As confidentially submitted to the U.S. Securities and Exchange Commission on February 12, 2021.
This draft registration statement has not been publicly filed with the U.S. Securities and Exchange Commission and all information herein remains strictly 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

Biomea Fusion, Inc.
(Exact name of registrant as specified in its charter)

Delaware	2834	82-2520134
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

726 Main Street
Redwood City, California 94063
(650) 980-9099
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Thomas Butler
Chief Executive Officer
Biomea Fusion, Inc.
726 Main Street
Redwood City, California 94063
(650) 980-9099
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Miles P. Jennings Brian J. Cuneo Latham & Watkins LLP 140 Scott Drive Menlo Park, California 94025 (650) 328-4600	Rainer (Ramses) Erdtmann President Biomea Fusion, Inc. 726 Main Street Redwood City, California 94063 (650) 980-9099	Charles Kim Jonie Kondracki Kristin VanderPas Denny Won Cooley LLP 4401 Eastgate Mall San Diego, California 92121 (858) 550-6000

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, 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 Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price[(1)]	Amount of registration fee[(2)]
Common Stock, $0.0001 par value per share	$	$

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the aggregate offering price of additional shares of common stock that the underwriters have the option to purchase.

(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the U.S. Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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Explanatory note

Pursuant to the applicable provisions of the Fixing America's Surface Transportation Act, we are omitting our unaudited financial statements as of September 30, 2020 and for the nine months ended September 30, 2019 and 2020 because they relate to historical periods that we believe will not be required to be included in the prospectus at the time of the contemplated offering. We intend to amend the registration statement to include all financial information required by Regulation S-X at the date of such amendment before distributing a preliminary prospectus to investors.

As disclosed in Note 8 to our audited financial statements included elsewhere in this prospectus, we received a $35,637 Paycheck Protection Plan loan in the form of a promissory note dated May 5, 2020 between us and Silicon Valley Bank as lender. We intend to fully repay such loan in the first quarter of 2021 and will update the disclosure in a subsequent amendment to the registration statement to reflect this repayment.

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

Subject to completion, dated , 2021

Preliminary prospectus

shares

biomea FUSION

Common stock

This is an initial public offering of shares of common stock of Biomea Fusion, Inc. We are offering shares of our common stock to be sold in the offering. The initial public offering price is expected to be between $ and $ per share of common stock.

Prior to this offering, there has been no public market for our common stock. We have applied to list our common stock on the Nasdaq Global Market under the symbol "BMEA."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions(1)	$	$
Proceeds to Biomea Fusion, Inc., before expenses	$	$

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters the option for a period of 30 days to purchase up to an additional shares of common stock.

Investing in our common stock involves a high degree of risk. See "Risk factors" beginning on page 12.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities nor passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

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

J.P. Morgan **Jefferies** **Piper Sandler**

, 2021

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

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We 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 offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in 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: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside the United States.

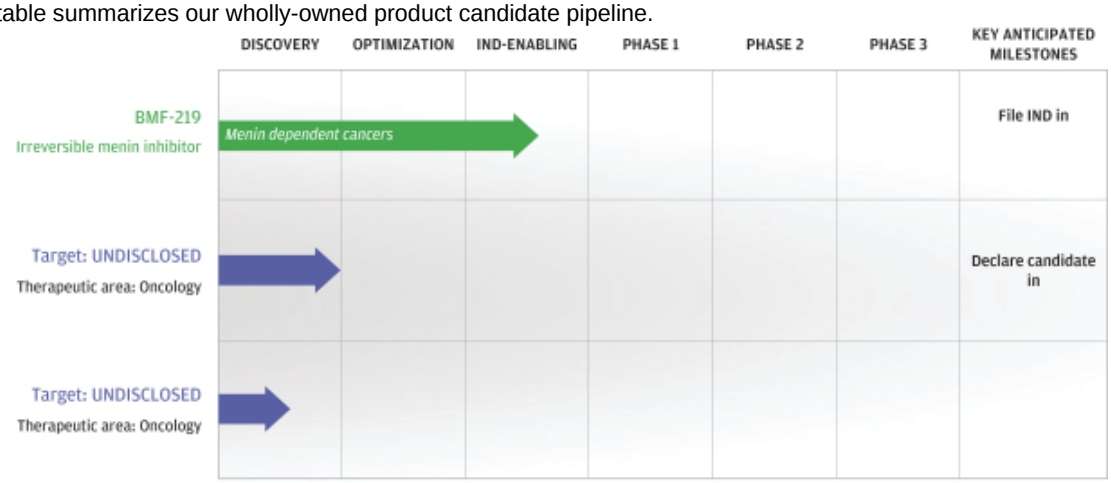
Prospectus summary

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by, the more detailed information and financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information under the sections titled "Risk factors," "Special note regarding forward-looking statements" and "Management's discussion and analysis of financial condition and results of operations" and our financial statements and related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "Biomea Fusion," "Biomea," the "Company," "we," "us" and "our" refer to Biomea Fusion, Inc.

Overview

We are a preclinical-stage biopharmaceutical company focused on the discovery, development and commercialization of irreversible small molecule drugs to treat patients with genetically defined cancers. An irreversible small molecule drug is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible drugs, including greater target selectivity, lower drug exposure and the ability to drive a deeper, more durable response. Leveraging our extensive expertise in irreversible binding chemistry and development, we built our proprietary FUSION System discovery platform to advance a pipeline of novel irreversible small molecule product candidates. Our lead product candidate, BMF-219, is designed to be an orally bioavailable, potent and selective irreversible inhibitor of menin, an important transcriptional regulator known to play a direct role in oncogenic signaling in multiple cancers. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models and has been well-tolerated in animal studies. We are developing BMF-219 for the treatment of liquid and solid tumors that are highly dependent on menin, including leukemias containing the mixed lineage leukemia (MLL) fusion protein. We are currently completing investigational new drug (IND) enabling studies and expect to file an IND application with the U.S. Food and Drug Administration (FDA) in . Beyond BMF-219, we are utilizing our novel platform to develop irreversible treatments against other high-value oncogenic drivers of cancer and expect to nominate our second development candidate in . We believe our capabilities and platform uniquely position us to be a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit when treating various cancers.

The following table summarizes our wholly-owned product candidate pipeline.



Key advantages of irreversible drugs

Since the discovery of aspirin in 1899, drugs that form permanent bonds with their target (irreversible drugs) have been known to offer a number of potential safety, tolerability and efficacy advantages over conventional reversible drugs through multiple mechanisms, including:

- ***High selectivity***: Irreversible drugs have the potential to confer high selectivity to a target by interacting with the unique surrounding structural elements of the protein and establishing a covalent bond to a key residue in the binding site. Leveraging non-covalent and covalent interactions can lead to greater selectivity versus reversible compounds, which rely solely on non-covalent binding. This has the potential to reduce the likelihood of non-specific, off-target interactions that often lead to safety and tolerability concerns.
- ***Deep inactivation of target***: Upon binding, an irreversible inhibitor may not only cause inactivation of the target, but may also result in the elimination of the target through normal cellular degradation processes. The diseased cell then either undergoes rapid apoptosis or differentiation into a normal, mature cell. Such transformation has the potential to provide the patient with a durable, lasting benefit.
- ***Greater therapeutic window*****:** Irreversible inhibitors are designed to create a permanent bond with high affinity and long residence time. Unlike conventional reversible drugs, which typically need to be present to provide benefit, irreversible drugs have the potential to maintain their effect in the absence of sustained drug exposure. The permanent inhibition of target function upon irreversible binding essentially uncouples pharmacodynamics (drug effects) (PD) from pharmacokinetics (drug exposure) (PK) as target inhibition persists after the drug has been cleared from the system. This property of irreversible drugs can potentially lead to lower drug doses and less frequent dosing regimens versus reversible approaches.

Our FUSION System discovery platform

Despite the potential advantages of irreversible small molecules, the majority of approved drugs are reversible binders due to the target protein structural requirements and chemistry expertise necessary to develop safe

and effective targeted irreversible therapies. Leveraging our management team's experience at Pharmacyclics (acquired by AbbVie in 2015 for a total transaction value of $21 billion) developing ibrutinib, an irreversible inhibitor of Bruton tyrosine kinase (BTK), we built a proprietary platform to enable the design and development of novel irreversible, small molecule product candidates against high-value oncogenic drivers of cancer. Our FUSION System discovery platform encompasses the following:

- ***Target selection***: We use our expertise in structural biology and irreversible binding chemistry to identify both validated and novel targets that we believe may have a demonstrable and specific impact on disease and have particular structural characteristics that would be amenable to direct intervention with an irreversible binder.
- ***Scaffold creation:*** We create novel chemical scaffolds using a computational platform to exploit the unique structural elements of a specific target protein. We then screen these scaffolds with in-house technologies to select the optimal candidates for further construction and design. This evaluation process is intended to increase the probability of advancing multiple targeted compounds through the discovery process and into the clinic.
- ***Molecule optimization:*** Using our proprietary suite of computational technologies, assays, analytical approaches, chemistry and know-how we strive to maximize the potential selectivity, potency, safety and convenience of our oral irreversible small molecule product candidates.

We believe that irreversible small molecules have the potential to address the key limitations of existing reversible therapeutics and treat diseases where targeted therapies are not yet approved.

Our product candidates

Our lead product candidate, BMF-219, is designed to be an orally bioavailable, potent and selective irreversible inhibitor of menin, a ubiquitously expressed scaffold protein that functions in histone modification and epigenetic gene regulation to impact multiple cellular processes, including cell cycle control, apoptosis and DNA damage repair. Interaction between menin and MLL proteins results in deregulated expression of downstream genes, which subsequently triggers uncontrolled cell proliferation. Internal and external studies have shown that disrupting the protein-protein interaction between menin and MLL can inhibit oncogenic signaling and potentially lead to cell death. In acute leukemias, MLL rearrangements (MLL-r) are caused by translocations of *KMT2A* (the gene that encodes the MLL protein), which leads to a modified MLL protein with enhanced affinity towards menin. This strengthened menin MLL-r interaction drives the oncogenic state of these cells. MLL rearrangements account for approximately 5% to 10% of acute myeloid leukemia (AML), or approximately 1,000 to 2,000 new patients per year in the United States. NPM1 mutant AML has also shown a strong dependence on the interaction of menin and MLL, representing over 25% to 30% of AML patients or approximately 6,000 new patients per year in the United States. While the role of menin-MLL interactions in oncogenic signaling has been extensively studied in AML and acute lymphoblastic leukemia (ALL), many liquid tumors (including diffuse large B-cell lymphoma (DLBCL)), and multiple myeloma) and multiple solid tumors (including breast, lung, pancreatic, bone and colon) have been shown to be dependent on menin for survival and propagation. Despite the high unmet need, there are currently no approved therapies directly targeting menin, and the only active clinical programs of which we are aware are studying reversible inhibitors.

BMF-219 is a potentially first-in-class irreversible menin inhibitor being developed for the treatment of cancers that are highly dependent on menin, including leukemias containing the MLL fusion protein. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models, including MLL-r AML, NPM1 mutant AML and KRAS mutant colorectal, lung and pancreatic tumors. BMF-219 was also well tolerated and showed PK properties consistent with a once-daily oral therapy. We are currently completing IND-enabling studies and expect to file an IND with the FDA in . If the IND is cleared, we expect to initiate a Phase 1/2 clinical trial of BMF-219 in patients with acute leukemia, including MLL-r, NPM1 mutant and other subtypes. We also plan to study BMF-219 across a range of menin dependent cancers, including multiple myeloma, DLBCL, breast cancer and KRAS mutant lung, pancreatic and colon tumors. Beyond cancer, based on a growing body of external scientific evidence, we plan to explore the potential of our irreversible menin inhibitor candidates to treat Type-2 diabetes.

In addition to BMF-219, we are utilizing our novel FUSION System to pioneer irreversible treatments against other high-value genetic drivers of disease. We are currently advancing two other preclinical irreversible programs for the treatment of select cancers and expect to nominate our second development candidate in .

Our team

After working closely together at Pharmacyclics, our Chief Executive Officer, Thomas Butler, and President, Ramses Erdtmann, founded Biomea Fusion in 2017 with the goal of developing targeted therapies for patients suffering from genetically defined cancers. Our management team has significant experience in precision oncology and in progressing products from early stage research to clinical trials, and ultimately to regulatory approval and commercialization. Together, they bring in-house expertise in medicinal chemistry, biology, translational medicine, computational biology and chemistry, *in vitro* and *in vivo* pharmacology, biomarker development and manufacturing. We have also established internal expertise in clinical development, clinical operations, pharmacovigilance, clinical pharmacology, regulatory and quality. Other members of the management team have held various positions at Genentech, Gilead Sciences, Pharmacyclics, and Celera. We are supported by our board of directors, scientific advisory board and a leading syndicate of investors, which includes Cormorant Asset Management, Boxer Capital of Tavistock Group, Janus Henderson Investors, Rock Springs Capital, RTW Investments LP, Aisling Capital, Point Sur Investors, Logos Capital, and Clifton Capital.

Our strategy

Our goal is to discover, develop and commercialize irreversible small molecules to treat patients with genetically defined cancers. The key elements of our business strategy to achieve this goal include:

- Deploy our irreversible platform against high-value oncogenic drivers of cancer;
- Rapidly advance our lead product candidate, BMF-219, into and through clinical development;
- Continue to expand our portfolio of irreversible small molecule drug candidates;
- Evaluate opportunities to accelerate development timelines and enhance the commercial potential of our programs in collaboration with third parties; and
- Maintain our entrepreneurial outlook, scientifically rigorous approach and culture of tireless commitment to patients.

Risks associated with our business

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled “Risk factors” immediately following this prospectus summary. These risks include, among others, the following:

- We have a limited operating history, have not initiated or completed any clinical trials, have no products approved for commercial sale, and have not generated any revenue, which may make it difficult for you to evaluate our current business and likelihood of success and viability.
- We have incurred significant net losses in each period since our inception, and we expect to incur significant net losses for the foreseeable future.
- Even if this offering is successful, we will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and product development programs or future commercialization efforts.
- Our discovery and preclinical development is focused on the development of small-molecule, irreversible therapies to treat patients with genetically defined cancers, which is a rapidly evolving area of science, and the approach we are taking to discover and develop such binders is novel, may never lead to marketable products and may not ultimately represent a significant market.
- Our novel approach to the discovery and development of our current and future product candidates is unproven, and we may not be successful in our efforts to use and expand our FUSION System to build a pipeline of product candidates with commercial value.
- We are very early in our development efforts and are substantially dependent on our lead product candidate, BMF-219. If we are unable to advance BMF-219 or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize BMF-219 or any of our future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.
- Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our clinical development and 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.
- The results of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. Successful preclinical studies and clinical trials cannot provide assurance of successful commercialization.
- We have no experience as a company in conducting clinical trials.
- The outbreak of the novel coronavirus disease 2019 (COVID-19) could materially adversely impact our business, results of operations and financial condition, including our preclinical studies and clinical trials.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our corporate and other information

We were incorporated under the laws of the State of Delaware on August 9, 2017 under the name "Biomea Fusion, LLC. On December 18, 2020, all outstanding membership interest in Biomea Fusion, LLC were converted to equity interests in Biomea Fusion, Inc. The capitalization information included in these financial statements is consistently presented as if it is that of Biomea Fusion, Inc., even during the prior period when investors held their equity interests in Biomea Fusion, LLC. Our principal executive offices are located at 726 Main Street, Redwood City, California 94063, and our telephone number is (650) 980-9099. Our corporate website address is www.biomeafusion.com. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this prospectus or the registration statement of which it forms a part. We have included our website in this prospectus solely as an inactive textual reference.

"Biomea," "Biomea Fusion," the Biomea Fusion logo and other trademarks, trade names or service marks of Biomea Fusion, Inc. appearing in this prospectus are the property of Biomea Fusion, Inc. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

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

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (Exchange Act), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- We will present in this prospectus only two years of audited financial statements, plus unaudited condensed financial statements for any interim period, and related management's discussion and analysis of financial condition and results of operations;
- We will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act);
- We will provide less extensive disclosure about our executive compensation arrangements; and

- We will not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

Accordingly, the information contained herein may be different than the information you receive from our competitors that are public companies or other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a “smaller reporting company” as defined in Regulation S-K under the Securities Act of 1933, as amended (Securities Act), and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. We may be a smaller reporting company even after we are no longer an emerging growth company.

The offering

Common stock offered by us	shares.
Option to purchase additional shares	The underwriters have been granted an option to purchase up to additional shares of common stock from us at any time within 30 days from the date of this prospectus.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase up to additional shares of common stock), based on 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 payable by us. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund: (i) our ongoing preclinical development and planned Phase 1/2 clinical trial of BMF-219, (ii) our research and development efforts with respect to our two undisclosed programs and (iii) the remainder, if any, for working capital and other general corporate purposes. We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so. See the section titled “Use of proceeds” for additional information.
Risk factors	See the section titled “Risk factors” for a discussion of factors to consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Proposed Nasdaq Global Market symbol	“BMEA”

The number of shares of our common stock to be outstanding after this offering is based on shares of common stock outstanding as of December 31, 2020 (including conversion of all of our outstanding shares of convertible preferred stock on an as-converted basis) and excludes:

- 103,074 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020, with a weighted-average exercise price of $45.41 per share;

- additional shares of our common stock reserved for issuance pursuant to future awards under our 2020 Equity Incentive Plan (2020 Plan), which will become available for issuance under our 2021 Plan (defined below) after the consummation of this offering;
- shares of our common stock reserved for future issuance under our 2021 Incentive Award Plan (2021 Plan), which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2021 Plan; and
- shares of our common stock reserved for future issuance under our Employee Stock Purchase Plan (ESPP), which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

Except as otherwise indicated, all information in this prospectus assumes or gives effect to:

- the adoption, filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the completion of this offering;
- the automatic conversion of all outstanding shares of our convertible preferred stock as of December 31, 2020 into an aggregate of shares of our common stock immediately prior to the completion of this offering;
- a -for- reverse stock split of our capital stock, which was effected on , 2021;
- no exercise of the outstanding options referred to above; and
- no exercise by the underwriters of their option to purchase up to additional shares of our common stock from us in this offering.

Summary financial data

The following tables set forth our summary statements of operations and balance sheet data. The summary statements of operations data for the years ended December 31, 2019 and 2020 and the balance sheet data as of December 31, 2020 are derived from our audited financial statements appearing elsewhere in this prospectus. You should read the following summary financial data together with the sections titled “Selected financial data” and “Management’s discussion and analysis of financial condition and results of operations” and our financial statements and the related notes included elsewhere in this prospectus. The summary financial data included in this section are not intended to replace the financial statements and related notes and are qualified in their entirety by our financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future.

(in thousands, except share and per share data)	Year ended December 31, 2019	2020
Statements of operations data:		
Operating expenses:		
Research and development	$ 1,092	$
General and administrative	103	
Total operating expenses	1,195	
Loss from operations	(1,195)	
Other expense, net	(3)	
Net loss attributable to common stockholders	$ (1,198)	$
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (1.75)	$
Weighted–average shares used in computing net loss per share attributable to common stockholders, basic and diluted[1]	684,582	
Pro forma net loss per share, basic and diluted (unaudited)[1]		$
Pro forma weighted–average shares outstanding, basic and diluted (unaudited)[1]		

(1) See Notes 1 and 7 to our audited financial statements included elsewhere in this prospectus for explanations of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

(in thousands)	As of December 31, 2020		
	Actual	Pro forma[1]	Pro forma as adjusted[2][3]
		(unaudited)	
Balance sheet data:			
Cash and cash equivalents	$	$	$
Working capital[4]			
Total assets			
Convertible preferred stock			
Accumulated deficit			
Total stockholders’ (deficit) equity			

(1) The pro forma column reflects: (i) the automatic conversion of all of our outstanding shares of convertible preferred stock into shares of our common stock, which will occur immediately prior to the completion of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation in Delaware, which will be in effect immediately prior to the completion of this offering.

(2) The pro forma as adjusted column reflects: (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of shares of our 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 payable by us.

(3) The pro forma as adjusted information discussed above is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing. Each $1.00 increase or 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 or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming the number of shares of common stock 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. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease, as applicable, each of our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' (deficit) equity by approximately $ million, assuming the assumed initial public offering price of $ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

Risk factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "Management's discussion and analysis of financial condition and results of operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Many of the following risks and uncertainties may be exacerbated by the coronavirus disease 2019 (COVID-19) pandemic and any worsening of the global business and economic environment as a result. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks related to our limited operating history, business, financial condition, results of operations, and need for additional capital

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

We are a preclinical stage biotechnology company with a limited operating history with which investors can evaluate our business and prospects. We commenced operations in August 2017, have never initiated or completed any clinical trials, have no products approved for commercial sale and have never generated any revenue, and our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and establishing arrangements with third parties for the manufacture of initial quantities of product candidates. Our lead product candidate, BMF-219, is still in preclinical development, and our goal is to file an investigational new drug application (IND), with the U.S. Food and Drug Administration (FDA) in the .

We have not demonstrated an ability to successfully initiate, conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you 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 company with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We expect our financial condition and results of operations to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

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

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We are still in the early stages of development of our product candidates and have not yet initiated our first clinical trial. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to discover, develop and market additional potential products. We have financed our operations primarily through private placements of our common and convertible preferred stock.

We have incurred significant net losses in each reporting period since we commenced operations in August 2017. Our net losses were $1.2 million and $ million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of $ million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit INDs for BMF-219 and any other product candidates;
- conduct preclinical studies and initiate clinical trials;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues, or other regulatory challenges;
- establish a sales, marketing, and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce, and protect our intellectual property portfolio;
- hire additional clinical, regulatory, and scientific personnel; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have not generated any revenue from our product candidates and may never generate revenue or be profitable. Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the discovery, development and commercialization of our product candidates.

Our ability to become profitable depends upon our ability to generate revenue. We have not received marketing approval for any product candidate, and we have not generated any revenue from any product sales or other sources since our inception. We do not expect to generate revenue unless or until we successfully complete preclinical and clinical development and obtain regulatory approval of, and then successfully commercialize, at least one product candidate. We have not initiated any clinical trials or evaluated any product candidate in humans, including BMF-219, our lead product candidate. As such, we face significant translational risk as our product candidates advance to the clinical stage, and promising results in preclinical studies may not be replicated in clinical trials. All of our current and future product candidates will require preclinical and clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely initiation and completion of our preclinical studies and clinical trials for BMF-219 and our future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- establishing and maintaining relationships with contract research organizations (CROs) and clinical sites for the clinical development of BMF-219 and our future product candidates;
- our ability to complete IND-enabling studies and successfully submit and receive authorization to proceed under INDs or comparable applications;
- whether we are required by the FDA or other comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy, consistent manufacturing quality, and acceptable risk-benefit profile of our small molecule product candidates or any future product candidates;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary regulatory approvals from the FDA and comparable foreign regulatory authorities;
- the willingness of physicians, operators of clinics, and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies, such as chemotherapy, to treat solid tumors;
- the actual and perceived availability, cost, risk profile and side effects and efficacy of our product candidates, if approved, relative to existing and future alternative cancer therapies and competitive product candidates and technologies;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices (cGMP);

- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- patient demand for our current product candidates and any future product candidates, if approved;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring, and retaining qualified personnel.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercializing our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain indications. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We are currently focused on biological targets that drive genetically-defined cancers. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between advancing our lead product candidate, BMF-219, as well as developing our other and any future product candidates.

Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. 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 future 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. In addition, if we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the cancer or pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected.

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

Since our inception, we have used substantial amounts of cash to fund our operations, and our expenses will increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of, and seek marketing approval for, our

product candidates. Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed significant amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for, BMF-219, and advance our future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing, and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. Following this offering, we also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2020, we had $ million in cash and cash equivalents, which includes net proceeds of $55.7 million from the sale of shares of Series A convertible preferred stock in December 2020. Based on our current operating plan, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next 12 months. Our estimate as to how long we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Such financing may dilute our stockholders or restrict our operating activities. To the extent we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation, or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including but not limited to:

- the scope, rate of progress, and costs of our drug discovery, preclinical development activities, laboratory testing, and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we discover and develop additional product candidates;

- the cost, timing, and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the timing, receipt, and amount of sales from our potential products;
- our need and ability to hire additional management, scientific, and medical personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the cost associated with commercializing our product candidates, if they receive regulatory approval; and
- the impact of the COVID-19 pandemic on our business, which may exacerbate the magnitude of the factors discussed above.

We do not have any committed external source of funds and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic and political conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Risks related to product development

Our discovery and preclinical development is focused on the development of small-molecule, irreversible therapies to treat patients with genetically-defined cancers, and the approach we are taking to discover and develop such binders is novel, may never lead to marketable products and may not ultimately represent a significant market.

The discovery and development of small-molecule irreversible therapies for patients with genetically-defined cancers is an emerging field. While there is scientific evidence to support the feasibility of developing irreversible therapies, the significant complexity and potential safety and toxicity concerns associated with poorly designed irreversible binders have historically discouraged drug developers from pursuing this drug class. In particular, a significant risk for toxicity is posed by these small-molecule irreversible binders if they demonstrate a more promiscuous binding profile than intended, which can potentially cause unacceptable levels of off-target interactions. While we believe the significant expertise, foundational knowledge and

capabilities that our management team members have accumulated over their extensive careers and that we have expanded and refined over the last three years positions us to overcome such challenges, there can be no assurance that we will be successful. Even if we are able to limit off-target interaction, there can be no assurance that treatment with any of our irreversible inhibitor product candidates will demonstrate the deep inactivation of their targets or offer greater therapeutic windows than conventional reversible drugs. It is possible that the targets we select could be effectively and safely treated by more frequent dosing of reversible drugs, which could limit the potential advantages or perceived benefits of our irreversible inhibitor product candidates. Furthermore, although we believe, based on our preclinical work and research on irreversible binders generally, that highly selective irreversible inhibitors of certain critically important oncogenic drivers, such as menin, known to impact cellular processes have potential as precision oncology targets, clinical results may not confirm this hypothesis or may only confirm it for certain inhibitors or certain tumor types.

