note to an accredited investor in the principal amount of $750,000.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in this transaction represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a

registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(b) Issuances of capital stock

In April 2020 and September 2020, in connection with two separate Contribution and Exchange Agreements with the shareholders of Monte Rosa Therapeutics AG, we issued an aggregate of 5,000,000 shares of our common stock, 612,705 shares of our common stock in the form of restricted stock and 19,250,000 shares of our Series A convertible preferred stock to the shareholders of Monte Rosa Therapeutics AG, which included accredited investors, directors and employees.

Concurrent with the execution of the April 2020 Contribution and Exchange Agreement, we converted the entire principal amount of our outstanding convertible promissory note issued in December 2019 to an accredited investor, plus interest, into 754,280 shares of our Series A convertible preferred stock (for an aggregate issuance of 20,004,280 shares of Series A convertible preferred stock).

In April 2020, accredited investors purchased an aggregate of 9,627,234 shares of our Series A-2 convertible preferred stock at a price per share of $1.2984.

In September 2020 and in February 2021, accredited investors purchased an aggregate of 48,000,000 shares of our Series B convertible preferred stock at a price per share of $2.00.

In March 2021, accredited investors purchased an aggregate of 32,054,521 shares of our Series C convertible preferred stock at a price per share of $2.9637.

No underwriters were involved in the foregoing sales of securities. The sales of securities described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering. All of the purchasers in these transactions represented to us in connection with their purchase that they were acquiring the securities for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. Such purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for the purposes of the Securities Act.

(c) Grants and exercises of stock options and restricted stock

As of May 21, 2021, we have granted stock options to purchase an aggregate of 17,256,378 shares of our common stock, with exercise prices ranging from $0.32 to $2.23 per share, to employees, directors and consultants. pursuant to 2020 Plan, and no shares of common stock have been issued upon the exercise of stock options pursuant to the 2020 Plan.

As of May 21, 2021, we have granted an aggregate of 1,250,446 shares of restricted stock to employees and consultants under the 2020 Plan and an additional 1,470,588 outside of the 2020 Plan.

The issuances of the securities under the 2020 Plan described above were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act or Rule 701 promulgated under the Securities Act as transactions pursuant to compensatory benefit plans. The shares of common stock issued upon the exercise of options are deemed to be restricted securities for purposes of the Securities Act.

The issuance of securities described above to employees and consultants outside of the 2020 Plan were deemed exempt from registration pursuant to Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering.

Item 16. Exhibits and financial statement schedules

(a) Exhibits.

Exhibit number	Exhibit table
1.1*	Form of Underwriting Agreement
3.1**	Third Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect
3.2*	Form of Fourth Amended and Restated Certificate of Incorporation of the Registrant (to be effective upon the closing of this offering)
3.3**	By-laws of the Registrant, as currently in effect
3.4*	Form of Amended and Restated By-laws (to be effective upon the closing of this offering)
4.1**	Second Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated March 11, 2021
4.2*	Form of Common Stock Certificate
5.1*	Opinion of Goodwin Procter LLP
10.1**#	2020 Stock Option and Grant Plan, as amended, and forms of award agreements thereunder
10.2*#	2021 Stock Option and Incentive Plan and forms of award agreements thereunder
10.3*#	2021 Employee Stock Purchase Plan
10.4*#	Senior Executive Cash Incentive Bonus Plan
10.5*#	Form of Officer Indemnification Agreement
10.6*#	Form of Director Indemnification Agreement
10.7*#	Employment Agreement between the Registrant and Markus Warmuth, to be in effect upon the closing of this offering
10.8*#	Employment Agreement between the Registrant and Ajim Tamboli, to be in effect upon the closing of this offering
10.9*#	Employment Agreement between the Registrant and Owen Wallace, to be in effect upon the closing of this offering
10.10*#	Employment Agreement between the Registrant and Sharon Townson, to be in effect upon the closing of this offering
10.11*#	Employment Agreement between the Registrant and John Castle, to be in effect upon the closing of this offering
10.12*	Contribution and Exchange Agreement, dated April 14, 2020, between certain shareholders of Monte Rosa Therapeutics AG and the Registrant
10.13*	Contribution and Exchange Agreement, dated September 1, 2020, between certain shareholders of Monte Rosa Therapeutics AG and the Registrant
10.14**†	Services Agreement, dated as of April 10, 2018, between Ridgeline Therapeutics GmbH and Monte Rosa Therapeutics AG
10.15**†	Services Agreement, dated as of December 29, 2020, between Monte Rosa Therapeutics AG and the Registrant

Exhibit number	Exhibit table
10.16**†	License Agreement, dated as of April 10, 2018, among Cancer Research Technology Limited, The Institute of Cancer Research: Royal Cancer Hospital and Monte Rosa Therapeutics AG
10.17**†	Collaboration and Option Agreement, dated as of April 10, 2018, among Cancer Research Technology Limited, The Institute of Cancer Research: Royal Cancer Hospital and Monte Rosa Therapeutics AG, as amended on February 25, 2019, January 20, 2020 and June 18, 2020.
10.18**	Lease Agreement, dated September 23, 2020, between OPG MP Parcel Owner (DE) LLC and the Registrant
21.1**	Subsidiaries of the Registrant
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)
24.1*	Power of Attorney (included on signature page to this registration statement)

* To be filed by amendment.

** Previously filed.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Portions of this exhibit (indicated by asterisks) will be omitted in accordance with the rules of the SEC.

(b) Financial Statement Schedules.

None.

Item 17. Undertakings

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(ii) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act, Monte Rosa Therapeutics, Inc. has duly caused this registration statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Commonwealth of Massachusetts, on the day of , 2021.

Monte Rosa Therapeutics, Inc.

By: _____
Markus Warmuth
President and Chief Executive Officer

Signatures and power of attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Markus Warmuth and Ajim Tamboli, and each of them, either of whom may act without the joinder of the other, as his true and lawful attorneys-in-fact and agents with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by the registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and all documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done or by virtue hereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities indicated on the day of , 2021.

Signature	Title
Markus Warmuth	President, Chief Executive Officer and Director (Principal Executive Officer)
Ajim Tamboli	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
Alexander Mayweg	Director
Bradley J. Bolzon	Director
Ali Behbahani	Director

Signature	Title
Kimberly L. Blackwell	Director
Andrew Schiff	Director
Chandra P. Leo	Director
Christine Siu	Director