In addition, we have not yet tested our molecules in humans and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. As such, even if we are able to develop small-molecule therapies that demonstrate positive results in preclinical studies there can be no assurance that such product candidates will subsequently demonstrate significant clinical benefit *in vivo* or be well-tolerated.

Further, even if our approach is successful in demonstrating the clinical benefit of using our lead product candidate, BMF-219, which is designed to be a highly potent and selective irreversible inhibitor of menin, in certain menin-driven cancers, we may never successfully identify additional irreversible binding product candidates to validated oncology targets through our FUSION system. Therefore, we do not know if our approach of treating patients with genetically-defined cancers will be successful, and if our approach is unsuccessful, our business will be materially adversely affected.

Our novel approach to the discovery and development of our current and future product candidates is unproven, and we may not be successful in our efforts to use and expand our FUSION System to build a pipeline of product candidates with commercial value.

A key element of our strategy is to utilize our FUSION System to build a pipeline of small molecule, irreversible product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery and preclinical development of BMF-219 and other programs, BMF-219 and such other programs may not be safe or effective as a cancer treatment, and we may not be able to further develop BMF-219 or develop any future product candidates. Our FUSION System is unproven and may not enable us to build a pipeline of product candidates. For example, we may not be successful in identifying validated and novel targets that are amenable to direct intervention with an irreversible binder, we may not succeed in creating novel chemical scaffolds to exploit target proteins and we may not be able to maximize the selectivity, potency and safety of our irreversible small molecules. There can be no assurance that any development problems we experience in the future related to our platform will not cause significant delays or unanticipated costs or that such development problems can be solved. Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. Furthermore, if one or more of our irreversible product candidates generally proves to be ineffective, unsafe or commercially unviable, the development of our entire platform and pipeline utilizing our FUSION System could be delayed, potentially permanently. Even if our product candidates are successful in inhibiting certain protein binding, such success would not provide a guarantee of the effectiveness of such product candidate in total tumor regression *in vivo*. For example, even if BMF-219 demonstrates an ability to inhibit menin *in vivo*, there can be no assurance that such inhibition will provide significant clinical benefit when evaluated in humans.

In addition, development of irreversible small molecules is highly complex and we may experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to manufacturing partners, which may prevent us from initiating or completing our planned clinical trials or commercializing any products we develop on a timely or profitable basis, if at all. In addition, since we have not yet entered clinical development, we do not know the specific doses that may be effective in the clinic or, if approved, commercially. Finding a suitable dose may delay our anticipated clinical development timelines.

If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue which could materially adversely affect our business, financial condition and results of operations.

We are very early in our development efforts and are substantially dependent on our lead product candidate, BMF-219. If we are unable to advance BMF-219 or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize BMF-219 or any of our future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We are very early in our development efforts. Our lead product candidate is in preclinical development and has never been tested in human subjects, and we not yet selected lead development candidates in our other two irreversible programs. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of BMF-219 and one or more of our future product candidates. The success of our product candidates will depend on several factors, including the following:

- our ability to continue our business operations and product candidate research and development, and adapt to any changes in the regulatory approval process, manufacturing supply or clinical trial requirements and timing due to the ongoing COVID-19 pandemic and otherwise, including complying with new regulatory guidance or requirements on conducting clinical trials during the COVID-19 pandemic;
- successful completion of preclinical studies;
- receipt of authorization to proceed under INDs for our planned clinical trials or future clinical trials;
- successful initiation, patient enrollment in, and completion of clinical trials, which may be impacted by the COVID-19 pandemic;
- safety, tolerability and efficacy profiles for our product candidates that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product from applicable regulatory authorities;
- completion of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;

- effectively competing with other cancer therapies;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following approval.

Many of these factors are beyond our control, and it is possible that we may never obtain regulatory approval for our product candidates even if we expend substantial time and resources seeking their development and approval. If we do not achieve regulatory approval in a timely manner or at all, we could experience significant delays or an inability to commercialize our current or future product candidates, which would materially adversely affect our business. If we do not receive regulatory approvals for our current or future product candidates, we will not be able to continue our operations.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating cost-effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production in accordance with cGMP, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenue from product sales, if ever. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our preclinical studies or clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by FDA before implementation, which could delay our preclinical studies, clinical trials and product candidate development, and could require additional preclinical studies and clinical trials, including bridging studies, to demonstrate consistent and continued safety and efficacy.

We have not previously submitted a new drug application (NDA) to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if they are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights for each product candidate, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

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 be initiated or completed, 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. At present, we only have one product candidate, BMF-219, in preclinical development and are currently selecting lead development candidates in our other two irreversible programs. 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 also have not received authorization to proceed under an IND for our lead product candidate, BMF-219, 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 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 FDA's good laboratory practice requirements and other applicable regulations;
- approval by an independent Institutional Review Board (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 clearly 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 in accordance with the FDA's or any other regulatory authority's good clinical practice requirements (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 trial of the same class of agents conducted by other companies;
- changes to the clinical trial protocols;
- clinical sites deviating from trial protocol or 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 (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.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials. Any inability to successfully initiate or complete preclinical studies or clinical trials could result in additional costs to us or impair our ability to generate revenue from product sales. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products, if and when approved, have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may seriously harm our business.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

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 success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities. Successful preclinical studies and clinical trials cannot provide assurance of successful commercialization.

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 regulatory and marketing approvals for their commercial sale. Success in preclinical studies does not mean that future clinical trials will be successful. For instance, we do not know whether BMF-219 will perform in future clinical trials as BMF-219 has performed in preclinical studies, nor can we predict how our future product candidates will perform in future preclinical studies or clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates or prevent regulatory approval. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We have no experience as a company in conducting clinical trials.

We have no experience as a company in conducting clinical trials. In part because of this lack of experience, we cannot be certain that our ongoing preclinical studies will be completed on time or if the planned preclinical studies and clinical trials will begin or be completed on time, if at all. Large-scale clinical trials would require significant additional financial and management resources and reliance on third-party clinical investigators, CROs, and consultants. Relying on third-party clinical investigators, CROs, and consultants may force us to encounter delays that are outside of our control. We may be unable to identify and contract with sufficient investigators, CROs, and consultants on a timely basis or at all. There can be no assurance that we will be able to negotiate and enter into services agreement with any CROs, as necessary, on terms that are acceptable to us on a timely basis or at all.

The outbreak of COVID-19 could materially adversely impact our business, results of operations, and financial condition, including our preclinical studies and clinical trials.

In January 2020, the World Health Organization declared the outbreak of COVID-19 as a "Public Health Emergency of International Concern," which continues to spread throughout the world and has adversely impacted global commercial activity and contributed to significant declines and volatility in financial markets. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic. The COVID-19 pandemic and government responses are creating disruption in global supply chains and adversely impacting many industries. The pandemic could have a continued material adverse impact on economic and market conditions and trigger a period of global economic slowdown. We continue to monitor the impact of the COVID-19 pandemic closely. The extent to which the COVID-19 pandemic will impact its operations or financial results is uncertain.

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 our administrative employees complying with state and county COVID-19 guidelines and protocols when working in our offices and limited the number of staff in any given research and development laboratory. Our research and development teams are currently operating on a staggered schedule, which has altered our operations and processes. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material adverse effect on our business, financial condition and results of operations. As a result of the COVID-19 pandemic, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays advancing our lead product candidate, BMF-219, through IND-enabling studies and into our planned Phase 1/2 clinical trial;
- interruptions in preclinical studies due to restricted or limited operations at our laboratory facility;
- delays or difficulties in clinical site initiation, including difficulties in recruiting CROs for our preclinical studies and clinical site investigators and clinical site staff for our planned clinical trials;
- delays or difficulties in enrolling and retaining patients in our planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- 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 CMOs due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- interruptions, difficulties, or delays arising in our existing operations and company culture as a result of all of our employees working remotely, including those hired during the COVID-19 pandemic;
- interruption or delays to our sourced discovery and clinical activities; and
- changes in clinical site procedures and requirements as well as regulatory requirements for conducting clinical trials during the pandemic.

We may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus. For example, in March 2020, the FDA issued a guidance, which FDA subsequently revised, on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the pandemic.

The COVID-19 pandemic continues to revolve rapidly, with the status of operations and government restrictions evolving weekly. The extent to which the outbreak impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The trading prices for shares of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic and following this offering the trading prices for shares of our common stock could also experience high volatility. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. In addition, a recession, depression, or other sustained adverse market event resulting from the spread of the COVID-19 could materially and adversely affect our business and the value of our common stock.

We have not experienced delays in our discovery and development activities as a result of the COVID-19 pandemic, but may in the future as some of our CRO and other service providers continue to be impacted. In addition, the ultimate impact of the COVID-19 pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and the actions taken to contain COVID-19 or address its impact in the short and long term, among others. We do not yet know the full extent of potential delays or impacts on our business, our preclinical studies or planned clinical trials, our research programs, healthcare systems or the global economy. We will continue to monitor the situation closely.

In addition, our business could be materially adversely affected by other business disruptions to us or our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Our operations, and those of our CROs, CMOs, and other contractors, consultants, and third parties could be subject to other global pandemics, earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, 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 materially adversely affect our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process 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.

To the extent the COVID-19 pandemic adversely affects our business, financial condition, and operating results, it may also have the effect of heightening many of the risks described in this “Risk factors” section.

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

We may not be able to initiate or continue 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 through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. 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.

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. 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. In addition, 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 trials 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 our planned or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or future product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- delays in or temporary suspension of the enrollment of patients in our planned clinical trials due to the COVID-19 pandemic;
- ability to obtain and maintain patient consents;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine, or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

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 market opportunities for our product candidates may be relatively small as it will be limited to those patients who are ineligible for or have failed prior treatments and our estimates of the prevalence of our target patient populations may be inaccurate.

Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA customarily approves new therapies only for a second line or later lines of use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapies, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor-targeted small molecules or a combination of these. Third line therapies can include chemotherapy, antibody drugs and small molecule tumor-targeted therapies, more invasive forms of surgery and new technologies. We expect to initially seek approval of our product candidates in second or later lines of therapy. Subsequently, depending on the nature of the clinical data and experience with any approved products or product candidates, if any, we may pursue approval as an earlier line therapy and potentially as a first line therapy. But there is no guarantee that our product candidates, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials.

The incidence and prevalence for target patient populations of BMF-219 are based on estimates and third-party sources. If the market opportunities for BMF-219, or any future product candidate we may develop, if and when approved, 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 might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations for particular diseases based on various third-party sources and internally generated analysis and use such estimates in making decisions regarding our drug development strategy, including acquiring or in-licensing product candidates and determining indications on which to focus in nonclinical or clinical trials.

The incidence and prevalence for target patient populations of BMF-219 are based on estimates and third-party sources. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity will depend on, among other things, acceptance of our drugs by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, or new patients may become increasingly difficult to identify or gain access to. If the market opportunities for BMF-219, or any future product candidate we may develop, if and when approved, 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 might be materially and adversely affected.

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

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with

competitive advantages, including, to our knowledge, our being the only company currently with the ability and mission to discover and develop irreversible binders specifically against menin. More broadly, we define ourselves as targeted oncology drug developers focused on irreversible drugs and as such expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do.

Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may be or may become interested in discovery and development of irreversible binders that may compete with us against menin or related targets at scale and in an integrated way. Even if they do not advance programs with the same mechanism of action as ours, these companies could develop products or product candidates that are competitive with ours or that have a superior product profile, and may do so at a rapid pace. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapies that target irreversible binding against protein targets of interest to us.

In particular, we are aware of Kura Oncology's KO-539 and Syndax Pharmaceuticals' SNDX-5613, both of which target menin through the use of reversible inhibition. Both KO-539 and SNDX-5613 are already in clinical trials and have demonstrated preliminary Phase 1 results that suggest encouraging clinical benefit and provide strong pharmacologic validation of menin as a therapeutic target. Other preclinical programs have been reported by Bayer (BAY-155), Janssen Pharmaceuticals, Novartis, and the University of Michigan.

We face competition with respect to our current product candidates and will face competition with respect to future product candidates, from segments of the pharmaceutical, biotechnology, and other related markets that pursue targeted therapies for patients with genetically-defined cancers. Our competitors will also include companies that are or will be developing other targeted therapies, including small molecule, antibody, or protein degraders for the same indications that we are targeting. If BMF-219 or our future product candidates do not offer sustainable advantages over competing products, we may otherwise not be able to successfully compete against current and future competitors.

Our competitors may obtain regulatory approval of their product candidates more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products.

Our competitors will also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Furthermore, we also face competition more broadly across the market for cost-effective and reimbursable cancer treatments. The most common methods of treating patients with cancer are surgery, radiation and drug therapy, including chemotherapy, hormone therapy and targeted drug therapy or a combination of such methods. There are a variety of available drug therapies marketed for cancer. In many cases, these drugs are

administered in combination to enhance efficacy. While our product candidates, if any are approved, may compete with these existing drug and other therapies, to the extent they are ultimately used in combination with or as an adjunct to these therapies, our product candidates may not be competitive with them. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

Product candidates that we may successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their potency, selectivity, inactivation of the target, therapeutic window, safety, convenience, price, the level of generic competition, our ability to market and commercialize the product candidate and the availability of reimbursement from government and other third-party payors. For additional information regarding our competition, see “Business—Competition.”

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

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

While we have not yet initiated clinical trials for any of our product candidates, as is the case with all oncology drugs, it is likely that there may be significant side effects associated with their use. BMF-219 or future product candidates may be used in populations for which safety concerns may be reviewed by regulatory agencies. For example, if the administration of BMF-219 leads to levels of menin inhibition that far exceed those achieved by well-studied reversible menin inhibitors, it is possible that patients responses could be both unexpected and negative. In addition, we or our future collaborators may study BMF-219 in combination with other therapies, which may exacerbate adverse events associated with the therapy. Further, our product candidates will be used in patients that have weakened immune systems, which may exacerbate any potential side effects associated with their use. Patients treated with BMF-219 or any of our future product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients’ illnesses. For example, it is expected that some of the patients enrolled in our BMF-219 clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially adversely affect our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and lead to a number of potentially significant negative consequences, including, but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a risk evaluation and mitigation strategy (REMS), which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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

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

From time to time, we may publicly disclose preliminary or top-line 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 top-line 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. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could materially adversely affect our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock after this offering.

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 material or otherwise appropriate information to include in our disclosure. If the interim, top-line, 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 adversely affected, which could materially adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community.

The use of precision medicines as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community. Various factors will influence whether our product candidates, if approved, are accepted in the market, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other cancer medicines;
- the prevalence and severity of any side effects;
- the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- pricing and the availability of adequate coverage and reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities;

- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue.

In addition, although our product candidates differ in certain ways from other precision medicine approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our product or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates.

Even if any products we develop achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete.

Coverage and reimbursement of newly-approved products from third-party payors is uncertain. Our product candidates may become subject to unfavorable pricing regulations and/or third-party coverage and reimbursement policies, either of which would adversely affect our business. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. 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 government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as gene therapy products. Sales of these or future product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the United States, recently enacted legislation may materially change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third-party payors for any approved products that we develop could have a material adverse effect on our business, financial condition and results of operations, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

If product liability lawsuits are brought against us, we may incur substantial liabilities, which may not be sufficiently covered by insurance, and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our product candidates or products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants

- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance that we believe is appropriate for our stage of development, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage and may need to obtain higher levels prior to marketing any of our product candidates if approved. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.

We have never commercialized a product candidate and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the product candidates which we may license to others, we will rely on the assistance and guidance of those collaborators. For product candidates for which we retain commercialization rights and marketing approval, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates, if approved, on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, developing adequate educational and marketing programs to increase public acceptance of our product candidates, ensuring regulatory compliance of our company, employees and third parties under applicable healthcare laws and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates upon approval. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenue from them or be able to reach or sustain profitability.

Risks related to regulatory process and other legal compliance matters

The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate BMF-219, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication.

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. Further, our 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.

The process of obtaining regulatory approvals, both in the United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. For example, FDA has recently issued guidance on conducting clinical trials during the pandemic, which describes a number of considerations for sponsors of clinical trials impacted by the COVID-19 pandemic, including recordkeeping and implementation of contingency measures in response to the ongoing pandemic. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or require us to modify the design of our clinical trials, including additional procedures and contingency measures in response to the COVID-19 pandemic or as required by clinical sites, IRBs, FDA or other regulatory authorities;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks, or that a product candidate has an acceptable benefit-risk ratio for its proposed indication;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures, specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- our third-party contractors may fail to comply with regulatory requirements or otherwise fail or be unable to adequately perform their obligations to allow for the conduct of our planned or future clinical studies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would materially adversely affect our business, results of operations and prospects.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, 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.

We may not be able to obtain orphan drug designation or obtain or maintain the benefits associated with orphan drug designation, such as orphan drug exclusivity and, even if we do, that exclusivity may not prevent the FDA or other comparable foreign regulatory authorities, from approving competing products.

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

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug

for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated.

Even if we obtain ODD for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process.

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

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 any products we develop in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be adversely affected.

Changes in funding or disruptions at the FDA, the Securities and Exchange Commission 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 Securities and Exchange Commission (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, in March 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities. In July 2020, the FDA resumed routine surveillance inspections of domestic manufacturing facilities on a risk-based basis. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. 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.

Even if we receive regulatory approval of 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.

Our 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 United States and by comparable authorities in other countries.

Following potential approval of any of our current or future product candidates, the FDA or other comparable regulatory authorities may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly and time consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient

registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements, good laboratory practice requirements, and good clinical practice requirements, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our product candidates, 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 requiring remediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional 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 our product candidates; 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.

In addition, 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 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. For example, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the former administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. 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 be subject to enforcement action and we may not achieve or sustain profitability.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of our product candidates or any future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. 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; (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.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (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 biological products to potential competition by lower-cost biosimilars, 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 the minimum Medicaid 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 new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 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.

Members of the U.S. Congress and the former presidential administration had taken efforts to fundamentally change or repeal parts of the ACA. While Congress has not passed repeal legislation to date, legislation informally titled the Tax Cuts and Jobs Act (Tax Act) repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Both the former administration and CMS stated that the ruling will have no immediate effect, and on December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. The U.S. Supreme Court is currently reviewing the case, although it is unclear how the Supreme Court will rule. Although the U.S. Supreme Court has 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 also unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA or our business. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

Other legislative changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and was to remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, unless additional Congressional action was taken. In addition, the American Taxpayer Relief Act of 2012, among other things, 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.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the former presidential administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. Individual states have also been increasingly active 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, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non-misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. Although physicians may prescribe products for "off-label" uses in the exercise of their independent professional judgment, if we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also imposed consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers, and vendors acting for or on our behalf may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and material adversely affect to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial

arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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;
- federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through civil “qui tam” or “whistleblower” actions, and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA 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 or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit 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 statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them in order to have committed a violation;
- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include payments and transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, and certified nurse midwives during the previous year;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices,

including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may be compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

We are or may become subject to stringent and changing laws, regulations, contractual obligations, and other obligations relating to privacy, data protection, and information security. The actual or perceived failure by us or our partners, customers, vendors, third-party payors or other related third parties to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

There are numerous domestic and foreign laws, regulations, and other legal obligations regarding privacy, data protection, and information security, the scope of which is changing and subject to differing applications and interpretations, and which may be inconsistent among jurisdictions or conflict with each other. Privacy, data protection, and information security laws and regulations worldwide are, and are likely to remain, uncertain for the foreseeable future, and the actual or perceived failure to address or comply with them by us or our partners, customers, vendors, or other related third-parties could increase our compliance and operational costs, expose us to regulatory scrutiny, actions, fines and penalties, result in reputational harm, lead to a loss of customers; reduce the use of our products, result in litigation and liability, cause a material adverse impact to business operations or financial results, or otherwise result in material harm to our business.

For example, the General Data Protection Regulation (GDPR), which took effect in the EU on May 25, 2018, imposes stringent privacy, data protection, and information security obligations on businesses and requires them to, among other things, obtain consent to collect sensitive personal information such as health

information, provide detailed disclosures on processing of personal information, make contractual privacy, data protection, and information security commitments, implement information security measures, notify regulators and affected individuals of certain data breaches, and honor individuals' rights to their personal information. Companies that violate the GDPR can face private litigation, restrictions on data processing, and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. Assisting our customers, partners, and vendors in complying with the GDPR, or complying with the GDPR ourselves (to the extent applicable), may cause us to incur substantial operational costs or require us to change our business practices.

European privacy, data protection, and information security laws and regulations, including the GDPR, generally restrict the transfer of personal information from Europe, including the European Economic Area, United Kingdom (U.K.), and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. A recent judicial decision from the Court of Justice of the European Union and recent announcements from European regulators regarding transfers of personal information outside Europe have increased the legal risks and liabilities, and compliance and operational costs, of lawfully making such transfers. Further, the U.K.'s vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to privacy, data protection, and information security in the U.K. In particular, it is unclear how data transfers to and from the U.K. will be regulated. Inability to import personal information from the European Economic Area, U.K. or Switzerland may also restrict our activities in Europe, limit our ability to collaborate with partners, vendors, and other relevant third parties subject to European privacy, data protection, and information security laws and regulations, and require us to increase our data processing capabilities in Europe at significant expense.

Other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency and restricting cross-border data transfer, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), which broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the GDPR.

In addition, U.S. states have begun to enact more and more comprehensive privacy, data protection, and information security laws. By way of example, California's California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, affords consumers expanded privacy protections. Aspects of the CCPA and its interpretation and enforcement remain uncertain. The potential effects of the CCPA are far-reaching and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. For example, the CCPA gives California residents expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that may increase our risk to data breach class action litigation. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 (CPRA) becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law.

Additionally, we are or may become subject to the terms of internal and external policies, representations, standards, contractual obligations, and other obligations to third parties related to privacy, data protection, and information security. Our actual or perceived failure to comply with them may cause us to suffer a material

adverse impact to our business operations or financial results, or otherwise result in material harm to our business.

In view of applicable privacy, data protection, and information security laws, regulations, and standards imposing complex and burdensome obligations, and with substantial uncertainty in their interpretation and compliance, we have faced and may face challenges in addressing and complying with them, and may expend significant resources in an effort to do so, any of which could result in a material adverse impact to our business operations or financial results, or otherwise result in material harm to our business.

In the United States, most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and their respective implementing regulations. HIPAA impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

We may in the future receive inquiries or be subject to investigations, proceedings, or actions by governmental entities, or litigation by private parties, regarding our privacy, data protection, and information security practices, which could result in a cause a material adverse impact to our business operations or financial results, or otherwise result in material harm to our business, including without limitation, interruptions of or require changes to our business practices, the diversion of resources and the attention of management from our business, regulatory oversights and audits, discontinuance of necessary data processing, or other remedies that adversely affect our business.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

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 are collectively referred 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. Such Trade Laws also govern export controls, as well as economic sanctions and embargoes on certain countries and persons. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase in time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities. 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.

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

We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Chief Executive Officer, Thomas Butler, and President, Ramses Erdtmann. We will need to hire additional personnel, including a Chief Medical Officer, as we initiate and expand our clinical development and if we initiate commercial activities. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could materially adversely affect our business, financial condition and results of operations. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

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

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

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

As of December 31, 2020, we had 12 full-time employees and 11 consultants, including 5 employees engaged in research and development activities. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining, retaining, and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, and other comparable foreign regulatory agencies' review process for BMF-219 and any future product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize BMF-219 and future product candidates will depend, in part, on our ability to effectively manage any future growth in company headcount. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third-party service providers is compromised for any reason, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of BMF-219 and any future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize BMF-219 and future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Business disruptions could materially adversely affect our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, CMOs, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, 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 adversely affect 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 ability to develop BMF-219 or any future product candidates we may develop could be disrupted if our operations or those of our suppliers are affected by man-made or natural disasters or other business interruptions. Our corporate headquarters are located in California near major earthquake faults and fire zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and business could suffer in the event of a major earthquake, fire or other natural disaster.

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

Our net operating loss (NOL) carryforwards that we generate in the future may be unavailable to offset future taxable income because of restrictions under U.S. tax law. Under the Tax Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), our federal NOLs generated in taxable years beginning after December 31, 2020 may be carried indefinitely, but such deductibility is limited to 80% of current year taxable income.

In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an “ownership change” (generally defined as a cumulative change (by value) in the corporation’s ownership by “5-percent shareholders” that exceeds 50 percentage points over a rolling three-year period), the corporation’s ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income or tax liabilities may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of this offering or subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine whether we have experienced an ownership change or the annual limitations, if any, that could result from such an ownership change. Our ability to utilize our NOLs and certain other tax attributes could be limited by an ownership change as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

A portion of our chemistry-based product development and sourcing of certain manufacturing raw materials for our product candidates takes place in outside the United States (US) through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We currently contract certain product development and manufacturing operations to third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers for such product candidates. Any disruption in production or inability of our manufacturers in outside US to produce adequate quantities to meet our needs, whether as a result of a natural disaster or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in outside US, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in outside US. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially adversely affect our business, financial condition and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher

interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to foreign currency fluctuations in the value of the local currency as future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines outside the United States, including in China.

Risks related to reliance on third parties

We currently rely, and plan to rely on in the future, third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, and strategic partners to conduct and support our preclinical studies and clinical trials under agreements with us. We are continuing to build our internal chemistry, manufacturing and controls, biology and preclinical development capabilities to supplement activities conducted by third parties on our behalf. As part of this personnel build out, we may incur additional costs or experience delays in engaging directly with other third-party CROs and CMOs.

We expect to have to negotiate budgets and contracts with CROs, trial sites and CMOs and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, 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, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our preclinical studies or clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they 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 preclinical studies, clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet

expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols or regulatory requirements or for other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be adversely affected, our costs could increase and our ability to generate revenue could be delayed.

Switching or adding third parties to conduct our preclinical studies and clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

We currently rely and may expect to rely in the future on the use of dedicated manufacturing suites in third-party facilities or on third parties general manufacturing facilities to manufacture our product candidates, and we may rely on third parties to develop processes and testing methods for our products, if approved. Our business could be adversely affected if we are unable to use third-party manufacturing suites or if the third-party manufacturers fail to develop appropriate processes and testing methods to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices.

We do not currently own any facility that may be used as our clinical-scale manufacturing and processing facility and must currently rely on outside vendors to manufacture our product candidates. We have not yet caused our product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates, if approved. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates and we may not be able to do so on favorable terms.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other comparable foreign regulatory authorities following inspections that will be conducted after we submit an 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 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 the incurrence of significant additional costs and delays, 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.

Our anticipated reliance on a limited number of third-party manufacturers exposes us to a number of risks, including the following:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other comparable foreign regulatory authority must inspect any manufacturers for cGMP compliance as part of our marketing application;
- manufacturing processes and testing methods will need to be transferred to a new manufacturer , or develop substantially equivalent processes and testing methods for, the production of our product candidates;

- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products, if any;
- contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA or other comparable foreign regulatory authority and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards and we have no control over third-party manufacturers' compliance with these changing and tightening regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- our third-party manufacturers may experience change of control of their ownership including ownership by a competitor,
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields, and we have no direct control over our contract manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel.

Our business could be materially adversely affected by business disruptions to our third-party providers that could materially adversely affect our potential future revenue and financial condition and increase our costs and expenses. Each of these risks could delay or prevent the initiation or completion of any clinical trials or the approval of any of our product candidates by the FDA or other comparable foreign regulatory authority, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA or other comparable foreign regulatory authority could place significant restrictions on our company until deficiencies are remedied.

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, components and materials used in, and the manufacturing processes required to develop, our product candidates.

We currently, and may in the future, depend on single-source suppliers for some of the ingredients, raw materials, components and materials used in, and development activities required to manufacture , our product candidates. There are, for certain of these components, relatively few alternative sources of supply and there is limited need for multiple suppliers at this stage of our business. We cannot ensure that these suppliers or

service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, ingredients, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. These suppliers may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would materially adversely affect our business, financial condition and results of operations.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates may be interrupted for an extended period, which could materially adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in or for our product candidates, if required, may not be accomplished quickly and would create increased cost, or adversely impact the quality of our product candidates. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, would need to process our technology transfer and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source ingredients, components and materials used in our product candidates, any interruption or delay in the supply of ingredients, components or materials or our inability to obtain ingredients, components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

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 and biological materials, by our third-party manufacturers. Our manufacturers may use highly flammable reagents at high reaction temperature, are subject to federal, state and local laws and regulations in the United States and their country 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 and regulations, 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.

We may, in the future, form or seek collaborations or strategic alliances or enter into licensing arrangements, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may, in the future, form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our 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 other alternative arrangements for our 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 product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

Further, collaborations involving our 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 product candidates or may elect not to continue or renew development or commercialization of our 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 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 product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we enter into future collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions 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 or license, we will achieve the revenue or specific net income that justifies such transaction. Furthermore, if conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Any delays in entering into future collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

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

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and/or acquire intangible assets that could result in significant future amortization expense.

Risks related to intellectual property

If we are unable to obtain, maintain, enforce and adequately protect our patents and other intellectual property rights with respect to our technology and product candidates, or if the scope of our patents or other intellectual property rights are not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology or product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technology and product candidates, and our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to such technology and product candidates. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secret protections cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal, factual and scientific questions and can be uncertain. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our technology or products or which effectively prevent others from commercializing competitive technologies and products.

The patent applications that we own may fail to result in issued patents with claims that cover our technology or product candidates in the United States or in other foreign countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our technology or product candidates, third parties may challenge the inventorship, ownership, validity, enforceability or scope of such patents, which may result in such patents being narrowed or invalidated, or being held unenforceable. Our pending and future patent applications may not issue to protect our technology or product candidates or which effectively prevent others from developing, manufacturing or commercializing competitive technologies and product candidates. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. This will require us to be cognizant of the time from invention to filing of a patent application, and beyond.

If the breadth or strength of protection provided or potentially provided by the patents and patent applications we hold with respect to our technology or product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Furthermore, even if our patents and patent applications are unchallenged, they may not adequately protect our intellectual property, provide exclusivity for our technology and product candidates or prevent others from designing around our claims. In addition, no assurances can be given that third parties will not create similar or alternative technologies, products or methods that achieve similar results without infringing upon our patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity or enforceability, and our patents may be challenged in courts or patent offices in the United States and abroad. In addition, the issuance of a patent does not give us the right to practice the patented invention, as third parties may have blocking patents that could prevent us from marketing our product candidate, if approved, or practicing our own patented technology.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. For example, we may become involved in litigation, opposition, interference, derivation, post grant review, inter partes review or other proceedings challenging our patent rights, and the outcome of any proceedings are highly uncertain. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

If any of our patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Likewise, if any of our patent applications issue as patents, the patents covering our proprietary technologies and our product candidates would be expected to expire in 2039.

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

However, trade secrets can be difficult to protect and trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and even then, the license may not be available on commercially-reasonable terms. Further, we cannot provide any assurances that competitors or other third parties will not otherwise gain access to our trade secrets and other confidential proprietary information or independently discover or develop substantially equivalent technology and processes. If we are unable to prevent disclosure of the trade secrets and other non-patented intellectual property related to our product candidates and technologies to third parties, there is no guarantee that we will have any such enforceable trade secret protection and we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, consultants, scientific advisors and other contractors. 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 technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and our trade secrets could be disclosed, and we may not have adequate remedies for any such breach.

Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, and this scenario could materially adversely affect our business, financial condition and results of operations.

Our success depends in part on our ability to protect our intellectual property rights. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to protect our intellectual property rights throughout the world.

Our commercial success will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and our product and product candidates. These candidates include BMF-219 and others, their respective components, formulations, methods used to manufacture them and methods of treatment. Our commercial success will also depend on successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our technology, product and product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

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. In addition, we may not pursue or obtain patent protection in all relevant markets. 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. Our pending and future patent applications may not result in issued patents that protect our technology or products, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technologies.

If we delay in filing a patent application, and a competitor files a patent application on the same or a similar technology before we do, we may face a limited ability to secure patent rights or we may not be able to patent the technology at all. Even if we can patent the technology, we may be able to patent only a limited scope of the technology, and the limited scope may be inadequate to protect our products, or to block competitor products that are similar or adjacent to ours. Our earliest patent filings have been published. A competitor may review our published patents and arrive at the same or similar technology advances for our products as we developed.

If the competitor files a patent application on such an advance before we do, then we may no longer be able to protect the technology or product, we may require a license from the competitor, and if then the license may not available on commercially-reasonable terms.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Any issued patents we may own covering our product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad, including the USPTO.

Any of our intellectual property rights could be challenged or invalidated despite measures we take to obtain patent and other intellectual property protection with respect to our product candidates and proprietary technology. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. 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.

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. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on a product candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. The cost of defending such a challenge, particularly in a foreign jurisdiction, and any resulting loss of patent protection could have a material adverse impact on one or more of our product candidates and our business. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially-reasonable terms or at all). Any efforts to enforce our intellectual property rights are also likely to be costly and may divert the efforts of our scientific and management personnel.

We may become involved in lawsuits or litigation at the USPTO to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors and other third parties may infringe or otherwise violate our or our future licensor's patents, trademarks, copyrights or other intellectual property. To counter infringement or other violations, we may be required to file infringement, misappropriation or other intellectual property-related claims against such parties, which can be expensive and time consuming. To counter infringement or other unauthorized use, we may be required to file claims on a country-by-country basis, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. There can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which often last for years before they are concluded. 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 addition, in a patent infringement proceeding, a court may decide that one or more of the patents we assert is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to prevent the other party from using the technology at issue on the grounds that our patents do not cover the technology. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In such a case, we could ultimately be forced to cease use of such marks. In any intellectual property litigation, even if we are successful, any award of monetary damages or other remedy we receive may not be commercially valuable. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade other companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

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 or distribution

activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Even if we establish infringement, misappropriation or other violation of our intellectual property, the court may decide not to grant an injunction against further such activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

We may be required to protect our patents through procedures created to attack the validity of a patent at the USPTO. The USPTO hears post-grant proceedings, including post grant review (PGR), inter partes review (IPR), and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product or product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized as products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

Depending upon the timing, duration and conditions of any FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union and certain other countries. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent

term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be expected, and our competitive position, business, financial condition, results of operations and prospects could be materially adversely affected.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book. We may be unable to obtain patents covering our product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such product candidate. Any of the foregoing could adversely affect our competitive position, business, financial condition, results of operations and prospects.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our technology, products and product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our or future licensor’s patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. United States Congress has in recent years considered legislation to reduce the term of certain drug patents in order to ease generic entry and increase competition. Evolving judicial interpretation of patent law could also adversely affect our business. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

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, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our technology or product candidates. Also, former employees may become employed by

competitors who develop similar technology or product candidates, and could assist the competitor in designing around our patents or trade secrets. While it is our policy to require our employees and contractors who may be involved in the development of our intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents, trade secrets or other 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, intellectual property that is important to our technology or product candidates. 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.

Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and any products that we develop. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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.

Our commercial success depends upon our ability to develop, manufacture, market and sell our technology, product candidates and products and use our proprietary technologies without infringing the proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our technology, product candidates and products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our technology, product candidates or products infringe 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 technology, product candidates and products.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents covering such technologies.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our technology, product candidates and/or products infringe or misappropriate their intellectual property rights.

If a third party claims that we infringe or misappropriate its intellectual property rights, we may face a number of issues, including, but not limited to: infringement, misappropriation and other intellectual property related claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business; substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement or misappropriation 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 products or product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us; however, the third party is not required to grant the license; if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and redesigning our technology, product candidates or products so they do not infringe such third party patents; redesign may not be possible or may require substantial monetary expenditures and time.

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

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in *ex-parte* re-exam, *inter partes* review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office (EPO), or other foreign patent office. The costs of these opposition proceedings could be substantial, and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO, or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our technology, product candidates or products.

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

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions and other interim proceedings in the litigation.

If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

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, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights from third parties in the future. For example, our programs may involve additional product candidates that may require the use of proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. Thus, we may in the future enter into license agreements with third parties under which we receive rights to intellectual property that are important to our business. These intellectual property license agreements may impose on 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, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license.

We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms,

or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses in the future from third parties to advance our research or allow commercialization of our technology, product candidates or products, and we cannot provide any assurances that there are no third-party patents which might be enforced against our technology, product candidates or products in the absence of such a license. We may fail to obtain any of these licenses on commercially-reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected technology, product candidates or products, 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 and/or other forms of compensation.

Licensing of intellectual property from third parties may become of critical importance to our business, which involves complex legal, business and scientific issues. Disputes may arise between us and our 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 on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially-reasonable terms, we may not be able to successfully develop and commercialize the affected technology, product candidates or products, which would have a material adverse effect on our business.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor’s express consent in order for an assignment or transfer to take place.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own;

- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents or intellectual property rights of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks related to our common stock and this offering

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this “Risk factors” section and elsewhere in this prospectus, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;

- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial, including due to the suspension of a clinical trial by the FDA or other regulatory authorities;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our product candidates and any future products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- changes in the structure of healthcare payment systems;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- expiration of lock-up agreements;

- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic;
- general economic, political, industry and market conditions, including the impending presidential election in the United States in 2020; and
- other events or factors, many of which are beyond our control.

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

In addition, the stock market in general, and the market for 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. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. In addition, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources, which would materially adversely affect our business, financial condition and results of operation.

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

Prior to this offering, no public market for shares of our common stock existed and an active trading market for our common stock may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships, alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have outstanding shares of common stock, based on the number of shares outstanding as of December 31, 2020, assuming: (i) assuming the conversion of all of our outstanding convertible preferred stock into an aggregate of 799,200 shares of our common stock in connection with the completion of this offering and (ii) assuming no exercise of the underwriters' option to purchase additional shares of common stock. This includes the shares that we sell in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Of the remaining shares, shares of our common stock are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold after this offering as described in the "Shares eligible for future sale" section of this prospectus. Moreover, after this offering, holders of an aggregate of shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

Our executive officers, directors and the holders of substantially all of our securities have entered into lock-up agreements with the representatives under which they have agreed, subject to specific exceptions described in the section titled "Underwriting," not to, among other things, sell, directly or indirectly, any shares of common stock without the permission of J.P. Morgan Securities LLC and Piper Sandler & Co., as the representatives of the underwriters, for a period of 180 days following the date of this prospectus. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement will be able to sell our shares in the public market. In addition, the representatives may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. See the description of the lock-up agreement with the underwriters in the section of this prospectus titled "Shares eligible for future sale" for more information. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

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

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 68.3% of our voting stock and, upon the closing of this offering, that same group will beneficially own approximately % of our outstanding voting stock (based on the number of shares of common stock outstanding as of January 31, 2021 assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the closing of this offering. Certain of our directors are affiliated with the holders of 5% or more of our capital stock. In particular, Thomas Butler and Ramses Erdtmann are affiliates of Biomea Healthcare, LLC, Sotirios Stergiopoulos is an affiliate of A2A Pharmaceuticals Inc., and Bihua Chen is an affiliate of the entities affiliated with Cormorant Asset Management, as indicated in the "Principal stockholders" section. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

As a result of being a public company, we are obligated to develop and maintain proper and effective controls over financial reporting. If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an "emerging growth company," as defined in the JOBS Act, and reach an accelerated filer threshold, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company, we intend to take advantage of an exemption available to emerging growth companies from these auditor attestation requirements. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor

confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The NASDAQ Stock Market, the SEC, or other regulatory authorities. Failure to remedy any material weakness or significant deficiencies in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are an emerging growth company and, for as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide 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;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- 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 stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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 avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

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.

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

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our capital stock. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

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

Our amended and restated certificate of incorporation and amended and restated bylaws, as they will be in effect upon closing of this offering, 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. These provisions will, among other things:

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws will provide for an exclusive forum in the Court of Chancery of the State of Delaware for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation or amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive-forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws to be effective immediately prior to the completion of this offering and our indemnification agreements that we have entered into with our directors and officers will provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain a directors' and officers' insurance policy, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may materially adversely affect our cash position.

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

After this offering, we will be subject to Section 404 of the Sarbanes-Oxley Act and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we will be required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. We will also be required to disclose changes made in our internal controls and procedures on a quarterly basis. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not.

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

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

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

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

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

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

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

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

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

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

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

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of approximately $ per share, representing the difference between the initial public offering price of $ per share, and our pro forma as adjusted net tangible book value per share as of December 31, 2020, after giving effect to this offering and the automatic conversion of all outstanding shares of our convertible preferred stock immediately prior to the closing of this offering. As of December 31, 2020, we had no outstanding stock options. Subsequent to December 31, 2020, we issued options to purchase 103,074 shares of common stock, with a weighted average exercise price of $45.41. To the extent these outstanding securities are ultimately exercised, investors

purchasing common stock in this offering will incur further dilution. See “Dilution” for a more detailed description of the dilution to new investors in the offering. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

General risk factors

We will incur significant 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 (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, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select 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 (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. Recent legislation permits emerging growth companies to 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 this new legislation 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 increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of any products that we develop, if approved. 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.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act, the regulations of the Nasdaq Global Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help

prevent financial fraud. Commencing with our fiscal year ending the year after this offering is completed, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. Prior to this offering, we have never been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new financing and accounting system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

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

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

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

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United

States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities. See the section titled “Management’s discussion and analysis of financial condition and results of operations—Recent accounting pronouncements.”

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the Tax Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, the CARES Act, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration 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 deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. 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 or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of proceeds,” and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. Our management might not apply the net proceeds in ways that ultimately increase or maintain the value of your investment. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

If our security measures are compromised, or the security, confidentiality, integrity, or availability of our information technology, software, services, communications or data is compromised, limited or fails, this could result in a material adverse impact.

If we or third parties related to us (such as our partners, CROs, and CMOs) have experienced or in the future experience any security incidents that result in any deletion or destruction of, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent exposure disclosure of, sensitive, confidential, or proprietary information ("Sensitive Information"), or a compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications, or data, it may result in a material adverse impact, including without limitation, regulatory investigations or enforcement actions, litigation, indemnity obligations, delays to the development and commercialization of our product candidates, disruption of our programs, negative publicity, and financial loss.

Systems containing Sensitive Information are vulnerable to service interruptions, malfunction, natural disasters, terrorism, war, software and hardware failures, telecommunication and electrical failures, theft or loss from inadvertent or intentional actions by employees, contractors, consultants, business partners and/or other third parties, malware, malicious code (such as viruses and worms), software bugs, ransomware, denial-of-service attacks (including credential stuffing), social engineering and other means that affect service reliability and threaten the security, confidentiality, integrity and availability of information).

We cannot assure you that our security efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties related to us, will prevent breakdowns or breaches in systems or other cyber incidents that cause loss, destruction, unavailability, alteration or dissemination of, or damage to, Sensitive Information that could have a material adverse impact. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal information), which could result in a material adverse impact including financial, legal, business and reputational harm. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under privacy, data protection, and information security laws and regulations, which could result in significant legal and financial exposure and reputational damages that could potentially have a material adverse impact.

Notifications and follow-up actions related to a security incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse impact. To the extent that any disruption or security incident were to result in a loss, destruction or alteration of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and

commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with applicable privacy, data protection, and information security laws and regulations.

Our insurance policies, if any, may not be adequate to compensate us for the potential losses arising from any such security incident. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

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 may involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations may 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. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Special note regarding forward-looking statements

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our strategy, future financial condition, future operations, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our financial performance;
- the sufficiency of our existing cash and cash equivalents to fund our future operating expenses and capital expenditure requirements;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our anticipated use of our existing cash and cash equivalents and the proceeds from this offering;
- the implementation of our strategic plans for our business and product candidates;
- the size of the market opportunity for our product candidates and our ability to maximize those opportunities;
- the initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials and, INDs, and other regulatory submissions;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our estimates of the patient populations addressable by BMF-219, if approved, and the number of participants that will enroll in our planned clinical trials;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other favorable results;
- our plans relating to the clinical development of our product candidates, including the disease areas to be evaluated;
- the timing, progress and focus of our future clinical trials, and the reporting of data from those trials;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to commercializing our product candidates, if approved;
- the expected benefits of potential future strategic collaborations with third parties and our ability to attract collaborators with development, regulatory and commercialization expertise;
- the success of competing therapies that are or may become available;
- the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations, such as orphan drug designation, for our product candidates;

- our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our plan to rely on third parties to conduct and support preclinical and clinical development;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- the impact of the ongoing COVID-19 pandemic or other related disruptions on our business; and
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act do not protect any forward-looking statements that we make in connection with this offering.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Market and industry data

This prospectus contains estimates, projections and other information concerning our industry and our business, as well as data regarding market research, estimates and forecasts prepared by our management. 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. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk factors.” Unless otherwise expressly stated, we obtained this industry, business, market and other data 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. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Use of proceeds

We estimate that the net proceeds to us from this offering will be approximately $ million (or approximately $ million if the underwriters exercise in full their option to purchase additional shares), based on 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 the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase or 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 or decrease, as applicable, the net proceeds to us from this offering by approximately $ million, assuming that the number of shares of common stock 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. Similarly, each increase or decrease of 1.0 million shares of common stock offered by us would increase or decrease, as applicable, the net proceeds to us by approximately $ million, assuming the assumed initial public offering price of $ per share, the midpoint of the price range 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.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public markets. We currently intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately $ million to $ million to fund our ongoing IND-enabling studies and planned Phase 1/2 clinical trial of BMF-219;
- approximately $ million to $ million to fund our research and development efforts with respect to our two undisclosed programs; and
- the remainder, if any, for working capital and other general corporate purposes.

We may also use a portion of the remaining net proceeds and our existing cash and cash equivalents to in-license, acquire or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments or obligations to do so.

Based upon our current operating plan, we believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses for at least the next months, including, with respect to BMF-219, and with respect to our two undisclosed programs, .

This expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. Further, due to the uncertainties inherent in the drug development process, it is difficult to estimate with certainty the exact amounts of the net proceeds from this offering that may be used for the above purposes. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above.

Our management will have broad discretion over the use of the net proceeds from this offering, and our investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering. The amounts and timing of our expenditures will depend upon numerous factors including the scope, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates, the cost, timing and outcome of regulatory review of our product candidates and the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval and other factors described in the section titled “Risk factors.”

The expected net proceeds from this offering will not be sufficient for us to fund any of our product candidates through regulatory approval, and we will need to raise additional capital to complete the development and commercialization of our product candidates. We expect to finance our cash needs through a combination of equity offerings, debt financings and potential collaborations, and license and development agreements. We have based these estimates on assumptions that may prove to be incorrect, and we could expend our available capital resources at a rate greater than we currently expect.

Pending the use of the net proceeds from this offering as described above, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Dividend policy

We have never declared or paid cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

Capitalization

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

- an actual basis;
- a pro forma basis, to reflect: (i) the automatic conversion of all of our outstanding shares of convertible preferred stock into 799,200 shares of our common stock, which will occur immediately prior to the completion of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation in Delaware, which will be in effect immediately prior to the completion of this offering; and
- a pro forma as adjusted basis, to reflect (i) the pro forma adjustments set forth above and (ii) the issuance and sale of shares of our 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 payable by us.

You should read this table together with the sections titled “Selected financial data,” “Management’s discussion and analysis of financial condition and results of operations” and our audited financial statements and the related notes included elsewhere in this prospectus. The pro forma information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

	As of December 31, 2020		
(in thousands, except per share amounts)	**Actual**	**Pro forma**	**Pro forma as adjusted[1]**
		(unaudited)	
Cash and cash equivalents	$	$	$
Convertible preferred stock, $0.0001 par value, per share; 799,200 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted			
Stockholders’ (deficit) equity:			
Preferred stock, $0.0001 par value per share; no shares authorized, issued and outstanding, actual; shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, $0.0001 par value per share; 2,862,000 shares authorized, shares issued and outstanding, actual; shares authorized and shares issued and outstanding, pro forma; shares authorized and shares issued and outstanding, pro forma as adjusted			
Additional paid—in capital			
Accumulated deficit			
Total stockholders’ (deficit) equity			
Total capitalization	$	$	$

(1) Each $1.00 increase or 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 or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders’ (deficit) equity and total capitalization by approximately $ million, assuming that the number of shares of common stock 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. Similarly, each increase or decrease of

1.0 million shares of common stock offered by us would increase or decrease, as applicable, each of pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately $ million, assuming that the assumed initial public offering price of $ per share remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares is exercised in full, our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' (deficit) equity, and total capitalization as of December 31, 2020, would be $ million, $ million, $ million, and $ million, respectively.

The number of shares of our common stock issued and outstanding, pro forma and pro forma as adjusted, in the table above is based on 799,200 shares of common stock outstanding as of December 31, 2020 (including conversion of all of our outstanding shares of convertible preferred stock on an as-converted basis), and excludes:

- 103,074 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020, with a weighted-average exercise price of $45.41 per share;
- additional shares of our common stock reserved for issuance pursuant to future awards under our 2020 Plan, which will become available for issuance under our 2021 Plan after the consummation of this offering;
- shares of our common stock reserved for future issuance under the 2021 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the 2021 Plan; and
- shares of our common stock reserved for future issuance under the ESPP, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

Dilution

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

Our historical net tangible book value as of December 31, 2020 was $ million, or $ per share of our common stock. Our historical net tangible book value represents our total tangible assets less capitalized deferred offering costs, total liabilities and convertible preferred stock. Historical net tangible book value per share is our historical net tangible book value divided by the number of shares of our common stock outstanding as of December 31, 2020.

Our pro forma net tangible book value as of December 31, 2020 was $ million, or $ per share of our common stock, based on the total number of shares of our common stock outstanding as of December 31, 2020. Pro forma net tangible book value per share represents our total tangible assets less capitalized deferred offering costs and our total liabilities, divided by the number of outstanding shares of common stock, after giving effect to the conversion of all of the outstanding shares of convertible preferred stock into an aggregate of shares of common stock.

After giving effect to 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, 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 December 31, 2020 would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share to new investors participating in this offering.

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

Assumed initial public offering price per share		$
Historical net tangible book value per share as of December 31, 2020	$	
Pro forma increase in net tangible book value per share as of December 31, 2020 attributable to the pro forma transactions described above		
Pro forma net tangible book value per share as of December 31, 2020		
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors participating in this offering		$

Each $1.00 increase or 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 or decrease, as applicable, our pro forma as adjusted net tangible book value per share after this offering by $ per share and the dilution per share to new investors participating in this offering by $ per share, assuming that the number of shares of common stock 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. Similarly, an increase of 1.0 million in the number of shares of common stock offered by us would increase the pro forma as adjusted net tangible book value after this offering by $ per share and decrease the dilution per share to new investors participating in this offering by $ per share, and a decrease of 1.0 million shares of common stock offered by us would decrease the pro forma as adjusted net

tangible book value by $ per share, and increase the dilution per share to new investors in this offering by $ per share, assuming that the assumed initial public offering price of $ per share remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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

The following table summarizes on the pro forma as adjusted basis described above, the differences between the number of shares purchased from us, the total consideration paid and the average price per share paid to us by existing stockholders and by investors purchasing shares in this offering at the assumed initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Weighted-average price per share
	Number	Percent	Amount	Percent	
Existing stockholders		%	$	%	$
New investors					$
Total		100.0%	$	100.0%	

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 foregoing discussion and tables above (other than the historical net tangible book value calculation) are based on shares of common stock outstanding as of December 31, 2020 (including the conversion of all of our outstanding shares of convertible preferred stock on an as-converted basis) and excludes:

- 103,074 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to December 31, 2020, with a weighted-average exercise price of $45.41 per share;
- additional shares of our common stock reserved for issuance pursuant to future awards under our 2020 Plan, which will become available for issuance under our 2021 Plan (defined below) after the consummation of this offering;
- shares of our common stock reserved for future issuance under the 2021 Plan, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under our 2021 Plan; and
- shares of our common stock reserved for future issuance under the ESPP, which will become effective immediately prior to the execution of the underwriting agreement related to this offering, as well as any future increases in the number of shares of common stock reserved for issuance under the ESPP.

To the extent that any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares in the future, there will be further dilution to new investors participating in this offering.

Selected financial data

The following tables set forth our selected statements of operations data for the years ended December 31, 2019 and 2020 and the selected balance sheet data as of December 31, 2019 and 2020 are derived from our audited financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. You should read the following selected financial data together with the section titled "Management's discussion and analysis of financial condition and results of operations" and our financial statements and the related notes included elsewhere in this prospectus. The selected financial data included in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and the related notes included elsewhere in this prospectus.

	Year ended December 31,	
(in thousands, except share and per share data)	**2019**	**2020**
Statements of operations data:		
Operating expenses		
Research and development	$ 1,092	$
General and administrative	103	
Total operating expenses	1,195	
Loss from operations	(1,195)	
Other expense, net	(3)	
Net loss attributable to common stockholders	$ (1,198)	$
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (1.75)	$
Weighted–average shares used in computing net loss per share attributable to common stockholders, basic and diluted[1]	684,582	
Pro forma net loss per share, basic and diluted (unaudited)[1]		$
Pro forma weighted–average shares outstanding, basic and diluted (unaudited)[1]		

(1) See Notes 1 and 7 to our audited financial statements included elsewhere in this prospectus for explanations of the calculations of our basic and diluted net loss per share, basic and diluted pro forma net loss per share and the weighted-average number of shares used in the computation of the per share amounts.

	As of December 31,	
(in thousands)	**2019**	**2020**
Balance sheet data:		
Cash and cash equivalents	$ 239	$
Working capital[1]	(21)	
Total assets	265	
Convertible preferred stock	—	
Accumulated deficit	(2,851)	
Total stockholders' (deficit) equity	(21)	

(1) We define working capital as current assets less current liabilities. See our audited financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and 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 of this prospectus titled "Selected financial data" and our financial statements and related notes included elsewhere in this prospectus. This discussion and other parts of this prospectus contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations, and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this prospectus entitled "Risk factors." Please also see the section of this prospectus titled "Special note regarding forward-looking statements."

Overview

We are a preclinical-stage biopharmaceutical company focused on the discovery, development and commercialization of irreversible small molecules to treat patients with genetically defined cancers. Leveraging our extensive expertise in irreversible binding chemistry and development, we built our proprietary FUSION System discovery platform to advance a pipeline of novel irreversible therapies. Our lead product candidate, BMF-219, is an orally bioavailable, potent and selective irreversible inhibitor of menin, an important transcriptional regulator known to play a direct role in oncogenic signaling in multiple cancers. In preclinical studies, BMF-219 demonstrated robust anti-tumor effects across a range of liquid and solid tumor models and has been well-tolerated in animal studies. We are developing BMF-219 for the treatment of liquid and solid tumors driven by menin-mixed lineage leukemia (MLL) fusions and other menin dependencies and expect to file an IND with the U.S. Food and Drug Administration (FDA), in the . Beyond BMF-219, we are utilizing our novel platform to develop irreversible treatments against other high-value oncogenic drivers of cancer and expect to nominate our second development candidate in the . We believe our capabilities and platform uniquely position us to be a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit for treating various cancers.

Since commencing operations in 2017, we have devoted substantially all of our efforts and financial resources to conducting research and development activities, including drug discovery and preclinical studies, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We have not generated any revenue from product sales and, as a result, we have never been profitable and have incurred net losses since commencement of our operations. As of December 31, 2020, we had an accumulated deficit of $ million, primarily as a result of research and development and general and administrative expenses. We incurred net losses of $ million in the year ended December 31, 2020. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities.

We have financed our operations to date primarily through the issuance and sale of shares of our common stock and convertible preferred stock. From the commencement of our operations through December 31, 2020, we had received an aggregate of $68.8 million in net proceeds from investments and, as of December 31, 2020, we had cash and cash equivalents of $ million. Based on our current business plan, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will provide sufficient resources to meet our working capital and capital expenditure needs for at least the next months following the date of this prospectus.

We do not expect to generate revenue from product sales unless and until we obtain regulatory approval for and commercialize a product candidate, and we cannot assure you that we will ever generate significant revenue or profits. We expect that our expenses and operating losses will continue to increase for the foreseeable future. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts and submit INDs for BMF-219 and any other product candidates;
- conduct preclinical studies and initiate clinical trials;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges;
- establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities, whether alone or with third parties, to commercialize any product candidates for which we may obtain regulatory approval, if any;
- obtain, expand, maintain, enforce and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel; and
- operate as a public company.

Our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities. We will need to raise additional capital in the future to fund our operations, including to complete clinical trials for any product candidates. If sufficient funds on acceptable terms are not available when needed, we could be required to significantly reduce our operating expenses and delay, reduce the scope of, or eliminate one or more of our development programs.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates. All of our drug candidates are small molecules and are manufactured in synthetic processes from available starting materials. The chemistry appears amenable to scale up and does not currently require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities. In addition, we do not yet have a marketing or sales organization or commercial infrastructure. Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval. Accordingly, we will incur significant expenses to develop a marketing and sales organization and commercial infrastructure in advance of generating any product sales.

The global COVID-19 pandemic continues to evolve rapidly, and we will continue to monitor it closely. The extent of the impact of the COVID-19 pandemic on our business, operations, and product development timelines and plans remains uncertain and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial enrollment, trial sites, clinical research organizations (CROs), contract manufacturing organizations (CMOs), and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. We have not experienced delays in our discovery and development activities as a result of the COVID-19 pandemic, but may in the future as some of our CRO and other service providers continue to be impacted.

We were established in the state of Delaware in August 2017 as Biomea Fusion, LLC. In December 2020, all outstanding membership interests in Biomea Fusion, LLC were converted into equity interests in Biomea Fusion, Inc. The capitalization information included in this prospectus is consistently presented as the information of Biomea Fusion, Inc., even during the prior period when our stockholders held their equity interests in Biomea Fusion, LLC.

Components of operating results

Operating expenses

Research and development

Our research and development expenses consist primarily of external and internal costs incurred in connection with the research and development of our research programs and product candidates.

External costs include:

- expenses incurred under agreements with third-party CMOs, CROs, research and development service providers, academic research institutions and consulting costs; and
- laboratory expenses, including supplies and services.

Internal costs include:

- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel in research and product development roles; and
- facilities and other allocated expenses, including expenses for rent and facilities maintenance, and amortization.

We expense research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. We track direct costs by stage of program, clinical or preclinical. However, we do not track indirect costs on a program specific or stage of program basis because these costs are deployed across multiple programs and, as such, are not separately classified.

We expect our research and development expenses to increase substantially during the next few years as we seek to initiate and complete clinical trials, pursue regulatory approval of BMF-219, and advance other programs through preclinical and clinical development. Predicting the timing or the final cost to complete our clinical program or validation of our manufacturing and supply processes is difficult and delays may occur because of many factors. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. To the extent that our product candidates continue to advance into clinical trials, as well as advance into larger and later stage clinical trials, our expenses will increase substantially and may become more variable.

Our future research and development costs may vary significantly based on a wide variety of factors, such as:

- the scope, rate of progress, expense and results of preclinical development activities, as well as of any future clinical trials of our product candidates, and other research and development activities we may conduct;
- uncertainties in clinical trial design;
- per patient trial costs;
- the number of trials required for approval;

- the number of sites included in the trials;
- the number of patients that participate in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the drop-out or discontinuation rates of patients, particularly in light of the COVID-19 pandemic environment;
- the safety and efficacy profiles of our product candidates;
- the timing receipt, and terms of any approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, if any of our product candidates;
- significant and changing government regulation and regulatory guidance;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that we or our third-party manufacturers are able to make product successfully;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work, particularly considering the COVID-19 pandemic environment; and
- the extent to which we establish additional strategic collaborations or other arrangements.

A change in the outcome of any of these variables with respect to the development of any or our product candidates could significantly change the costs and timing associated with the development of that product candidate. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, investment in our clinical programs, manufacturing capability and competition with other products. As a result of these variables, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for any of our product candidates.

General and administrative

General and administrative expenses consist principally of personnel-related costs including payroll for personnel in executive, finance, human resources, business and corporate development, and other administrative functions, professional fees for legal, consulting, and accounting services, rent and other facilities costs, depreciation, and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase substantially during the next few years as a result of staff expansion and additional occupancy costs, as well as costs associated with being a public company, including compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, higher legal and auditing fees, investor relations costs, higher insurance premiums and other compliance costs associated with being a public company. We also expect that our future intellectual property expenses may increase as we expand our product portfolio of drug candidates due to advances in our research and development programs.

Other expense, net

Other expense, net consists primarily of expenses recognized related to foreign currency transactions.

Results of operations

Comparison of the years ended December 31, 2019 and 2020

The following table summarizes our results of operations for the periods indicated (in thousands):

	Year ended December 31,			%
	2019	2020	Change	Change
Operating expenses:				
Research and development	$ 1,092	$	$	
General and administrative	103			
Total operating expenses	1,195			
Loss from operations	(1,195)			
Other expense, net	(3)			
Net loss	$(1,198)	$	$	

Research and development expenses

The following table summarizes our research and development expenses for the years ended December 31, 2019 and 2020 (in thousands):

	Year ended December 31,	
	2019	2020
External costs[1]	$ 954	$
Internal costs:		
Personnel-related expenses (including stock-based compensation)	138	
Facilities and other allocated expenses	—	
Total research and development expenses	$1,092	$

(1) In future periods when clinical trial expenses are incurred, external costs will be broken out between our clinical programs and our preclinical programs.

Research and development expenses were $1.1 million for the year ended December 31, 2019, compared to $ million for the year ended December 31, 2020. The increase of $ million was primarily due to .

General and administrative expenses

General and administrative expenses were $0.1 million for the year ended December 31, 2019, compared to $ million for the year ended December 31, 2020. The increase of $ million was primarily due to .

Liquidity and capital resources

To date, we have financed our operations primarily through private placements of our equity securities. We received net proceeds of $1.4 million from the sale and issuance of shares of our common stock in 2019, and an aggregate of $9.9 million from the sale and issuance of shares of our common stock in June and October 2020. We received net proceeds of $55.7 million from the sale and issuance of shares of our Series A convertible preferred stock in December 2020. Our cash equivalents are held in money market accounts. Our cash and cash equivalents balance as of December 31, 2020 was $ million.

Based on our current business plan, we believe that our existing cash and cash equivalents will provide sufficient resources to meet our working capital and capital expenditure needs for at least the next 12 months following the date of this prospectus. However, based on our current business plan, we believe that our existing cash and cash equivalents, together with the net proceeds from this offering, will provide sufficient resources to meet our working capital and capital expenditure needs for at least the next months following the date of this prospectus.

We will continue to require additional capital to develop our product candidates and fund operations for the foreseeable future. We may seek to raise capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the scope, rate of progress and costs of our drug discovery, preclinical development activities, laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the scope and costs of manufacturing development and commercial manufacturing activities;
- the extent to which we discover and develop additional product candidates;
- the cost, timing and outcome of regulatory review of our product candidates;
- the cost and timing of establishing sales and marketing capabilities, if any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements;
- the timing, receipt and amount of sales from our potential products;
- our need and ability to hire additional management, scientific and medical personnel;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;

- the costs associated with being a public company;
- the cost associated with commercializing our product candidates, if they receive regulatory approval; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we are unable to raise additional funds when needed, we may be required to delay, reduce, or terminate some or all of our development programs and clinical trials. We may also be required to sell or license to others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

See the section of this prospectus titled “Risk factors” for additional risks associated with our substantial capital requirements.

Debt

On May 5, 2020, the Company entered into a promissory note with City National Bank, which provided a loan in the amount of $35,637 (the “PPP Loan”) pursuant to the Paycheck Protection Program, or PPP, administered by the Small Business Administration under the CARES Act. The PPP Loan has a two-year term and bears interest at a rate of 1% per annum. Monthly principal and interest payments are deferred for seven months after the date of disbursement. The PPP Loan may be prepaid at any time prior to maturity with no prepayment penalties. The PPP loan may be partially or wholly forgiven if the funds are used for certain qualifying expenses as described in the CARES Act. The Company has used the entire PPP loan amount for qualifying expenses and intends to repay the loan during the first quarter of 2021.

Summary statement of cash flows

The following table sets forth the primary sources and uses of cash and cash equivalents for each of the periods presented below (in thousands):

	Year ended December 31,	
	2019	**2020**
Net cash (used in) provided by:		
Operating activities	$(1,279)	$
Investing activities	—	
Financing activities	1,440	
Net increase in cash and cash equivalents	$ 161	$

Cash used in operating activities

Net cash used in operating activities was $1.3 million for the year ended December 31, 2019. Cash used in operating activities in 2019 was primarily due to the use of funds in our operations and the resulting net loss of $1.2 million.

Cash used in investing activities

Cash used in investing activities was $0 for the year ended December 31, 2019.

Cash provided by financing activities

Cash provided by financing activities was $1.4 million for the year ended December 31, 2019 which consisted of net proceeds from the issuance and sale of shares of our common stock.

Contractual obligations and commitments

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

	Payments due by period				
	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years	Total
Lease obligations, net	$	$	$	$	$

Critical accounting policies, significant judgments and use of estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these 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 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 expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of personnel costs for our research and product development employees. Also included are non-personnel costs such as professional fees payable to third parties for preclinical studies and research services, laboratory supplies, equipment maintenance, and other consulting costs.

We estimate preclinical study and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical studies and research services on our behalf. We estimate these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. We estimate preclinical study and research expenses based on the services performed, pursuant to contracts with research institutions that conduct and manage preclinical studies and research services on our behalf. We estimate these expenses based on discussions with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. Payments made to third parties under these arrangements in advance of the performance of the related services by the third parties are recorded as prepaid expenses until the services are rendered. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the estimates accordingly. To date, we have not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations. Payments associated with licensing arrangements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternative commercial use are expensed as incurred.

Stock-based compensation

We measure stock options and other stock-based awards granted to directors, employees and non-employees based on their fair value on the date of the grant and recognize the corresponding compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued stock options and restricted share awards with service-based vesting conditions and record the expense for these awards using the straight-line method. We determine the fair value of restricted stock awards granted based on the fair value of our common stock. Forfeitures are accounted for as they occur.

We estimate the fair value of each stock option grant using the Black-Scholes option pricing model, which uses as inputs the following assumptions:

- *Fair value of common stock*—See the subsection titled "—Common stock valuations" below.
- *Expected term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We use the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the options.
- *Expected volatility*—Because we have been privately held and do not have any trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded biotechnology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. We will continue to take this approach until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *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 awards.
- *Dividend yield*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note to our financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options. We first granted restricted stock awards in the fourth quarter of 2020, and our first stock options in January 2021.

We recorded stock-based compensation expense of $0 million and $ million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had $ million of total unrecognized stock-based compensation cost, which we expect to recognize over an estimated weighted-average period of years. We expect to continue to grant stock options and other stock-based awards in the future, and to the extent that we do, our stock-based compensation expense recognized in future periods will likely increase.

The intrinsic value of all outstanding options as of was $ million based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, of which approximately $ million is related to vested options and approximately $ million is related to unvested options.

Common stock valuations

Historically, for all periods prior to this offering, the fair values of the shares of common stock underlying our stock-based awards were estimated on each grant date by our board of directors. Our board of directors

considered, among other things, valuations of our common stock which were prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (Practice Aid).

Our first restricted stock awards were granted in October 2020 to employees and consultants. At the time of these grants, we had a contemporaneous valuation performed by an independent third-party. We also had an updated valuation report prepared as of December 31, 2020. We granted our first options to purchase common stock in January 2021.

For our October 13, 2020 valuation, in accordance with the Practice Aid, we determined that a hybrid approach using a combination of the Option Pricing Method (OPM) and an initial public offering outcome was the most appropriate method for determining the fair value of our common stock based on our stage of development, the presence of a reasonably recent third-party equity transaction, the then current plans for an initial public offering and other relevant factors. The OPM used a market approach to estimate our enterprise value based on the price paid for investments in the Company in June of 2020. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. We also included the valuation impact of a potential future initial public offering. Under this approach all, in the money securities are assumed to convert to common stock at the time of the initial public offering, thus removing the allocation impact of preferred stock liquidation preferences. An adjustment for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

For our valuations after October 13, 2020, in accordance with the Practice Aid, we determined that the hybrid probability-weighted expected return method (PWERM) method was the most appropriate method for determining the fair value of our common stock based on our stage of development, our progress towards an initial public offering, the presence of a reasonably concurrent third-party equity financing and other relevant factors. The hybrid PWERM is a market-based approach, where the equity value in one or more scenarios is calculated using an OPM intended to calibrate the valuation to the price paid for equity securities in a concurrent financing. The OPM component of the valuation is coupled with a PWERM which is a scenario-based methodology that estimates the fair value of our common stock based upon an analysis of our future values, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted together with the OPM indication to arrive at an indication of value for the common stock. An adjustment for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

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

Given the absence of a public trading market, our board of directors with input from management considered numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to:

- contemporaneous valuations performed by an independent third-party valuation firm;
- our stage of development and material risks related to our business;

- the progress of our research and development programs, including the status and results of preclinical studies and clinical trials for our product candidates;
- our business conditions and projections;
- sales of our convertible preferred stock;
- the rights, preferences and privileges of our convertible preferred stock relative to those of our common stock;
- lack of marketability of our common and convertible preferred stock as a private company;
- our operating results and financial performance;
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company, in light of prevailing market conditions;
- the trends, developments and conditions in the life sciences and biotechnology industry sectors;
- analysis of initial public offerings and the market performance and stock price volatility of similar public companies in the life sciences and biopharmaceutical sectors; and
- the economy in general.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recent accounting pronouncements

See Note 2 to our financial statements included elsewhere in this prospectus for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent it has made one yet, of their potential impact on our financial condition of results of operations.

Quantitative and qualitative disclosures about market risk

Interest rate risk

Our primary exposure to market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of December 31, 2019, we had a cash balance of $0.2 million, consisting of non-interest bearing checking accounts, for which the fair market value would not be affected by changes in the general level of United States interest rates. We believe a hypothetical 100 basis point change in interest rates during any of the periods presented would not have had a material effect on our financial statements included elsewhere in this prospectus.

Foreign currency exchange risk

All of our employees and our operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in local currency. As a result, our operations may be subject to fluctuations in foreign currency exchange rates in the future. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 100 basis point change in exchange rates during any of the periods presented would not have a material effect on our financial statements included elsewhere in this prospectus.

Effects of inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We believe that inflation has not had a material effect on our financial statements included elsewhere in this prospectus.

Emerging growth company and smaller reporting company status

The Jumpstart Our Business Startups Act of 2012 (the JOBS Act), permits an “emerging growth company” to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have elected to use the extended transition period for complying with new or revised accounting standards; and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts the Company from having to (i) provide an auditor attestation of internal controls over financial reporting under Sarbanes-Oxley Act Section 404(b); (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act; (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis); and (iv) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation.

We will remain an emerging growth company until the earliest of (i) the last day of our first fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million of the prior June 30th and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

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 take advantage of many of the same exemptions from disclosure requirements including not being required to comply for a period of time with the auditor attestation requirements of Section 404 of Sarbanes-Oxley, and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements.

Business

Overview

We are a preclinical-stage biopharmaceutical company focused on the discovery, development and commercialization of irreversible small molecule drugs to treat patients with genetically defined cancers. An irreversible small molecule drug is a synthetic compound that forms a permanent bond to its target protein and offers a number of potential advantages over conventional reversible drugs, including greater target selectivity, lower drug exposure and the ability to drive a deeper, more durable response. Leveraging our extensive expertise in irreversible binding chemistry and development, we built our proprietary FUSION System discovery platform to advance a pipeline of novel irreversible small molecule product candidates. Our lead product candidate, BMF-219, is designed to be an orally bioavailable, potent and selective irreversible inhibitor of menin, an important transcriptional regulator known to play a direct role in oncogenic signaling in multiple cancers. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models and has been well-tolerated in animal studies. We are developing BMF-219 for the treatment of liquid and solid tumors that are highly dependent on menin, including leukemias containing the mixed lineage leukemia (MLL) fusion protein. We are currently completing investigational new drug (IND) enabling studies and expect to file an IND application with the U.S. Food and Drug Administration (FDA) in . Beyond BMF-219, we are utilizing our novel platform to develop irreversible treatments against other high-value oncogenic drivers of cancer and expect to nominate our second development candidate in . We believe our capabilities and platform uniquely position us to be a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit when treating various cancers.

Since the discovery of aspirin in 1899, drugs that form permanent bonds with their target (irreversible drugs) have been known to offer a number of potential safety, tolerability and efficacy advantages over conventional reversible drugs through multiple mechanisms, including:

- ***High selectivity***: Irreversible drugs have the potential to confer high selectivity to a target by interacting with the unique surrounding structural elements of the protein and establishing a covalent bond to a key residue in the binding site. Leveraging non-covalent and covalent interactions can lead to greater selectivity versus reversible compounds, which rely solely on non-covalent binding. This has the potential to reduce the likelihood of non-specific, off-target interactions that often lead to safety and tolerability concerns.
- ***Deep inactivation of target***: Upon binding, an irreversible inhibitor may not only cause inactivation of the target, but may also result in the elimination of the target through normal cellular degradation processes. The diseased cell then either undergoes rapid apoptosis or differentiation into a normal, mature cell. Such transformation has the potential to provide the patient with a durable, lasting benefit.
- ***Greater therapeutic window*:** Irreversible inhibitors are designed to create a permanent bond with high affinity and long residence time. Unlike conventional reversible drugs, which typically need to be present to provide benefit, irreversible drugs have the potential to maintain their effect in the absence of sustained drug exposure. The permanent inhibition of target function upon irreversible binding essentially uncouples pharmacodynamics (drug effects) (PD) from pharmacokinetics (drug exposure) (PK) as target inhibition persists after the drug has been cleared from the system. This property of irreversible drugs can potentially lead to lower drug doses and less frequent dosing regimens versus reversible approaches.

Despite the potential advantages of irreversible small molecules, the majority of approved drugs are reversible binders due to the target protein structural requirements and chemistry expertise necessary to develop safe and effective targeted irreversible therapies. Leveraging our management team’s experience at Pharmacyclics

(acquired by AbbVie in 2015 for a total transaction value of $21 billion) developing ibrutinib, an irreversible inhibitor of Bruton tyrosine kinase (BTK), we built a proprietary platform to enable the design and development of novel irreversible, small molecule product candidates against high-value oncogenic drivers of cancer. Our FUSION System discovery platform encompasses the following:

- ***Target selection***: We use our expertise in structural biology and irreversible binding chemistry to identify both validated and novel targets that we believe may have a demonstrable and specific impact on disease and have particular structural characteristics that would be amenable to direct intervention with an irreversible binder.
- ***Scaffold creation:*** We create novel chemical scaffolds using a computational platform to exploit the unique structural elements of a specific target protein. We then screen these scaffolds with in-house technologies to select the optimal candidates for further construction and design. This evaluation process is intended to increase the probability of advancing multiple targeted compounds through the discovery process and into the clinic.
- ***Molecule optimization:*** Using our proprietary suite of computational technologies, assays, analytical approaches, chemistry and know-how we strive to maximize the potential selectivity, potency, safety and convenience of our oral irreversible small molecule product candidates.

We believe that irreversible small molecules have the potential to address the key limitations of existing reversible therapeutics and treat diseases where targeted therapies are not yet approved. The following table summarizes our wholly-owned product candidate pipeline.

Our lead product candidate, BMF-219, is designed to be an orally bioavailable, potent and selective irreversible inhibitor of menin, a ubiquitously expressed scaffold protein that functions in histone modification and epigenetic gene regulation to impact multiple cellular processes including cell cycle control, apoptosis and DNA damage repair. Interaction between menin and MLL proteins results in deregulated expression of downstream genes, which subsequently triggers uncontrolled cell proliferation. Internal and external studies have shown that disrupting the protein-protein interaction between menin and MLL can inhibit oncogenic signaling and potentially lead to cell death. In acute leukemias, MLL rearrangements (MLL-r) are caused by translocations of *KMT2A* (the gene that encodes the MLL protein), which leads to a modified MLL protein with enhanced affinity towards menin. This strengthened menin MLL-r interaction drives the oncogenic state of these cells. MLL rearrangements account for approximately 5% to 10% of acute myeloid leukemia (AML), or approximately 1,000 to 2,000 new patients per year in the United States. NPM1 mutant AML has also shown a strong

dependence on the interaction of menin and MLL, representing over 30% of AML patients or approximately 5,000 to 6,000 new patients per year in the United States. While the role of menin-MLL interactions in oncogenic signaling has been extensively studied in AML and acute lymphoblastic leukemia (ALL), many liquid tumors (including diffuse large B-cell lymphoma (DLBCL)), and multiple myeloma) and multiple solid tumors (including breast, lung, pancreatic, bone and colon) have been shown to be dependent on menin for survival and propagation. Despite the high unmet need, there are currently no approved therapies directly targeting menin, and the only active clinical programs of which we are aware are studying reversible inhibitors.

BMF-219 is a potentially first-in-class irreversible menin inhibitor being developed for the treatment of cancers that are highly dependent on menin, including leukemias containing the MLL fusion protein. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models, including MLL-r AML, NPM1 mutant AML and KRAS mutant colorectal, lung and pancreatic tumors. BMF-219 was also well tolerated and showed PK properties consistent with a once-daily oral therapy. We are currently completing IND-enabling studies and expect to file an IND with the FDA in . If the IND is cleared, we expect to initiate a Phase 1/2 clinical trial of BMF-219 in patients with acute leukemia, including MLL-r, NPM1 mutant and other subtypes. We also plan to study BMF-219 across a range of menin dependent cancers including multiple myeloma, DLBCL, breast cancer, and KRAS mutant lung, pancreatic and colon tumors. Beyond cancer, based on a growing body of external scientific evidence, we plan to explore the potential of our irreversible menin inhibitor candidates to treat Type-2 diabetes.

In addition to BMF-219, we are utilizing our novel FUSION System to pioneer irreversible treatments against other high-value genetic drivers of disease. We are currently advancing two other preclinical irreversible programs for the treatment of select cancers and expect to nominate our second development candidate in .

After working closely together at Pharmacyclics, our Chief Executive Officer, Thomas Butler, and President, Ramses Erdtmann, founded Biomea Fusion in 2017 with the goal of developing targeted therapies for patients suffering from genetically defined cancers. Our management team has significant experience in precision oncology and in progressing products from early stage research to clinical trials, and ultimately to regulatory approval and commercialization. Together, they bring in-house expertise in medicinal chemistry, biology, translational medicine, computational biology and chemistry, *in vitro* and *in vivo* pharmacology, biomarker development and manufacturing. We have also established internal expertise in clinical development, clinical operations, pharmacovigilance, clinical pharmacology, regulatory and quality. Other members of the management team have held various positions at Genentech, Gilead Sciences, Pharmacyclics, and Celera. We are supported by our board of directors, scientific advisory board and a leading syndicate of investors, which includes Cormorant Asset Management, Boxer Capital of Tavistock Group, Janus Henderson Investors, Rock Springs Capital, RTW Investments LP, Aisling Capital, Point Sur Investors, Logos Capital, and Clifton Capital.

Our strategy

Our goal is to discover, develop and commercialize irreversible small molecules to treat patients with genetically defined cancers. The key elements of our business strategy to achieve this goal include:

- ***Deploy our irreversible platform against high-value oncogenic drivers of cancer.*** Leveraging our extensive experience developing irreversible drugs and our structural biology and irreversible binding chemistry expertise, we built our proprietary FUSION System to design and develop a pipeline of novel irreversible small molecule drug candidates. We believe irreversible binders offer a number of potential advantages over conventional reversible drugs, including greater target selectivity and the ability to drive deeper, more

durable responses with lower drug exposure. We believe our capabilities and platform uniquely position us to become a leader in developing irreversible drugs.

- ***Rapidly advance our lead product candidate, BMF-219, into and through clinical development.*** BMF-219 is a potentially first-in-class irreversible menin inhibitor being developed for the treatment of cancers that are highly dependent on menin, including leukemias containing the MLL fusion protein. We are currently completing IND enabling studies and expect to file an IND with the FDA in the . If the IND is cleared, we expect to initiate a Phase 1/2 clinical trial of BMF-219 in patients with acute leukemia, including MLL-r, NPM1 mutant and other subtypes. We also plan to study BMF-219 across a range of menin dependent cancers including multiple myeloma, DLBCL, breast cancer, and KRAS mutant lung, pancreatic and colon tumors.
- ***Continue to expand our portfolio of irreversible small molecule drug candidates.*** In addition to BMF-219, we are advancing two other preclinical irreversible programs for the treatment of select cancers and expect to nominate our second development candidate in the . Both of these programs target clinically validated mechanisms of action and are complimentary to the menin pathway. Beyond cancer, based on a growing body of external scientific evidence, we also plan to explore the potential of our irreversible menin inhibitor candidates to treat Type-2 diabetes.
- ***Evaluate opportunities to accelerate development timelines and enhance the commercial potential of our programs in collaboration with third parties.*** We own full worldwide development and commercialization rights to each of our programs. In the future, we may selectively enter into collaborations where we believe there is an opportunity to accelerate the development and commercialization of our product candidates. We intend to commercialize our product candidates in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.
- ***Maintain our entrepreneurial outlook, scientifically rigorous approach, and culture of tireless commitment to patients***. We will continue to apply transformative science in the development of novel targeted therapies for patients suffering from cancers with limited therapeutic options. We intend to continue building our team of qualified individuals who share our commitment to collaboration and scientific rigor in the development of novel irreversible product candidates that may have the potential to treat patients with genetically-defined cancers.

Background on irreversible drugs

An irreversible small molecule drug is a synthetic compound that forms a permanent bond to its target protein through a combination of non-covalent and covalent interactions, and can either stimulate or inhibit target protein function. Reversible drugs, which make up the majority of approved drugs, exert their action by establishing an equilibrium between free drug, target protein, and drug-target complex. Therefore, a reversible inhibitor, by definition, can allow an inhibited drug-protein complex to convert back to free drug and active protein unless sufficient concentration of free drug is present in the local environment. This need for constant coverage typically requires continuous systemic exposure, which can pose safety and tolerability challenges.

Forming an irreversible bond between a target protein and irreversible drug can be described as a two-step process. First, the compound creates a reversible, non-covalent bond to the target protein that can enable an irreversible, covalent bond by placing a reactive atom on the drug compound close to a complementary reactive atom on the target protein. The second step involves the formation of a specific and long-lived covalent bond between the complementary moieties, resulting in a complex that persists throughout the lifetime of the target protein and effectively permanently disables target protein function.

Key advantages of irreversible drugs

Since the discovery of aspirin in 1899, irreversible drugs have shown the potential to offer a number of potential safety, tolerability, and efficacy advantages over conventional reversible drugs through multiple mechanisms, including:

- ***High selectivity***: Irreversible drugs have the potential to confer high selectivity to a target by interacting with the unique surrounding structural elements of the protein and establishing a covalent bond to a key residue in the binding site. Leveraging non-covalent and covalent interactions can lead to greater selectivity versus reversible compounds, which rely solely on non-covalent binding. This has the potential to reduce the likelihood of non-specific, off-target interactions that often lead to safety and tolerability concerns.
- ***Deep inactivation of target***: Upon binding, an irreversible inhibitor may not only cause inactivation of the target, but may also result in the elimination of the target through normal cellular degradation processes. The diseased cell then either undergoes rapid apoptosis or differentiation into a normal, mature cell. Such transformation has the potential to provide the patient with a durable, lasting benefit.
- ***Greater therapeutic window*:** Irreversible inhibitors are designed to create a permanent bond with high affinity and long residence time. Unlike conventional reversible drugs, which typically need to be present to provide benefit, irreversible drugs have the potential to maintain their effect in the absence of sustained drug exposure. The permanent inhibition of target function upon irreversible binding essentially uncouples PD (drug effects) from PK (drug exposure), as target inhibition persists after the drug has been cleared from the system. This property of irreversible drugs can potentially lead to lower drug doses and less frequent dosing regimens versus reversible approaches. Figure 1 below highlights the potential PD and PK benefits of an FDA approved irreversible BTK inhibitor (ibrutinib). In particular, the results from this model showed that an irreversible inhibitor quickly achieved maximum target engagement and sustained inhibition while the drug was rapidly cleared from the body, which we believe further reduced the potential for off-target interactions and non-mechanism-based toxicities. These features contribute to ibrutinib's sustained efficacy with lower exposure and a favorable safety profile.

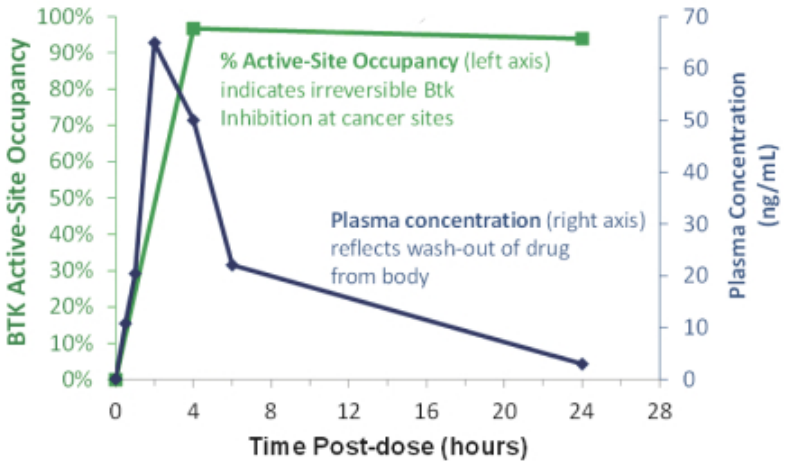


Fig. 1. *Persistent site occupancy of a marketed irreversible inhibitor observed in the absence of sustained drug exposure.*

Beyond aspirin and ibrutinib, a number of irreversible inhibitors have been approved by the FDA, including sofosbuvir (marketed as SOVALDI for hepatitis C virus), tenofovir (marketed as VIREAD for hepatitis B virus),

osimertinib (marketed as TAGRISSO for NSCLC), and bortezomib (marketed as VELCADE for multiple myeloma and mantle cell lymphoma).

Challenges in developing irreversible drugs

Despite the potential advantages of irreversible drugs, the majority of approved drugs are reversible binders. The inherent challenges in creating irreversible drugs presents significant barriers to entry to discover and develop these molecules. The key challenges in developing irreversible drugs include:

- ***Complexity*.** The discovery and development of irreversible drugs requires significant structural knowledge and medicinal chemistry capabilities, including the ability to construct complex novel chemical scaffolds. In addition, not all disease-causing proteins have the properties necessary for the application of irreversible binding. While advancements in structural knowledge of the proteome provides greater opportunity to identify potential targets for irreversible binding, we believe the lack of specialized medicinal chemistry expertise needed to leverage this knowledge has impeded the development of irreversible drugs.
- ***Safety and toxicity*.** While the irreversible binding modality can provide a high degree of selectivity, poorly conceived molecules with promiscuous binding profiles can pose a risk of significant off-target interactions and safety concerns. Given this significant and long-standing challenge, without the structural biology and irreversible binding chemistry expertise, drug developers have historically been discouraged from pursuing irreversible binders.

At Biomea, we believe we are uniquely positioned to leverage the significant expertise, foundational knowledge and capabilities that our management team first acquired while developing ibrutinib and that we have expanded and refined over the last three years to create our FUSION System discovery platform.

Our FUSION System discovery platform

We believe that irreversible small molecules have the potential to address the key limitations of existing reversible therapeutics and treat diseases where targeted therapies are not yet approved. Leveraging our extensive experience developing irreversible drugs and irreversible binding chemistry expertise, we built our proprietary FUSION System to enable the design and development of novel irreversible, small molecule product candidates against high-value oncogenic drivers of cancer. Our FUSION System discovery platform encompasses the following:

- ***Target selection***: We use our expertise in structural biology and irreversible binding chemistry to identify both validated and novel targets that we believe may have a demonstrable and specific impact on disease and have particular structural characteristics that would be amenable to direct intervention with an irreversible binder.
- ***Scaffold creation:*** We create novel chemical scaffolds using a computational platform to exploit the unique structural elements of a specific target protein. We then screen these scaffolds with in-house technologies to select the optimal candidates for further construction and design. This evaluation process is intended to increase the probability of advancing multiple targeted compounds through the discovery process and into the clinic.
- ***Molecule optimization:*** Using our proprietary suite of computational technologies, assays, analytical approaches, chemistry and know-how we strive to maximize the potential selectivity, potency, safety, and convenience of our oral irreversible small molecule product candidates.

We aim to leverage our capabilities and platform to establish ourselves as a leader in developing irreversible small molecules in order to maximize the depth and durability of clinical benefit for patients with various cancers.

Our initial focus: menin

Menin is a protein important to transcriptional regulation, impacting major processes such as cell cycle control, apoptosis and DNA damage repair. It plays an essential role in oncogenic signaling in subgroups of genetically-defined leukemias, such as MLL-r, and other cancers dependent on menin. MLL-r leukemias are characterized by *MLL* gene (also known as *KMT2A*) translocation abnormalities. These abnormalities result in the formation of fusion genes encoding fusion proteins comprised of MLL1 and a corresponding fusion partner domain. The interaction of these fusion proteins with menin drives the expression of downstream target genes such as *HOXA9* and *MEIS1*, triggering leukemic cell proliferation.

Menin binds directly to the conserved N-terminus of MLL proteins, making it a promising target that could potentially be exploited consistently by a menin inhibitor therapeutic. Preventing the MLL proteins from binding to menin has been shown to abolish the oncogenic effects *in vitro* and *in vivo.*

Approximately 20,000 and 6,000 patients in the United States are diagnosed annually with AML and ALL, respectively. MLL-r leukemia has limited therapeutic options and affects approximately 10% of acute leukemias in adults and approximately 70% of acute leukemias in infants. In addition to MLL-r, MLL signaling in some forms of MLL wild-type (MLL-wt) AML have also been implicated, including those bearing independent oncogenic mutations in nucleophosmin (NPM1), a molecular chaperone, and DNA-methyltransferase 3A (DNMT3A), a methyl transferase. These subpopulations together represent approximately 45% of AML cases.

Patients with MLL rearrangements often suffer from failure of induction therapy or disease relapse, resulting in poor clinical outcomes. In pediatric AML, the five-year event-free survival rate on average is 44%, but ranges between 11% and 92% depending on the MLL-translocation subtypes. In ALL, the five-year survival rate for people age 20 and older is approximately 37% and for people under the age of 20 it is approximately 89%. However, pediatric MLL-r ALL patients fare much worse, with four-year survival rates as low as 10%, compared to 64% for those without MLL rearrangements.

A perhaps more dire area of unmet need is relapsed/refractory AML. Despite evolving insights into the pathogenesis of AML, over 11,000 patients with AML die each year from the disease in the United States. Relapse is the most common cause of treatment failure. The five-year overall survival (OS) for adult patients with AML after disease relapse is only approximately 10%. Furthermore, a published study shows that approximately 20% of patients demonstrate primary induction failure adding even more patients to this refractory category. Currently, allogeneic hematopoietic cell transplantation (HCT) is considered to be the only reliable option with curative potential, with OS estimated between 15% to 25% three to five years post-transplant. The latest National Comprehensive Cancer Network (NCCN) guidelines do not provide uniform, data-driven guidance for the management of relapsed or refractory patients. To improve overall quality of life for patients, physicians are favoring oral targeted agents and strategies that avoid intensive chemotherapy and prolonged inpatient admissions. Key in this effort is a focus on molecular testing to identify the potential for targeted therapies.

Given the clear involvement of MLL and NPM1 in acute leukemias, and the poor clinical outcomes provided by available treatments, we believe a new treatment that can inhibit the function of both targets by disrupting or preventing interactions with menin could address this unmet need.

The role of menin-MLL interactions in oncogenic signaling has been extensively studied in liquid tumors, predominantly AML and ALL as discussed above. Elevated menin and MLL levels and association with disease has also been observed in other liquid tumors (including multiple myeloma and DLBCL) and multiple solid tumors (including tumors of the breast, liver, lung, pancreas, bone and colon).

To date, the only therapies currently being studied in humans that directly target menin are Kura Oncology's KO-539 and Syndax Pharmaceuticals' SNDX-5613, both reversible menin inhibitors. These product candidates have demonstrated encouraging Phase 1 efficacy results, and we believe provide strong pharmacologic validation of menin as a therapeutic target.

We believe that a well-designed, selective irreversible menin inhibitor could lead to deep inactivation of menin without the need for high, sustained drug exposure.

Our programs

We are developing irreversible small molecule product candidates to treat patients with genetically defined cancers. We believe that irreversible small molecule drugs have the potential to address the key limitations of existing reversible therapeutics and to treat diseases where targeted therapies are not yet approved. The following table summarizes our wholly-owned product candidate pipeline.

BMF-219

Our lead product candidate, BMF-219, is designed to be a potent, selective, orally-bioavailable, irreversible inhibitor of menin that disrupts the protein-protein interaction between menin and MLL. We are developing BMF-219 for the treatment of cancers that are highly dependent on menin including leukemias containing the MLL fusion protein. In preclinical studies, administration of BMF-219 has resulted in robust anti-tumor responses across a range of liquid and solid tumor models, including MLL-r AML, NPM1 mutant AML, and KRAS mutant colorectal, lung, and pancreatic tumors. BMF-219 was also generally well-tolerated in these studies and showed PK properties consistent with a once-daily oral therapy. Based on our preclinical findings, our irreversible approach may have significant advantages over reversible inhibitors, including selectivity, potency, durability and safety. We are currently completing IND enabling studies and expect to file an IND with the FDA in the .

Target engagement studies: gene expression

Published studies have shown that inhibition of the menin-MLL interaction leads to reduction in *MEN1* (the gene that encodes menin) transcription, resulting in down regulation of *MEIS1*, *HOXA9* and *DMNT3A*, which are common gene signatures for menin-MLL, and differentiation of leukemic cells into myeloid cells. Our lead product candidate, BMF-219, is intended to irreversibly inhibit the interaction between menin and wild type MLL and MLL fusions.

In preclinical studies, administration of BMF-219 has resulted in the inhibition of the menin-MLL interaction in multiple cancer cell models with known dependency on menin binding for survival. We characterized the molecular responses following treatment with BMF-219 across multiple model cell lines, including MOLM-13 cells in culture. MOLM-13 is an acute myeloid leukemia cell line with a KMT2A-MLLT3 fusion.

As reflected in the figure below, in this model we observed substantial down regulation of *MEN1* along with *MEIS1*, *HOXA9*, and *DNMT3A*, which are common gene signatures for menin-MLL and NPM1 altered leukemias. Published studies of reversible menin inhibitors have shown down regulation of signature genes after six days of inhibition. To evaluate target engagement and explore potential differences in onset of action for our reversible and irreversible menin inhibitors, we evaluated expression levels at six and 24 hours following treatment. Our reversible inhibitor showed limited impact on signature genes over 24 hours, but we observed rapid down regulation of menin dependent genes for BMF-219, and observed up to approximately 80% reduction in readout genes by six hours and approximately 95% reduction at 24 hours compared to control.

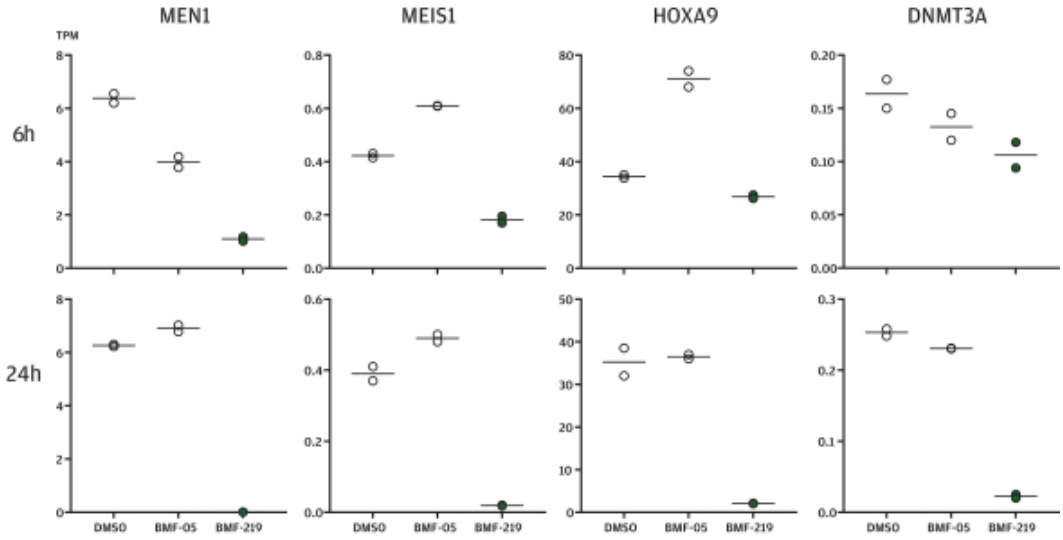


Fig. 2. *Reduction in menin dependent gene expression demonstrated target engagement. Profiling of signature genes in menin-MLL and NPM1 altered leukemias shows rapid down-regulation upon treatment with BMF-219, an irreversible menin inhibitor. Treatment with BMF-05, a reversible menin inhibitor, shows limited impact on signature genes similar to dimethyl sulfoxide (DMSO) vehicle control at these time points, which is consistent with published findings for other reversible menin inhibitors. Y-axis represents Transcripts Per Million (TPM).*

Published studies have also shown that disruption of the menin-MLL interaction led to differentiation of leukemic cells to myeloid cells. As a result, we have tested reversible and irreversible menin inhibitors in MOLM-13 cells to determine if treatment would promote differentiation, as exhibited by an increase in integrin subunit alpha M (ITGAM), which encodes CD11b, a surface marker associated with myeloid differentiation. As reflected in the figure below, at 24 hours following administration, we observed dose dependent elevation of myeloid marker gene expression with BMF-219 treatment. Meanwhile, comparable exposures of reversible menin inhibitors (BMF-05, BMF-13, BMF-214 three of our proprietary reversible menin inhibitors) reflected no change from vehicle controls. However, the reversible inhibitors were able to upregulate ITGAM at a 10-fold increase in exposure. While we believe these results support our hypothesis regarding the role of the menin pathway, they also highlight the potential need for reversible inhibitors to have high clinical exposures in order to achieve sufficient menin suppression to affect disease.

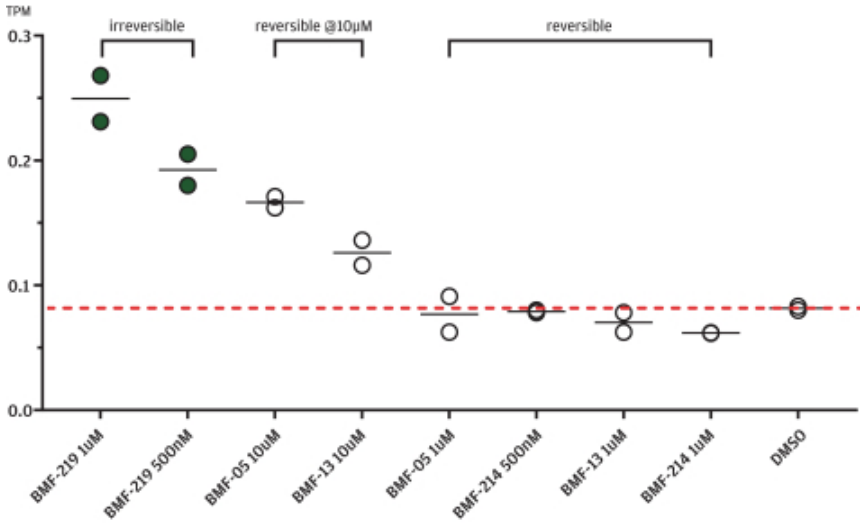


Fig. 3. *Responses of myeloid differentiation marker ITGAM at 24 hours demonstrated target engagement. Y-axis represents the Transcripts Per Million (TPM). Data are presented for DMSO vehicle control, proprietary reversible menin inhibitors (BMF-05, BMF-13, BMF-214), and BMF-219.*

In-vitro studies:

We have also conducted cell proliferation assays on a panel of well-characterized leukemia cell lines to evaluate the potency of BMF-219. The panel included: MLL-AF4 translocated, internal tandem FLT3 duplicated bi-phenotypic B-myelomonocytic leukemia (i.e. ALL/AML) cell line MV4;11, MLL-AF9 translocated, internal tandem FLT3 duplicated AML cell line MOLM-13, and NPM1-mutated AML cell line OCI-AML3. We tested BMF-219 against a reference compound, MI-503, which is an investigational, potent and well-studied, reversible menin inhibitor developed by the University of Michigan. While MI-503 has not advanced into clinical development, to our knowledge, it has exhibited strong potency, making it a good comparator for *in vitro* studies of menin inhibition.

The figure below reflects the dose-response curves for MI-503 and our proprietary reversible menin inhibitor BMF-05 and BMF-219 in multiple leukemia model cell lines. In the study, BMF-219 demonstrated IC_{50}s ranging from 50-100 nM, with consistently superior potency to the tested reversible inhibitors. The greatest potency differences versus comparators were observed in the MLL-r driven cell line MOLM-13, which had the strongest menin dependency of tested cells. In comparison, potency differences were less pronounced in the NPM1 mutated AML line OCI-AML3 and the bi-phenotypic AML/ALL cell line MV4;11, which is consistent with the lower menin dependency known in these cell lines.

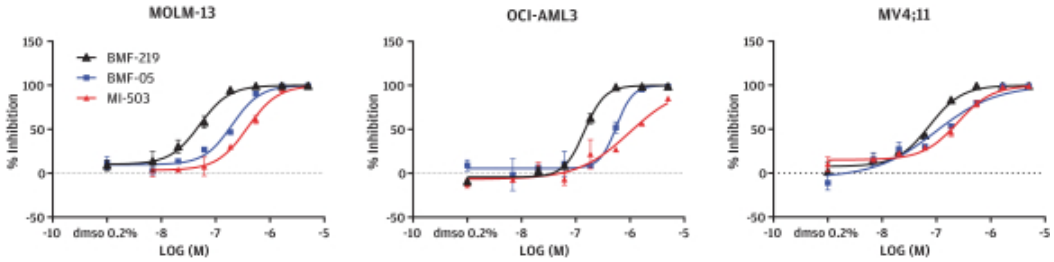


Fig. 4. *Potency of menin inhibitors observed in leukemia models. Decreasing menin dependence of model cell lines (left to right).*

To evaluate potential activity of the irreversible menin inhibitor BMF-219 in leukemia models, we examined the impact of menin inhibition on metabolic activity and cell survival. As reflected in the figures below, treatment with BMF-219 demonstrated rapid shut down of metabolic activity, which was sustained over the 14-hour study duration. BMF-219 responses were superior to tested reversible menin inhibitors (BMF-05 and MI-503) with respect to both onset and durability of metabolic suppression.

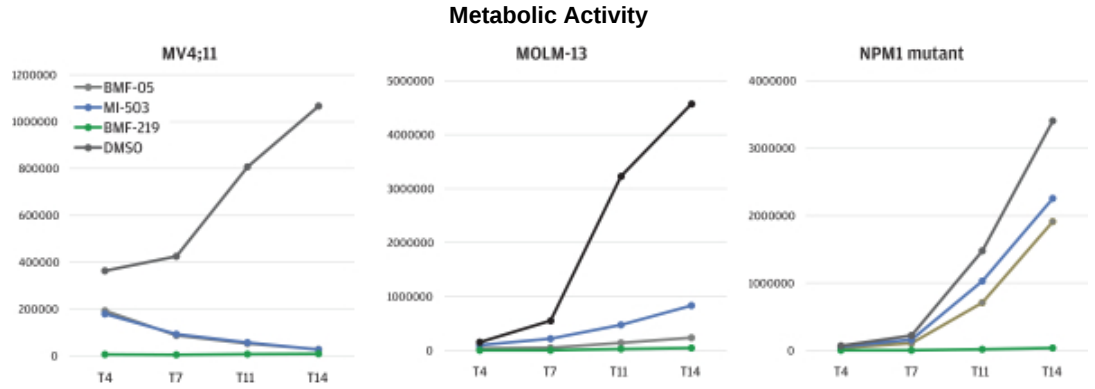


Fig. 5. *Metabolic activity in menin inhibitor treated leukemia cell lines reflected rapid and durable responses following administration of irreversible menin inhibitor BMF-219 (560nM exposure of all compounds). Y-axis represents fluorescence units, a measure of viable cells.*

Treatment with BMF-219 also led to apoptosis in menin driven leukemia models, resulting in a notable reduction in cell survival. Responses were observed for BMF-219 treatment at the lowest tested doses across all cell lines, while the reversible inhibitors showed limited responses at the lowest dose and were unable to eliminate tumor cells at any tested dose.

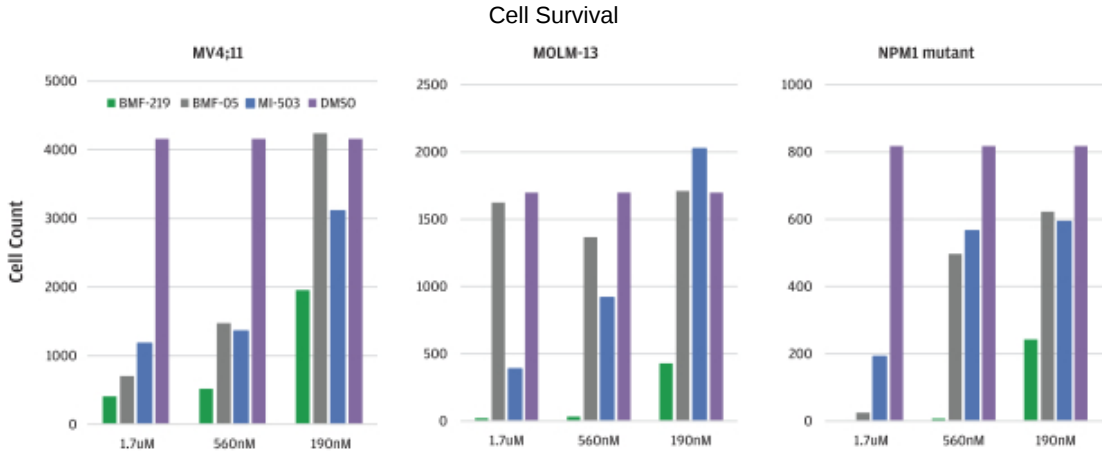


Fig. 6. *Survival assay across AML cell lines after seven days shows differentiated responses to irreversible menin inhibitor BMF-219 relative to reversible inhibitors.*

In addition to impact on leukemic cell lines, menin is a known dependency in other liquid tumors, including multiple myeloma and DLBCL. Menin dependency has also been seen in multiple solid tumors including Ewing's sarcoma and KRAS driven cancers. As part of our ongoing discovery efforts, we screened BMF-219 against a

panel of tumor models and observed potent growth inhibition in multiple menin-dependent cancer cell lines. Observed menin inhibitor potency was correlated to the level of menin dependency of each cell line, which we believe indicates the importance of menin in the underlying mechanism of proliferation in these cancer models.

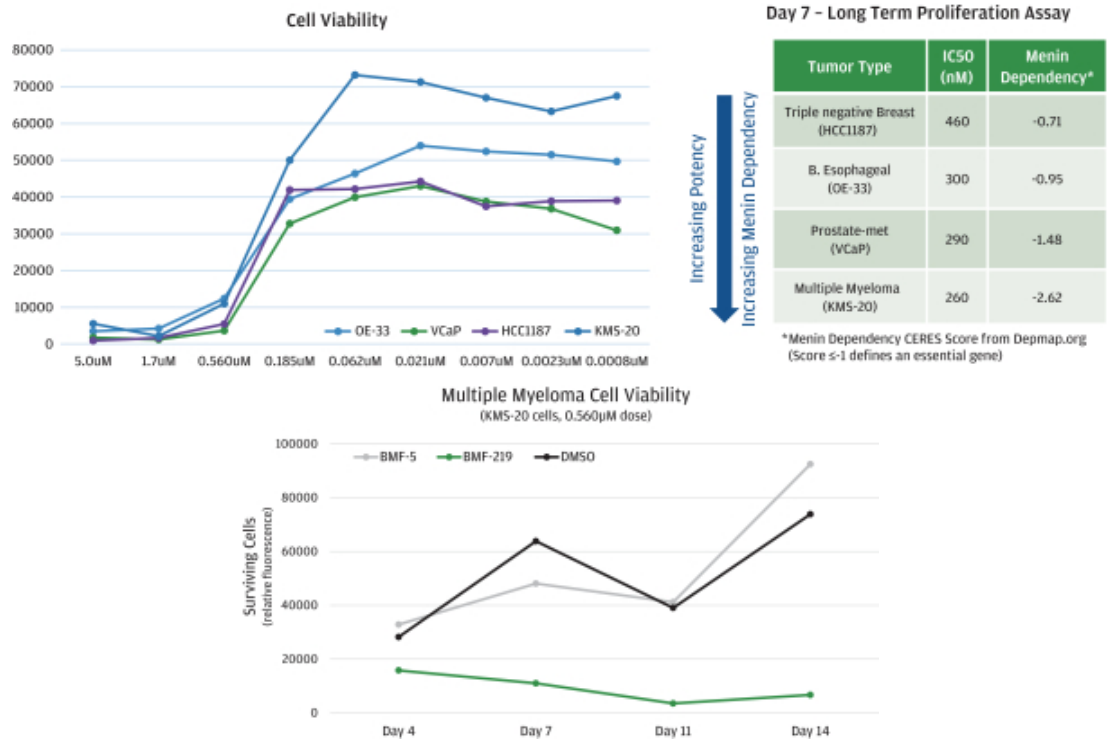
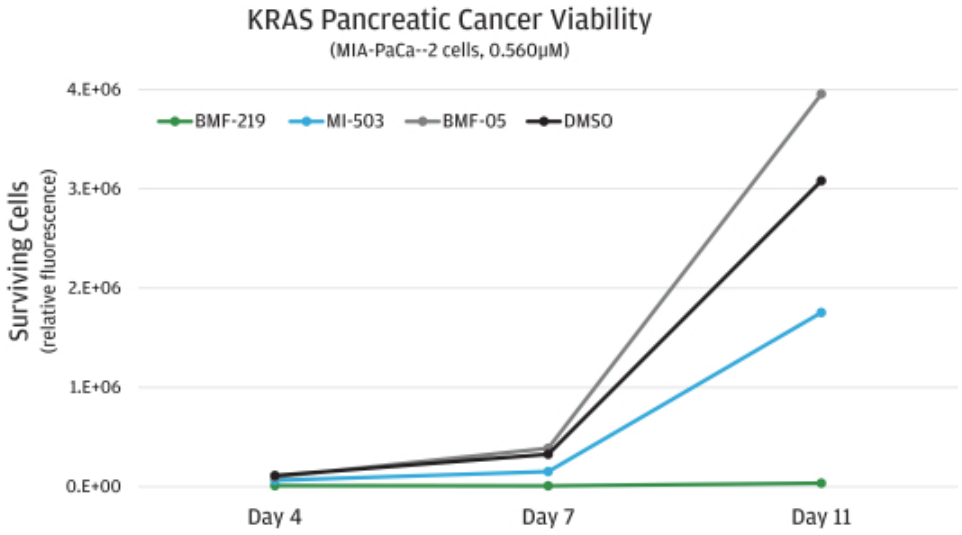


Fig. 7. *The potential to inhibit proliferation at sub micro-molar concentrations was demonstrated by the irreversible menin inhibitor BMF-219 across multiple menin-dependent cancer cell lines (top panel). Representative cell survival time course from a multiple myeloma model (KMS-20 cell line, 0.56μM doses) shows relative effect of the irreversible inhibitor BMF-219 versus a reversible inhibitor BMF-05 (bottom panel).*

We also explored the potential potency of BMF-219 in KRAS dependent tumors using a long-term proliferation assay. A representative cell survival time course from a G12C KRAS mutation driven pancreatic cancer line (MIA-PaCa-2, 0.56μM doses) shows the effects of treatment with the irreversible inhibitor BMF-219. A broader panel of these studies demonstrated potent growth inhibition in multiple models covering both G12C and G12D KRAS mutations at exposures far below those that were necessary for a different reversible menin inhibitor (MI-503) to show similar activity.



Cell Line	Tumor Type	Mutation	BMF-219 IC50 (nM)	MI-503 IC50 (nM)
SK-LU-1	Lung	KRAS-G12D	370	1100
MIA-PaCa-2	Pancreatic	KRAS-G12C	220	550
NCI-H23	Lung	KRAS-G12C	190	450
Panc 10.05	Pancreatic	KRAS-G12D	280	760

In summary, we have screened the effects of BMF-219 across a range of cancer cell lines and observed potent growth inhibition as shown in the figure below. These findings support our belief that BMF-219 has significant potential to address a broad range of cancers.

	Cell Line/Tumor Type	IC50 (µM)
Fusion	MOLM-13/AML	0.05
	MV4;11/ALL-AML	0.07
NPM1 Mutation	OCI-AML3/AML	0.14
KRAS	MIA-PaCa-2/Pancreatic	0.23
	NCI-H23/Lung	0.26
Menin Dependent	KMS-20/Plasma Cell Myeloma	0.26
	VCaP/Prostate Adenocarcinoma (met)	0.29
	OE-33/Barrett Esophageal Adenocarcinoma	0.30
	KG-1/AML	0.33
	HCI187/Ductal Breast Carcinoma (TNBC)	0.46
KRAS	Panc 10.05/Pancreatic	0.49
	NCIH23/NSCLC	0.49
Menin Dependent	BT-474/invasive ductal carcinoma NOS	0.52
KRAS	SK-LU-1/Lung	0.59

Ex vivo efficacy results

Continuing our focus on the well-characterized menin dependency in leukemia, we investigated patient derived AML samples and the impact of reversible and irreversible inhibition of the menin-MLL interaction on proliferation. As reflected in the figure below, irreversible inhibition with BMF-219 and BMF-T2 (a derivative of BMF-219) lead to dramatic growth inhibition and showed substantial advantages over the selected reversible inhibitors.

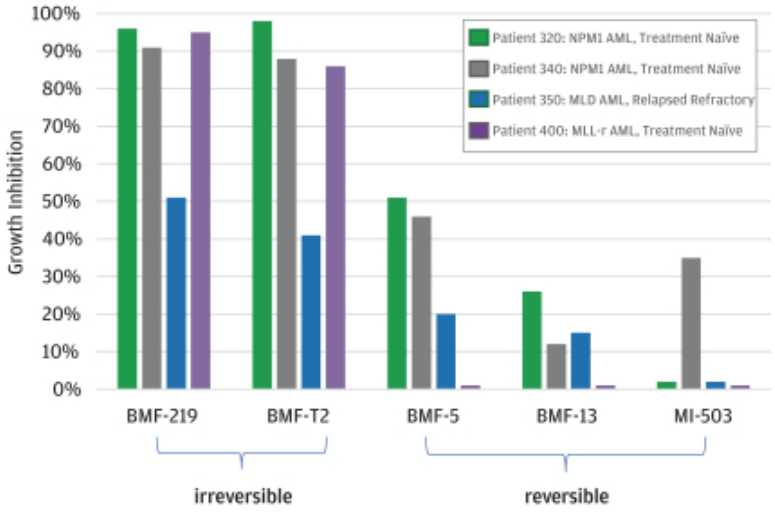


Fig. 8. *Treatment of patient derived AML cells with menin inhibitors showed potent inhibition of proliferation with irreversible drugs (BMF-219 and BMF-T2) versus reversible drugs (BMF-5, BMF-13, MI-503). 1μM exposure, six days.*

In comparison, to achieve similar levels of growth inhibition, the selected reversible inhibitors studied required dose concentrations approximately ten-fold greater than their respective IC90 values. We believe these findings support our hypothesis that an irreversible inhibitor could potentially provide greater therapeutic benefit at lower exposure-levels versus reversible inhibitors.

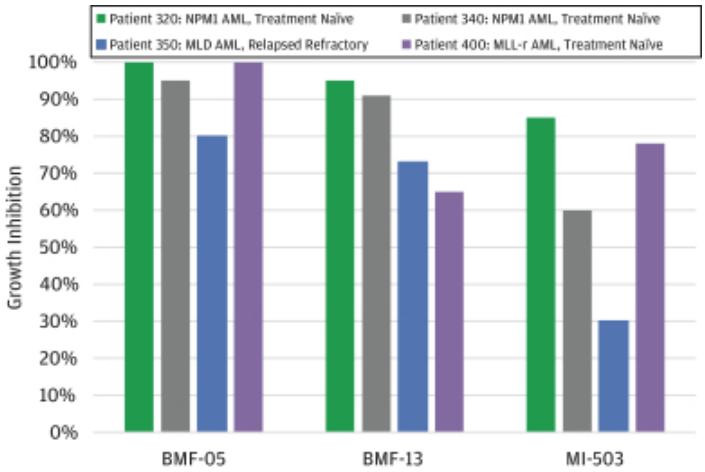


Fig. 9. *Treatment of patient derived AML cells with reversible menin inhibitors at drug exposures 10-fold greater than IC90 (10μM) showed robust inhibition of proliferation at six days.*

In Vivo efficacy results

A xenograft model using a MV4;11 leukemia cell line was used to evaluate the potency of BMF-219 as a single agent. We utilized a luciferase-transduced MV4;11 model over sub-cutaneous models as we believe the disseminated model better reflects the normal etiology of leukemias, including homing of leukemic cells to the bone marrow and spleen. Also, the disseminated model offered the ability to frequently monitor disease progression through fluorescence imaging which provided a more detailed understanding of the kinetics of the observed response to therapy.

Disseminated MV4;11-luc models were run in female NSG mice. Mice were inoculated with xenograft cancer cells at high levels ($1x10^7$ MV4;11 cells) with greater than 90% viability via tail vein injection. BMF-219 or vehicle was administered (once daily) at various dose levels and via various routes (intravenously (IV), PO: 80-160 mg/kg, IP: 40-80 mg/kg).

As reflected in the figure below, the MV4;11-luc disseminated xenograft study showed substantial tumor reduction and survival benefit for BMF-219 treatment at both the 20 mg/kg and 40 mg/kg doses. Fluorescence imaging showed notable reductions in tumor burden between the control (vehicle treated) animals as compared to the BMF-219 treated animals. Both tested doses showed substantial reductions in tumor burden (-47% at 20 mg/kg; -63% at 40 mg/kg), which translated into survival benefit (over vehicle control) of 72% and 94% for the respective doses (calculated using total days of survival versus control).

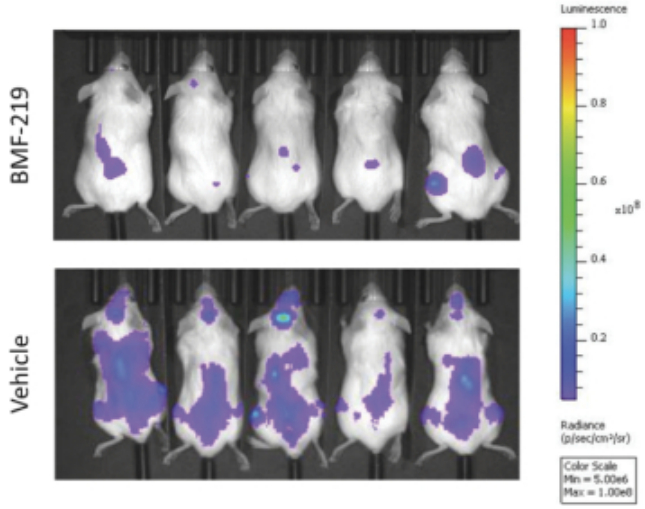


Fig. 10. *Fluorescence imaging of the disseminated MV4;11-luc xenograft model treated for 14 days at 40mg/kg with BMF-219 vs. control. Pseudo-colored area and intensity indicates level of tumor burden.*

Mean body weight data from our xenograft studies provided an early assessment of safety and tolerability showing that BMF-219 treatment was generally well tolerated at various doses in a rodent model system. BMF-219 was administered once daily at 20 mg/kg or 40 mg/kg via IV for 14 days and caused minimal changes in body weight from baseline or vehicle control.

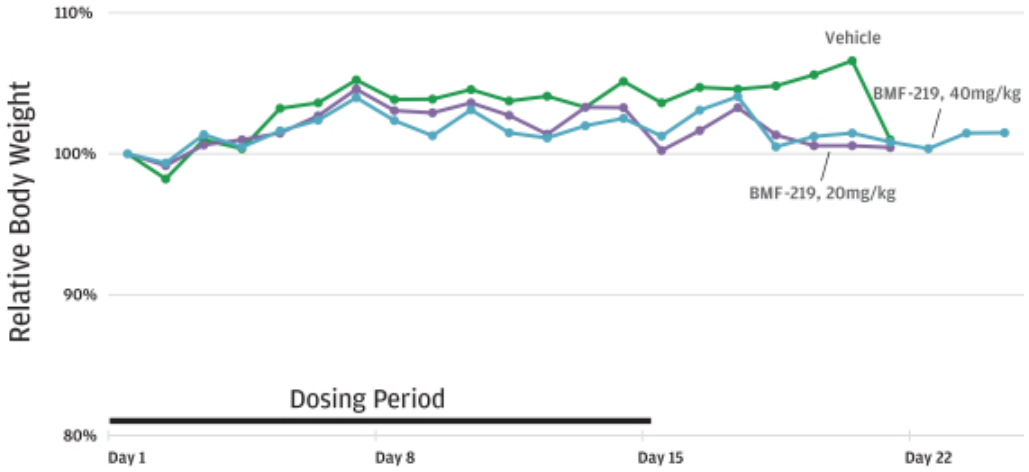


Fig. 11. *Body weight with BMF-219 treatment showed limited change from baseline and vehicle controls.*

We have also completed seven-day, non-GLP toxicology studies in rats and dogs where daily oral administration of BMF-219 showed that the compound was well tolerated in both species. Additionally, our PD studies, which dosed daily up to 14 consecutive days, showed that BMF-219 was well-tolerated. We believe these results further support the advancement of BMF-219 into IND-enabling toxicology studies.

Selectivity profiling

OncoPanel screening

We examined the selectivity of BMF-219 for menin-dependent disease to assess potential off-target risk. We observed negligible impact of BMF-219 treatment on cell metabolism in leukemia and lymphoma cell lines that have wild type MLL, but no menin-linked mechanism for disease. We believe these findings were consistent with external studies showing that menin-MLL interaction was not generally cell-essential and only critical to survival in those cells that contain aberrant biology.

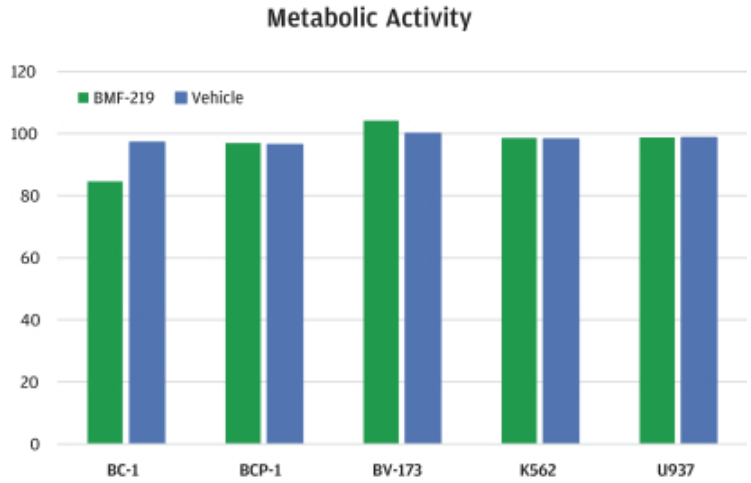


Fig. 12. *OncoPanel: Screening of metabolic activity in BMF-219 treated cells with WT MLL, but no menin-driven disease mechanism showed negligible impact on viability. 0.25μM exposure. The cell lines BC-1, BCP-1, BV-173, K562, and U937 were composed of, respectively, cells that were hematopoietic (B lympho-blast), hematopoietic (B lympho-blast), leukemia (B-cell pre), hematopoietic (bone marrow), and hematopoetic (bone marrow).*

Kinase screening

We have also conducted extensive in-house comparative 3D structural analysis of the protein, which has revealed that the binding pocket we seek to target on menin showed limited structural similarity to some tyrosine kinases known to be of functional relevance in hematological cancers. At a standard compound test concentration of 0.1 μM, BMF-219 displayed high selectivity and limited off-target kinase inhibition. Of the 169 kinases tested, only six showed any inhibition by any of our novel molecules tested. Furthermore, only two wild type kinases showed greater than 50% inhibition upon treatment with BMF-219. We believe this result supports the potential of our FUSION System to generate target-specific compounds.

Glutathione reactivity

We have also employed the widely-used glutathione (GSH) reactivity assay to investigate potential non-specific binding liabilities from electrophilic residues necessary to enable irreversible binding. The assay measures the depletion of the tested drug as it forms non-specific complexes with the strong nucleophile GSH and returns drug half-life ($t_{1/2}$) as a readout. Drugs with limited non-specific interactions have long half-lives, as the drug does not get consumed in a reaction with GSH. In such studies, BMF-219 showed negligible interaction with the strong nucleophile GSH and showed less reactivity than the approved irreversible drugs omeprazole and neratinib. We believe this result, if replicated in humans, could lead to less non-specific binding and potential off-target effects for BMF-219. The table below shows GSH reactivity studies showed limited non-specific binding liability of BMF compounds. 1µM of compound was incubated with 5mM of glutathione (5,000 eq).

Drug	Mean half-life (min)
Omeprazole	123.3
Neratinib	197.7
Ibrutinib	>360
BMF-213	322.3
BMF-214	>360
BMF-219	>360

Safety screen

In order to investigate the safety of BMF-219, we have assayed a selective group of compounds (including BMF-219) at 10 µM on the SafetyScreen 44 panel (CEREP/Eurofins Discovery). This panel was created from the collective experience of multiple large pharmaceutical companies. Our findings showed no meaningful impact (greater than 50% activation or inhibition) of BMF-219 across these key safety assays.

Drug properties

We believe the results observed for BMF-219 in our preclinical studies suggest the potential for this compound to be further evaluated as an oral, once-daily treatment for menin driven cancers. With limited formulation work, the compound showed favorable PK and PD results half-life, area under curve and bioavailability that enabled sufficient exposure for us to conduct *in vivo* efficacy and safety studies with oral dosing in mouse, rat and dog studies. We also tested the metabolic stability of BMF-219 and have observed no CYP inhibition to date.

Clinical development plan

We expect to file an IND for BMF-219 with the FDA in the . If cleared, we expect to initiate a Phase 1/2 clinical trial of BMF-219 in patients with acute leukemia, including MLL-r, NPM1 mutant and other subtypes. We anticipate the Phase 1 trial will consist of monotherapy dose escalation to evaluate the safety, PK, PD, and preliminary anti-tumor activity of BMF-219 and to determine the maximum tolerated dose (MTD), and/or the recommended Phase 2 dose (RP2D). We expect that the expansion phase will enroll patients at the RP2D in order to explore preliminary potency in selected patient populations. We plan to study BMF-219 in MLL-r and NPM1 mutant acute leukemias. In addition, based on results from preclinical studies, we also plan to study BMF-219 across a range of menin dependent cancers including multiple myeloma, DLBCL, breast cancer, and KRAS mutant lung, pancreatic, and colon tumors.

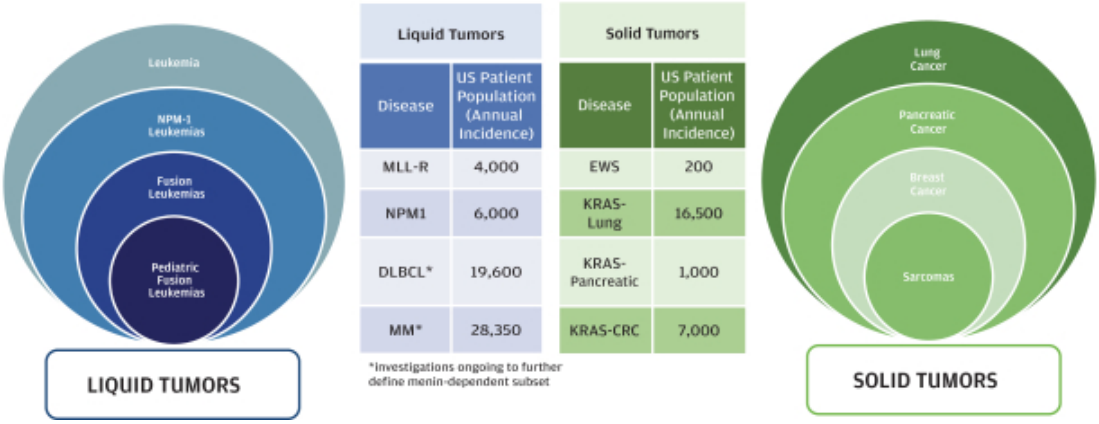


Fig. 13. *The graphic above describes potentially addressable patient populations for BMF-219.*

Additional programs

In addition to BMF-219, we are advancing two other pre-clinical irreversible programs for the treatment of select cancers and expect to nominate our second development candidate in the . Both of these programs target clinically validated mechanisms of action and are complimentary to the menin pathway. Beyond cancer, based on a growing body of external scientific evidence, we also plan to explore the potential of our irreversible menin candidates to treat Type-2 diabetes.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages, including, to our knowledge, our being the only company with the ability and mission to discover and develop irreversible binders specifically against menin. More broadly, we define ourselves as targeted oncology drug developers focused on irreversible drugs and as such expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may be or may become interested in discovery and development of irreversible binders that may compete with us against menin or related targets at scale and in an integrated way. Even if they do not advance programs with the same mechanism of action as ours, these companies could develop products or product candidates that are competitive with ours or that have a superior product profile, and may do so at a rapid pace. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of therapies that target irreversible binding against protein targets of interest to us.

To our knowledge there are two active programs that target menin in clinical development at this time; one being developed by Kura Oncology (KO-539) and other by Syndax Pharmaceuticals (SNDX-5613). Both KO-539 and SNDX-5613 are already in clinical trials and have demonstrated preliminary Phase 1 results that suggest encouraging clinical benefit and provide strong pharmacologic validation of menin as a therapeutic target. Other preclinical programs have been reported from Bayer (BAY-155), Janssen Pharmaceuticals, Novartis, and the University of Michigan.

Our competitors will also include companies that are or will be developing other targeted therapies, including small molecule, antibody, or protein degraders for the same indications that we are targeting. We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient to administer, are less expensive or with more favorable labeling than our product candidates. 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 are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their potency, selectivity, inactivation of the target, therapeutic window, safety, convenience, price, the level of generic competition, our ability to market and commercialize the product candidate, and the availability of reimbursement from government and other third-party payors.

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 other relevant inventions and improvements that we believe to be 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 (PCT) 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 or commercialize our product candidates. The PCT is a treaty with more than 150 contracting states that makes it possible to seek patent protection across multiple states by filing a single “international” application. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent

application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO) in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of a new drug application, plus the time between the submission date of a new drug application and the ultimate approval date. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. A patent that covers multiple products for which extension is sought can only be extended in connection with one of the approvals. The USPTO reviews the application for any patent term extension or restoration in consultation with the FDA. In the future, if any of our product candidates receive approval by the FDA, we expect to apply for a patent term extension on an issued patents covering the product, depending upon the length of the clinical studies for the product and other factors. Outside the US, similar applications for patent term extensions or supplementary protection certificates are available in a limited number of countries. We expect to apply for such coverage where available. There can be no assurance that the USPTO or any other patent office outside the US will approve any of our applications for patent term extensions or supplementary protection certificates. There can be no assurance that patents will issue from our current or future pending patent applications, or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products, if approved, for an adequate amount of time.

As of December 31, 2020, we owned three pending U.S. provisional patent applications, two pending U.S. non-provisional patent applications, two pending PCT applications, and one pending ex-U.S. patent applications. We currently do not own or in-license any issued patents with respect to any of our product candidates, including BMF-219, or our platform technology, and our intellectual property portfolio is in its very early stages.

Prosecution of our PCT patent applications and our provisional patent applications has not commenced, and will not commence unless and until they are timely converted into U.S. non-provisional or national stage applications. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO or other foreign jurisdiction are often significantly narrowed by the time they issue, if they issue at all. Any of our pending PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Our provisional patent applications may never result in issued patents and are not eligible to become issued patents until, among other things, we file a non-provisional and/or PCT patent application within 12 months of filing the related provisional patent application. If we do not timely file non-provisional or PCT patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional and PCT patent applications relating to our provisional patent applications, and we intend to timely file national stage patent applications relating to our PCT patent applications, we cannot predict whether any of our current or future patent applications related to BMF-219, or

any of our other product candidates, will issue as patents. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we obtain our product candidates or technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Additionally, even if any of our patent applications issue as patents, the patents covering our proprietary technologies and our product candidates would be expected to expire in 2039.

In addition to patent applications, we rely on unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and confidential know-how are difficult to protect. In particular, we consider various aspects of our irreversible binder discovery platform to constitute our trade secrets and know-how. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors and non-competition, non-solicitation, confidentiality and invention assignment agreements with our employees and consultants. We cannot guarantee that we will have executed such agreements with all applicable employees and contractors, or that these agreements will afford us adequate protection of our intellectual property and proprietary information rights. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party or misused by any person to whom we disclose such information. These agreements may also be breached, and we may not have an adequate remedy for any such breach. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our product candidates or any future proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information. For more information regarding the risks related to our intellectual property, please see “Risk factors—Risks related to our intellectual property.”

License and partnership agreements

As of December 31, 2020, we do not have any license or partnership agreements related to any of our programs. As these programs and our business evolves we may consider entering into a potential license or partnership. A potential partnership could provide non-dilutive funding and access to additional capabilities and expertise that a partner could provide to enhance the overall probability of program success.

Manufacturing

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates undergoing preclinical testing, as well as for clinical testing if our INDs for BMF-219 and other programs are accepted and commercial manufacture if our product candidates receive marketing approval. Certain of our suppliers of ingredients, raw materials, components and materials are single source suppliers. All of our drug candidates are small molecules and are manufactured in synthetic processes from available starting materials. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product

candidates that obtain marketing approval. We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Government regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, and export and import of drug products. A new drug must be approved by the FDA through the New Drug Application (NDA) process before it may be legally marketed in the United States. We, along with any third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

U.S. drug development process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in accordance with FDA's Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB), or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices (GCPs), to establish the safety and efficacy of the proposed drug for its intended use;
- preparation of and submission to the FDA of an NDA after completion of all pivotal trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is 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, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning the first clinical trial with a product candidate in the United States, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. 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. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2: The product candidate is administered 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. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3: The product candidate is administered 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.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies, may be conducted after initial marketing approval, and may be used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, 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.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

In addition, during the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

U.S. review and approval process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. 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 conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product’s identity, strength, quality and purity. Under the Prescription Drug User Fee Act (PDUFA) guidelines

that are currently in effect, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted.

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, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA will typically 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 and adequate to assure consistent production of the product within required specifications. Additionally, before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and 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. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act (PREA), requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and

administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited development and review programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product 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. A Fast Track product may also be eligible for rolling review, where the FDA may consider for 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.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. A product candidate can receive Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For new-molecular-entity NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date.

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other

clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval, but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug in the United States will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity 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.

Post-approval requirements

Drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors 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 cGMP, which impose certain procedural and

documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. 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;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending 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;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Other healthcare laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and

may constrain the financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other healthcare provider payment transparency laws and regulations. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Coverage and reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare reform

In March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 percent 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; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. The U.S. Supreme Court is currently reviewing the constitutionality of the ACA in its entirety. Although the U.S. Supreme Court has 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. Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which was temporarily suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, and reduced payments to several types of Medicare providers. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the President designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Individual states in the United States have also become increasingly active in 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.

Facilities

Our corporate headquarters are located in Redwood City, California, where we lease approximately 2,938 square feet of office space pursuant to a lease agreement which expires on August 31, 2021. We believe our existing facilities are adequate to meet our business requirements for the near-term, and that additional space will be available on commercially reasonable terms, if required.

Employees and human capital resources

As of December 31, 2020, we had 12 full-time employees, and 11 consultants, including five employees engaged in research and development activities. We believe we have good relationships with our employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

Legal proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Management

The following table sets forth information regarding our executive officers and directors as of January 31, 2021:

Name	Age	Position(s)
Executive Officers		
Thomas Butler	40	Chief Executive Officer, Co-Founder and Director
Rainer (Ramses) Erdtmann	57	President, Co-Founder and Director
Sunny Lee Ryan	51	Executive Vice President of Finance
Key Employees		
Thorsten Kirschberg	51	Executive Vice President of Chemistry
Heow Tan	61	Chief Technology and Quality Officer
Non-Employee Directors		
Eric Aguiar, M.D.	59	Director
Bihua Chen(4)	52	Director
John Kwon	47	Director
Sotirios Stergiopoulos, M.D.	49	Director

(1) Member of our audit committee.

(2) Member of our compensation committee.

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

(4) Ms. Chen is expected to resign from our board of directors prior to the effectiveness of the registration statement of which this prospectus is a part.

Executive officers

Thomas Butler co-founded Biomea Fusion in August 2017 and has served as our Chief Executive Officer and as a member of our board of directors since August 2018. He has also been a Managing Member of Point Sur Investors LLC, a biotech investment fund, since January 2016. From 2013 to 2015, Mr. Butler was Senior Manager of Investor Relations at Pharmacyclics Inc., a publicly-traded pharmaceutical company. Prior to joining Pharmacyclics, Mr. Butler was a medicinal chemist at Gilead Sciences Inc., a publicly-traded company, engaging in novel drug design and drug development of HCV polymerase and protease inhibitors, from 2007 to 2013. Mr. Butler holds a B.S. in Chemistry from California State University, Chico, an M.B.A. from the University of California, Los Angeles, and an M.S. in Organic Chemistry from the University of California, Santa Barbara. We believe that Mr. Butler is qualified to serve on our board of directors due to the valuable expertise and perspective he brings in his capacity as a co-founder and our Chief Executive Officer and because of his extensive experience and knowledge of our industry.

Ramses Erdtmann co-founded Biomea Fusion in August 2017 and has served as our President and as a member of our board of directors since September 2020. He has also been a Managing Member of Point Sur Investors LLC, a biotech investment fund, since January 2016. From 2008 to 2016, he held a number of leadership roles at Pharmacyclics Inc., a publicly-traded pharmaceutical company, including as the Principal Financial and Accounting Officer, and most recently, Executive Vice President of Corporate Affairs. Prior to joining Pharmacyclics, Mr. Erdtmann founded the asset management firm United Properties Immobilien and Anlagen Gmbh and Oxygen Investments, LLC, which he ran from its founding in 1995 to 2009. From 1992 to 1995,

Mr. Erdtmann worked at Commerzbank, Germany, where he was an investment banker and portfolio manager for institutional international accounts. Mr. Erdtmann currently serves on the board of directors of Summit, Inc., a publicly-traded biotechnology company and previously served on the board of directors of PolarityTE, Inc., a publicly-traded biotechnology and regenerative biomaterials company. Mr. Erdtmann holds a Diplom Kaufmann degree in Finance and Banking from the Westfaelische Wilhelms Universität of Muenster, Germany. We believe that Mr. Erdtmann is qualified to serve on our board of directors due to his perspective, experience and leadership as a co-founder and the President of our company.

Sunny Lee Ryan, CPA has served as our Executive Vice President of Finance since September 2020. From March 2016 to May 2020, Ms. Ryan was Vice President of Finance at Menlo Therapeutics Inc., a publicly-traded biopharmaceutical company, until it merged with Foamix Pharmaceuticals Ltd., a publicly-traded pharmaceutical company, in March 2020. Prior to joining Menlo Therapeutics, Ms. Ryan worked as an independent contractor from June 2013 to March 2016. From 2013 to 2014, Ms. Lee Ryan served as Interim Controller for Avalanche Biotechnologies, Inc., a publicly-traded biotechnology company. Ms. Ryan also worked from 2011 to 2012 as Controller at Alios BioPharma, Inc., a privately-held biopharmaceutical company, which was later acquired by Johnson and Johnson, Inc. From 2008 to 2011, Ms. Ryan worked at Achaogen, Inc., a then privately-held biopharmaceutical company, as Director of Finance and Controller. From 2006 to 2008, Ms. Ryan served as Senior Director of Finance and Controller at CoMentis, Inc., a privately-held biotechnology company. Ms. Ryan also worked as Controller at Rinat Neuroscience Corp. (acquired by Pfizer), a privately-held biotechnology company, from 2005 to 2006. She previously served as Senior Director of Finance and Controller from 2001 to 2005 at Genelabs Technologies, Inc., a publicly-traded biopharmaceutical company, which was later acquired by GlaxoSmithKline plc, a publicly-traded pharmaceutical company. From 1993 to 2001, Ms. Ryan worked as an auditor at PricewaterhouseCoopers, LLC in the Audit, Tax and Transaction Services practice. Ms. Ryan holds a B.S. in Accounting from Pepperdine University and is a Certified Public Accountant (Inactive).

Key employees

Thorsten Kirschberg has served as our Executive Vice President of Chemistry since September 2020. Prior to joining our company, from April 2017 to September 2020, he served as the Senior Director of Chemistry at Terns Pharmaceuticals, Inc., a then privately-held biopharmaceutical company. From July 2003 to April 2017, Mr. Kirschberg held various roles, most recently Senior Research Scientist II, at Gilead Sciences, Inc., a publicly-traded biopharmaceutical company. Prior to joining Gilead, Mr. Kirschberg was a Senior Scientist at CellGate, Inc., a privately-held pharmaceutical company, from 1993 to 2003. Mr. Kirschberg holds a B.S. in Chemistry and a Ph.D. in Organic Chemistry from the University of Münster and an M.B.A. from Golden Gate University. Mr. Kirschberg also conducted postdoctoral research at Stanford University.

Heow Tan has served as our Chief Technology and Quality Officer since November 2020. From May 2012 to November 2020, Mr. Tan was Chief Technology and Quality Officer at Pharmacyclics Inc., a publicly-traded pharmaceutical company. Prior to joining Pharmacyclics, Mr. Tan served from 2006 to 2012 as Senior Vice President, Technical Operations at Collegium Pharmaceutical, Inc., a then privately-held pharmaceutical company. Additionally, from 1998 to 2006, Mr. Tan was Vice President, Technical Operations and Development at Praecis Pharmaceuticals, Inc. a privately-held pharmaceutical company, which was subsequently acquired by GlaxoSmithKline plc, a publicly-traded pharmaceutical company. Mr. Tan holds a B.S. in Industrial and Systems Engineering and an M.S. in Engineering from The Ohio State University and an M.B.A. from Santa Clara University.

Non-employee directors

Eric Aguiar, M.D. has served as a member of our board of directors since December 2020. Dr. Aguiar has been a partner at Aisling Capital, a healthcare-focused venture fund, since January 2016. Prior to Aisling Capital, from October 2007 to December 2015, he was a partner at Thomas, McNerney and Partners, a healthcare venture

capital and growth equity fund. From 2001 to 2007, Dr. Aguiar was Managing Director of HealthCare Ventures, a healthcare-focused venture capital firm. Previously, Dr. Aguiar was Chief Executive Officer of Genovo, Inc., a privately-held biopharmaceutical company, from 1998 to 2000. Dr. Aguiar currently serves on the board of directors of Invitae Corporation and BridgeBio Pharma, Inc., both publicly-traded pharmaceutical companies. Dr. Aguiar previously served on the board of directors of numerous publicly-traded life sciences companies, including Biohaven Pharmaceuticals, Inc., Eidos Therapeutics, Inc. (prior to its merger with BridgeBio), and Amarin Corporation plc. Dr. Aguiar also served on the board of directors of privately-held Oriel Therapeutics, Inc. (prior to its acquisition by Novartis). Dr. Aguiar is also a member of the board of overseers of the Tufts School of Medicine and a member of the Council on Foreign Relations. Dr. Aguiar holds a B.A. in College Scholar from Cornell University, a M.D. from Harvard Medical School and is a Chartered Financial Analyst. We believe that Dr. Aguiar is qualified to serve on our board of directors due to his medical background and his extensive experience as an investor in biotechnology and pharmaceutical companies.

Bihua Chen has served as a member of our board of directors since December 2020. Ms. Chen is the founder of Cormorant Asset Management, LP, an investment firm focused on innovative biotechnology, medical technology and life science companies, and has managed Cormorant's hedge fund, as well as its private equity funds since its founding in February 2013. Prior to founding Cormorant, from 2005 to 2010, Ms. Chen served as a sub-adviser to Millennium Management LLC, a multi-strategy hedge fund. Previously, from 2001 to 2002, Ms. Chen was a healthcare analyst and sector portfolio manager for investment advisor American Express Asset Management. Ms. Chen also served as a portfolio manager for the Asterion Life Science Fund from 2001 to 2002, an equity analyst and portfolio manager for Bellevue Research from 2000 to 2001 and an equity analyst for Putnam Investments from 1998 to 2001. Ms. Chen currently serves on the board of directors of Atia Vision, U.S., a privately-held medical innovation hub. Ms. Chen holds a B.S. in Genetics and Genetic Engineering from Fudan University, Shanghai, China, an M.S. in Molecular Biology from the Graduate School of Biomedical Science at Cornell Medical College and an M.B.A. from the Wharton School of Business. We believe that Ms. Chen is qualified to serve on our board of directors due to her demonstrated leadership in her field, her experience as a board member of biotechnology and pharmaceutical companies and her experience as an investor in life sciences companies.

John Kwon has served as a member of our board of directors since December 2020. Since May 2019, Mr. Kwon has served as Managing Director at Clifton Capital LP, an investment fund based in the United Kingdom that focuses on early-stage biotechnology and technology ventures. Prior to joining Clifton Capital, he was a Senior Analyst at Sabby Management, LLC, a biotechnology focused investment fund, from April 2014 to April 2019. From 2012 to 2014, Mr. Kwon was a Managing Director at Stifel Nicolaus in Healthcare Investment Banking. Mr. Kwon also held various roles at Leerink Swann LLC from 2009 to 2012 and was an analyst at Neuberger Berman LLC, a privately-held investment management company, and at LibertyView Capital Management, LLC, a Lehman Brothers fund, from 2004 to 2008. Mr. Kwon holds a B.S. in Applied Science from the University of Pennsylvania. We believe Mr. Kwon is qualified to serve on our board of directors due to his demonstrated expertise as a life science investor, depth of knowledge in company creation and structure and experience as an investor in early-stage life science companies.

Sotirios Stergiopoulos, M.D. has served as a member of our board of directors since August 2017. Since July 2019, Dr. Stergiopoulos has been the President and Chief Executive Officer of A2A Pharmaceuticals, Inc., which is a privately-held biotechnology and pharmaceutical company. Prior to joining A2A, Dr. Stergiopoulos was the Chief Medical Officer, Senior Vice President and Head of Global Medical Affairs at Ipsen Pharmaceuticals, a publicly-traded biopharmaceutical company, from January 2017 to June 2019. From January 2016 to October 2016, Dr. Stergiopoulos was the Vice President and Head of Global Medical Affairs Oncology at Baxalta Incorporated (and then at Shire plc when it acquired Baxalta), both publicly-traded biopharmaceutical companies. From April 2014 to January 2016, Dr. Stergiopoulos was the Executive Director US Medical Affairs Oncology, Breast Disease Lead at Celgene Corporation, a publicly-traded biopharmaceutical company that was

later purchased by Bristol-Myers Squibb. From 2012 to 2014, Dr. Stergiopoulos served in numerous roles, most recently Senior Global Brand Medical Director-Oncology Medical Affairs and Development, at Novartis AG, a publicly-traded pharmaceutical company. Additionally, Dr. Stergiopoulos held several roles at Bayer Healthcare from 2009 to 2012, most recently Deputy Director, Global Medical Affairs Oncology, at Bayer HealthCare LLC, a subsidiary of publicly-traded pharmaceutical and life sciences company Bayer AG. Dr. Stergiopoulos continues to practice medicine as an Attending in Internal Medicine at Albert Einstein College of Medicine, which he has done since November 2011. Dr. Stergiopoulos currently serves as a member of the board of directors of Ricovr Healthcare Inc., a private oral diagnostic company. Dr. Stergiopoulos holds a B.S. in Biology from Stony Brook University, a Master of Biotechnology Enterprise and Entrepreneurship from The Johns Hopkins University and an M.D. from Poznan University of Medical Sciences. We believe that Dr. Stergiopoulos is qualified to serve on our board of directors due to his background as a practicing physician and extensive management and leadership experience in the biotechnology and pharmaceutical industries.

Family relationships

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

Board composition

Director independence

Our board of directors currently consists of six members. Our board of directors has determined that all of our directors, other than Mr. Butler and Mr. Erdtmann, qualify as independent directors in accordance with the listing rules of The Nasdaq Stock Market LLC, or the Listing Rules. Mr. Butler is not considered independent by virtue of his position as our Chief Executive Officer. Mr. Erdtmann is not considered independent by virtue of his position as our President. Under the Listing Rules, the definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Listing Rules, our board of directors has made a subjective determination as to each independent director that no relationship exists that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's relationships as they may relate to us and our management.

Classified board of directors

In accordance with our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- The Class I directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2022;
- The Class II directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- The Class III directors will be and , and their terms will expire at the annual meeting of stockholders to be held in 2024.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Voting arrangements

The election of the members of our board of directors is currently governed by the voting agreement that we entered into with certain holders of our common stock and convertible preferred stock and the related provisions of our amended and restated certificate of incorporation. Pursuant to our voting agreement and amended and restated certificate of incorporation, our current directors were elected as follows:

- Ms. Chen, Dr. Aguiar, Mr. Erdtmann, Dr. Stergiopoulos and Mr. Kwon were elected as the designees of the entities affiliated with Cormorant Asset Management LP, Aisling Capital V, LP, Biomea Healthcare, LLC, A2A Pharmaceuticals Inc., and Clifton Capital LP., respectively;
- Mr. Butler was elected and designated as our then serving and current Chief Executive Officer; and
- was designated by the mutual agreement of the Chief Executive Officer and the directors then serving as our independent director.

Our voting agreement will terminate and the provisions of our current amended and restated certificate of incorporation by which our directors were elected will be amended and restated in connection with this offering. After this offering, the number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the completion of this offering. Each of our current directors will continue to serve as a director until the election and qualification of his or her successor, or until his or her earlier resignation, removal or death.

Leadership structure of the board

Our amended and restated bylaws and corporate governance guidelines provide our board of directors with flexibility to combine or separate the positions of Chair of the board of directors and Chief Executive Officer.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of board in risk oversight process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings, and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the risks facing us. Throughout the year, senior management reviews these risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. While our board of directors is responsible for monitoring and assessing strategic risk exposure, our audit committee is responsible for overseeing our major financial risk exposures and the steps our management has taken to monitor and control these exposures. The audit committee also approves or disapproves any related person transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee intends to adopt a written charter that satisfies the applicable rules and regulations of the SEC and Listing Rules, which we will post on our website at www.biomeafusion.com upon the completion of this offering. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website.

Audit committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee:

- appoints our independent registered public accounting firm;
- evaluates the independent registered public accounting firm's qualifications, independence and performance;
- determines the engagement of the independent registered public accounting firm;
- reviews and approves the scope of the annual audit and pre-approves the audit and non-audit fees and services;
- reviews and approves all related party transactions on an ongoing basis;
- establishes procedures for the receipt, retention and treatment of any complaints received by us regarding accounting, internal accounting controls or auditing matters;
- discusses with management and the independent registered public accounting firm the results of the annual audit and the review of our quarterly financial statements;
- approves the retention of the independent registered public accounting firm to perform any proposed permissible non-audit services;
- discusses on a periodic basis, or as appropriate, with our management's policies and procedures with respect to risk assessment and risk management;
- consults with management to establish procedures and internal controls relating to cybersecurity;

- is responsible for reviewing our financial statements and our management's discussion and analysis of financial condition and results of operations to be included in our annual and quarterly reports to be filed with the SEC;
- investigates any reports received through the ethics helpline and reports to the board of directors periodically with respect to any information received through the ethics helpline and any related investigations; and
- reviews the audit committee charter and the audit committee's performance on an annual basis.

Our audit committee consists of , and . Our board of directors has determined that all members are independent under the Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is . Our board of directors has determined that is an audit committee financial expert as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements, in accordance with applicable requirements.

Compensation committee

Our compensation committee oversees policies relating to compensation and benefits of our officers and employees. The compensation committee reviews and approves or recommends corporate goals and objectives relevant to compensation of our executive officers (other than our Chief Executive Officer), evaluates the performance of these officers in light of those goals and objectives and approves the compensation of these officers based on such evaluations. The compensation committee also reviews and approves or makes recommendations to our board of directors regarding the issuance of stock options and other awards under our stock plans to our executive officers (other than our Chief Executive Officer). The compensation committee reviews the performance of our Chief Executive Officer and makes recommendations to our board of directors with respect to his compensation, and our board of directors retains the authority to make compensation decisions relative to our Chief Executive Officer. The compensation committee will review and evaluate, on an annual basis, the compensation committee charter and the compensation committee's performance.

Our compensation committee consists of , and . Our board of directors has determined that all members are independent under the Listing Rules and are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation committee is .

Nominating and corporate governance committee

Our nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the size and composition of our board of directors. In addition, the nominating and corporate governance committee is responsible for overseeing our corporate governance policies and making recommendations to our board of directors concerning governance matters.

Our nominating and corporate governance committee consists of , and . Our board of directors has determined that all members of the nominating and corporate governance committee are independent under the Listing Rules. The chair of our nominating and corporate governance committee is .

Compensation committee interlocks and insider participation

None of the members of our compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Board diversity

Upon consummation of this offering, our nominating and corporate governance committee will be responsible for reviewing with the board of directors, on an annual basis, the appropriate characteristics, skills and experience required for the board of directors as a whole and its individual members. In evaluating the suitability of individual candidates (both new candidates and current members), the nominating and corporate governance committee, in recommending candidates for election, and the board of directors, in approving (and, in the case of vacancies, appointing) such candidates, may take into account many factors, including but not limited to the following:

- personal and professional integrity;
- ethics and values;
- experience in corporate management, such as serving as an officer or former officer of a publicly held company;
- professional and academic experience relevant to our industry;
- experience as a board member of another publicly held company;
- strength of leadership skills;
- experience in finance and accounting and/or executive compensation practices;
- ability to devote the time required for preparation, participation and attendance at board of directors meetings and committee meetings, if applicable;
- background, gender, age and ethnicity;
- conflicts of interest; and
- ability to make mature business judgments.

Following the consummation of this offering, our board of directors will evaluate each individual in the context of the board of directors as a whole, with the objective of ensuring that the board of directors, as a whole, has the necessary tools to perform its oversight function effectively in light of our business and structure.

Code of business conduct and ethics

In connection with this offering, we intend to adopt a written code of business conduct and ethics that applies to all of our directors, officers and employees, including those officers responsible for financial reporting. The full text of our code of business conduct and ethics will be posted on our website at www.biomeafusion.com upon the completion of this offering. Any substantive amendment to, or waiver of, a provision of the code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions will be disclosed on our website.

Limitation on liability and indemnification matters

Our amended and restated certificate of incorporation and our amended and restated bylaws, both of which will become effective immediately prior to the completion of this offering, limit our directors' liability, and provide that we may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

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

Executive and director compensation

The following is a discussion and analysis of compensation arrangements of our named executive officers, or NEOs. This discussion contains forward looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt may differ materially from currently planned programs as summarized in this discussion. As an “emerging growth company” as defined in the JOBS Act, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to emerging growth companies.

We seek to ensure that the total compensation paid to our executive officers is reasonable and competitive. Compensation of our executives is structured around the achievement of individual performance and near-term corporate targets as well as long-term business objectives.

Our NEOs for fiscal year 2020 were as follows:

- Thomas Butler, Chief Executive Officer;
- Ramses Erdtmann, President; and
- Sunny Lee Ryan, Executive Vice President, Finance.

Mr. Butler and Mr. Erdtmann founded the company and worked at the company since its inception in August 2017. Mr. Butler became an employee of the company in August 2018, Mr. Erdtmann became an employee in September 2020 and Ms. Lee joined the company in September 2020.

2020 Summary compensation table

The following table sets forth total compensation paid to our NEOs for the fiscal year ending on December 31, 2020.

Name and principal position	Year	Salary ($)	Bonus[1] ($)	Stock awards[2] ($)	Total ($)
Thomas Butler, Chief Executive Officer	2020	228,750	134,400	1,153,215	1,516,365
Ramses Erdtmann, President	2020	14,773	21,420	270,690	306,883
Sunny Lee Ryan, Executive Vice President, Finance	2020	83,333	75,000	230,090	388,423

(1) For the bonus awards column, amounts shown represent the discretionary annual cash bonuses earned by our NEOs for their services during 2020. These amounts were paid to the NEOs after the company determined the achievement and were paid in December 2020. Please see the descriptions of the discretionary annual bonuses paid to our NEOs under “2020 Bonuses” below, including target amounts.

(2) For the stock awards column, amounts shown represents the grant date fair value of restricted stock during fiscal year 2020 after the conversion of the company from a limited liability company into a corporation as calculated in accordance with ASC Topic 718. See Note of the financial statements included in this registration statement for the assumptions used in calculating this amount.

Narrative to summary compensation table

2020 Salaries

Our NEOs each receive a base salary to compensate them for services rendered to our company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive’s

skill set, experience, role and responsibilities. For fiscal year 2020, Mr. Butler's base salary was $336,000 (effective as of his date of hire in July 2020), Mr. Erdtmann's base salary was $50,000 (effective as of his date of hire in September 2020) and Ms. Ryan's base salary was $250,000 (effective as of her date of hire in September 2020). Our board of directors and compensation committee may adjust base salaries from time to time in their discretion.

2020 Bonuses

For 2020, each of our NEOs is eligible to receive a discretionary annual cash bonus. Each NEO's target bonus is expressed as a percentage of his or her annual base salary which can be achieved by meeting company and individual goals as determined in the discretion of the company. The 2020 annual bonuses for Messrs. Butler and Erdtmann and Ms. Ryan were targeted at 40%, 43% and 30% of their respective base salaries. Our board of directors has historically reviewed these target percentages to ensure they are adequate, but does not follow a formula. Instead, our board of directors set these rates based on each NEO's experience in his or her role with us and the level of responsibility held by the NEO, which we believe directly correlates to his or her ability to influence corporate results.

Following its review and determinations of corporate and individual performance for 2020, our board of directors awarded each NEO a discretionary cash annual set forth above in the Summary compensation table in the column titled "Non-equity incentive plan compensation."

Equity-based compensation

In fiscal year 2020, we made equity award grants to each of our NEOs. In December 2020, in connection with the company's conversion for a limited liability company into a corporation, each NEO was granted an equivalent restricted stock award upon conversion of the profits interest units they previously held. Mr. Butler received 32,949 restricted shares, Mr. Erdtmann received 7,734 restricted shares and Ms. Ryan received 6,574 restricted shares. Each of the restricted stock awards vests as to 1/16th of the shares on each quarterly anniversary of the vesting commencement date, subject to the holder's continued service to the company through the applicable vesting date.

We intend to adopt a 2021 Incentive Award Plan, referred to below as the 2021 Plan, in order to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants of our company and certain of its affiliates and to enable us to obtain and retain services of these individuals, which is essential to our long-term success. We expect that the 2021 Plan will be effective on the date on which it is adopted by our board of directors, subject to approval of such plan by our stockholders. For additional information about the 2021 Plan, please see the section titled "—Equity compensation plans" below.

Other elements of compensation

We do not maintain any 401(k) plan or any other similar retirement plan.

All of our full-time employees, including our NEOs, are eligible to participate in our health and welfare plans, including medical, dental and vision benefits; medical and dependent care flexible spending accounts; short-term and long-term disability insurance; and life and AD&D insurance.

Perquisites and other personal benefits

We determine perquisites on a case-by-case basis and will provide a perquisite to an NEO when we believe it is necessary to attract or retain the NEO. In 2020, we did not provide any perquisites or personal benefits to our NEOs not otherwise made available to our other employees.

Outstanding equity awards at 2020 fiscal year end

The following table lists all outstanding equity awards held by our NEOs as of December 31, 2020.

		Stock awards	
Name	Vesting commencement date[1]	Number of shares that have not vested (#)	Market value of shares that have not vested ($)[2]
Thomas Butler	7/1/2020	28,830	1,309,170
Ramses Erdtmann	9/15/2020	7,251	329,268
Sunny Lee Ryan	9/1/2020	6,163	279,862

(1) Except as otherwise noted, the restricted stock vests as to 1/16th of the shares on each quarterly anniversary of the vesting commencement date, subject to the holder continuing to provide services to us through such vesting date.

(2) The market value of shares that have not vested is calculated based on the fair market value of our common stock as of December 31, 2020 which our board of directors determined to be $45.41.

Narrative to 2020 summary compensation table and outstanding equity awards at 2020 fiscal year end

Executive compensation arrangements

Employment agreements

We have entered into offer letters with each of our NEOs which sets forth an initial base salary, discretionary bonus and eligibility to participate in our benefit plans. Pursuant to the terms of such agreement and the accompanying proprietary information and inventions assignment agreement, each NEO is subject to indefinite confidentiality restrictions, standard intellectual property provisions and non-competition and customer non-solicitation restrictions during each NEOs employee and an employee non-solicitation restriction effective during and 12 months post-employment.

Equity compensation plans

The following summarizes the material terms of the long-term incentive compensation plan in which our named executive officers will be eligible to participate following the consummation of this offering and our 2020 Equity Incentive Plan (the “2020 Plan”), under which we have previously made periodic grants of equity and equity-based awards to our named executive officers and other key employees.

2021 Incentive Award Plan

We intend to adopt the 2021 Plan, which will be effective on the day prior to the first public trading date of our common stock. The principal purpose of the 2021 Plan is to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards. The material terms of the 2021 Plan, as it is currently contemplated, are summarized below.

Share reserve. Under the 2021 Plan, shares of our common stock will be initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, stock appreciation rights, or SARs, restricted stock awards, restricted stock unit awards and other stock-based awards. The number of shares initially reserved for issuance or transfer pursuant to awards under the 2021 Plan will be increased by an annual increase on the first day of each fiscal year beginning in 2022 and ending in 2031, equal to the lesser of (i) % of the shares of stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (ii) such smaller number of shares of stock as determined by our board of directors; provided, however, that no more than shares of stock may be issued upon the exercise of incentive stock options.

The following counting provisions will be in effect for the share reserve under the 2021 Plan:

- to the extent that an award terminates, expires or lapses for any reason or an award is settled in cash without the delivery of shares, any shares subject to the award at such time will be available for future grants under the 2021 Plan;
- to the extent shares are tendered or withheld to satisfy the grant, exercise price or tax withholding obligation with respect to any award under the 2021 Plan, such tendered or withheld shares will be available for future grants under the 2021 Plan;
- to the extent shares subject to stock appreciation rights are not issued in connection with the stock settlement of stock appreciation rights on exercise thereof, such shares will be available for future grants under the 2021 Plan;
- to the extent that shares of our common stock are repurchased by us prior to vesting so that shares are returned to us, such shares will be available for future grants under the 2021 Plan;
- the payment of dividend equivalents in cash in conjunction with any outstanding awards will not be counted against the shares available for issuance under the 2021 Plan; and
- to the extent permitted by applicable law or any exchange rule, shares issued in assumption of, or in substitution for, any outstanding awards of any entity acquired in any form of combination by us or any of our subsidiaries will not be counted against the shares available for issuance under the 2021 Plan.

Administration. The compensation committee of our board of directors is expected to administer the 2021 Plan unless our board of directors assumes authority for administration. The compensation committee must consist of at least three members of our board of directors, each of whom is intended to qualify as a “non-employee director” for purposes of Rule 16b-3 under the Exchange Act and an “independent director” within the meaning of the rules of the applicable stock exchange, or other principal securities market on which shares of our common stock are traded. The 2021 Plan provides that the board or compensation committee may delegate its authority to grant awards to employees other than executive officers and certain senior executives of the company to a committee consisting of one or more members of our board of directors or one or more of our officers, other than awards made to our non-employee directors, which must be approved by our full board of directors.

Subject to the terms and conditions of the 2021 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2021 Plan. The administrator is also authorized to adopt, amend or rescind rules relating to administration of the 2021 Plan. Our board of directors may at any time remove the compensation committee as the administrator and revest in itself the authority to administer the 2021 Plan. The full board of directors will administer the 2021 Plan with respect to awards to non-employee directors.

Eligibility. Options, SARs, restricted stock and all other stock-based and cash-based awards under the 2021 Plan may be granted to individuals who are then our officers, employees or consultants or are the officers, employees or consultants of certain of our subsidiaries. Such awards also may be granted to our directors. Only employees of our company or certain of our subsidiaries may be granted incentive stock options (ISOs).

Awards. The 2021 Plan provides that the administrator may grant or issue stock options, SARs, restricted stock, restricted stock units, other stock- or cash-based awards and dividend equivalents, or any combination thereof. Each award will be set forth in a separate agreement with the person receiving the award and will indicate the type, terms and conditions of the award.

- *Nonstatutory Stock Options* (NSOs) will provide for the right to purchase shares of our common stock at a specified price which may not be less than fair market value on the date of grant, and usually will become exercisable (at the discretion of the administrator) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of corporate performance targets and individual performance targets established by the administrator. NSOs may be granted for any term specified by the administrator that does not exceed ten years.
- *ISOs* will be designed in a manner intended to comply with the provisions of Section 422 of the Code and will be subject to specified restrictions contained in the Code. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, and must not be exercisable after a period of ten years measured from the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) at least 10% of the total combined voting power of all classes of our capital stock, the 2021 Plan provides that the exercise price must be at least 110% of the fair market value of a share of common stock on the date of grant and the ISO must not be exercisable after a period of five years measured from the date of grant.
- *Restricted Stock* may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted stock, typically, may be forfeited for no consideration or repurchased by us at the original purchase price if the conditions or restrictions on vesting are not met. In general, restricted stock may not be sold or otherwise transferred until restrictions are removed or expire. Purchasers of restricted stock, unlike recipients of options, will have voting rights and will have the right to receive dividends, if any, prior to the time when the restrictions lapse, however, extraordinary dividends will generally be placed in escrow, and will not be released until restrictions are removed or expire.
- *Restricted Stock Units* may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. Like restricted stock, restricted stock units may not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Unlike restricted stock, stock underlying restricted stock units will not be issued until the restricted stock units have vested, and recipients of restricted stock units generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied.
- *Stock Appreciation Rights* (SARs) may be granted in connection with stock options or other awards, or separately. SARs granted in connection with stock options or other awards typically will provide for payments to the holder based upon increases in the price of our common stock over a set exercise price. The exercise price of any SAR granted under the 2021 Plan must be at least 100% of the fair market value of a share of our common stock on the date of grant. SARs under the 2021 Plan will be settled in cash or shares of our common stock, or in a combination of both, at the election of the administrator.
- *Other Stock or Cash Based Awards* are awards of cash, fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include vesting conditions based on continued service, performance and/or other conditions.
- *Dividend Equivalents* represent the right to receive the equivalent value of dividends paid on shares of our common stock and may be granted alone or in tandem with awards other than stock options or SARs. Dividend equivalents are credited as of dividend payments dates during the period between a specified date

and the date such award terminates or expires, as determined by the plan administrator. In addition, dividend equivalents with respect to shares covered by a performance award will only be paid to the participant at the same time or times and to the same extent that the vesting conditions, if any, are subsequently satisfied and the performance award vests with respect to such shares.

Any award may be granted as a performance award, meaning that the award will be subject to vesting and/or payment based on the attainment of specified performance goals.

Change in control. In the event of a change in control, unless the plan administrator elects to terminate an award in exchange for cash, rights or other property, or cause an award to accelerate in full prior to the change in control, such award will continue in effect or be assumed or substituted by the acquirer, provided that any performance-based portion of the award will be subject to the terms and conditions of the applicable award agreement. In the event the acquirer refuses to assume or replace awards granted, prior to the consummation of such transaction, awards issued under the 2021 Plan will be subject to accelerated vesting such that 100% of such awards will become vested and exercisable or payable, as applicable. The administrator may also make appropriate adjustments to awards under the 2021 Plan and is authorized to provide for the acceleration, cash-out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions.

Adjustments of awards. In the event of any stock dividend or other distribution, stock split, reverse stock split, reorganization, combination or exchange of shares, merger, consolidation, split-up, spin-off, recapitalization, repurchase or any other corporate event affecting the number of outstanding shares of our common stock or the share price of our common stock that would require adjustments to the 2021 Plan or any awards under the 2021 Plan in order to prevent the dilution or of the potential benefits intended to be made available thereunder, the administrator will make appropriate, proportionate adjustments to: (i) the aggregate number and type of shares subject to the 2021 Plan; (ii) the number and kind of shares subject to outstanding awards and terms and conditions of outstanding awards (including, without limitation, any applicable performance targets or criteria with respect to such awards); and (iii) the grant or exercise price per share of any outstanding awards under the 2021 Plan.

Amendment and termination. The administrator may terminate, amend or modify the 2021 Plan at any time and from time to time. However, we must generally obtain stockholder approval to the extent required by applicable law, rule or regulation (including any applicable stock exchange rule). Notwithstanding the foregoing, an option may be amended to reduce the per share exercise price below the per share exercise price of such option on the grant date and options may be granted in exchange for, or in connection with, the cancellation or surrender of options having a higher per share exercise price without receiving additional stockholder approval.

No incentive stock options may be granted pursuant to the 2021 Plan after the tenth anniversary of the effective date of the 2021 Plan, and no additional annual share increases to the 2021 Plan's aggregate share limit will occur from and after such anniversary. Any award that is outstanding on the termination date of the 2021 Plan will remain in force according to the terms of the 2021 Plan and the applicable award agreement.

2021 Employee Stock Purchase Plan

We intend to adopt and ask our stockholders to approve the 2021 Employee Stock Purchase Plan, which we refer to as our ESPP, which will be effective upon the day prior to the effectiveness of the registration statement to which this prospectus relates. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at semi-annual intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code. The material terms of the ESPP, as it is currently contemplated, are summarized below.

Administration. Subject to the terms and conditions of the ESPP, our compensation committee will administer the ESPP. Our compensation committee can delegate administrative tasks under the ESPP to the services of an agent and/or employees to assist in the administration of the ESPP. The administrator will have the discretionary authority to administer and interpret the ESPP. Interpretations and constructions of the administrator of any provision of the ESPP or of any rights thereunder will be conclusive and binding on all persons. We will bear all expenses and liabilities incurred by the ESPP administrator.

Share reserve. The maximum number of shares of our common stock which will be authorized for sale under the ESPP is equal to the sum of (i) shares of common stock and (ii) an annual increase on the first day of each year beginning in 2022 and ending in 2031, equal to the lesser of (1) 1% of the shares of common stock outstanding (on an as converted basis) on the last day of the immediately preceding fiscal year and (2) such number of shares of common stock as determined by our board of directors; provided, however, no more than shares of our common stock may be issued under the ESPP. The shares reserved for issuance under the ESPP may be authorized but unissued shares or reacquired shares.

Eligibility. Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our subsidiaries on the first day of the offering period, or the enrollment date. Our employees (and, if applicable, any employees of our subsidiaries) who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (or is deemed to own through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation. Employees will enroll under the ESPP by completing a payroll deduction form permitting the deduction from their compensation of at least 1% of their compensation but not more than the lesser of 15% of their compensation or $50,000. Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount, and the accumulated deductions will be applied to the purchase of shares on each purchase date. However, a participant may not purchase more than 15,000 shares in each offering period and may not subscribe for more than $25,000 in fair market value of shares of our common stock (determined at the time the option is granted) during any calendar year. The ESPP administrator has the authority to change these limitations for any subsequent offering period.

Offering. Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, the duration and timing of which will be determined by the ESPP administrator. However, in no event may an offering period be longer than 27 months in length.

The option purchase price will be the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each offering period.

Unless a participant has previously canceled his or her participation in the ESPP before the purchase date, the participant will be deemed to have exercised his or her option in full as of each purchase date. Upon exercise, the participant will purchase the number of whole shares that his or her accumulated payroll deductions will buy at the option purchase price, subject to the participation limitations listed above.

A participant may cancel his or her payroll deduction authorization at any time prior to the end of the offering period. Upon cancellation, the participant will have the option to either (i) receive a refund of the participant's account balance in cash without interest or (ii) exercise the participant's option for the current offering period for the maximum number of shares of common stock on the applicable purchase date, with the remaining account balance refunded in cash without interest. Following at least one payroll deduction, a participant may also decrease (but not increase) his or her payroll deduction authorization once during any offering period. If a

participant wants to increase or decrease the rate of payroll withholding, he or she may do so effective for the next offering period by submitting a new form before the offering period for which such change is to be effective.

A participant may not assign, transfer, pledge or otherwise dispose of (other than by will or the laws of descent and distribution) payroll deductions credited to a participant's account or any rights to exercise an option or to receive shares of our common stock under the ESPP, and during a participant's lifetime, options in the ESPP shall be exercisable only by such participant. Any such attempt at assignment, transfer, pledge or other disposition will not be given effect.

Adjustments upon changes in recapitalization, dissolution, liquidation, merger or asset sale. In the event of any increase or decrease in the number of issued shares of our common stock resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the common stock, or any other increase or decrease in the number of shares of common stock effected without receipt of consideration by us, we will proportionately adjust the aggregate number of shares of our common stock offered under the ESPP, the number and price of shares which any participant has elected to purchase under the ESPP and the maximum number of shares which a participant may elect to purchase in any single offering period. If there is a proposal to dissolve or liquidate us, then the ESPP will terminate immediately prior to the consummation of such proposed dissolution or liquidation, and any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our dissolution or liquidation. We will notify each participant of such change in writing at least ten business days prior to the new exercise date. If we undergo a merger with or into another corporation or sell all or substantially all of our assets, each outstanding option will be assumed or an equivalent option substituted by the successor corporation or the parent or subsidiary of the successor corporation. If the successor corporation refuses to assume the outstanding options or substitute equivalent options, then any offering period then in progress will be shortened by setting a new purchase date to take place before the date of our proposed sale or merger. We will notify each participant of such change in writing at least ten business days prior to the new exercise date.

Amendment and termination. Our board of directors may amend, suspend or terminate the ESPP at any time. However, the board of directors may not amend the ESPP without obtaining stockholder approval within 12 months before or after such amendment to the extent required by applicable laws.

2020 Equity Incentive Plan

Our board of directors adopted the 2020 Plan on December 18, 2020. Following this offering, and in connection with the effectiveness of our 2020 Plan, no further awards will be granted under the 2020 Plan. However, all outstanding awards under the 2020 Plan will continue to be governed by their existing terms under the 2020 Plan. Upon the circumstances set forth under the description of our 2021 Plan, shares subject to outstanding awards under the 2020 Plan will be added to the share reserve of the 2021 Plan. The purpose of the 2020 Plan is to attract, retain and motivate eligible persons whose present and potential contributions are important to our success by offering eligible persons an opportunity to participate in the 2020 Plan.

Share reserve. Under the 2020 Plan, we have previously reserved 489,570 shares of common stock. Upon the effectiveness of the 2021 Plan, no additional stock awards may be granted under the 2020 Plan. Any equity awards granted under the 2020 Plan will remain subject to the terms of the 2020 Plan and applicable award agreement, until such outstanding awards that are stock options are exercised, terminate or expire by their terms, and until any restricted stock awards become vested, terminate or are forfeited.

Administration. Our board of directors or a committee appointed by our board of directors, acts as the administrator of the 2020 Plan. The 2020 Plan provides that the board may delegate its authority to grant to a committee consisting of one or more members of our board of directors or one or more of our officers so long

as such officer is a member of the board, other than awards made to our non-employee directors, which must be approved by our full board of directors. Subject to the terms and conditions of the 2020 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the number of shares to be subject to awards and the terms and conditions of awards, and to make all other determinations and to take all other actions necessary or advisable for the administration of the 2020 Plan. The administrator has the full power to implement and carry out the 2020 Plan.

Eligibility. Options, restricted stock, restricted stock units and other stock-based awards under the 2020 Plan may be granted to officers, employees, directors and consultants of the Company and its affiliates. Only employees of our company or certain of our subsidiaries may be granted ISOs.

Awards. The 2020 Plan provides for the grant or issue of stock options (both incentive and nonstatutory stock options), restricted stock, restricted stock units, other stock- or cash-based awards and dividend equivalents, or any combination thereof. Each award is set forth in a separate agreement with the person receiving the award which indicates the type, terms and conditions of the award.

Adjustments of awards. In the event that the number of outstanding shares of our common stock is changed by a stock dividend, recapitalization, stock split, reverse stock split, subdivision, combination, reclassification or similar change in our capital structure without consideration, then (i) the number of shares of common stock reserved for issuance under the 2020 Plan, (ii) the number and kind of shares of common stock subject to outstanding awards, (iii) the exercise prices of and number of shares subject to outstanding options and (iv) the terms and conditions of any awards, including, any applicable financial or performance targets specified in an award agreement will be proportionately adjusted.

Change in control. In the event of a change in control, unless the administrator elects to terminate an award (including in exchange for cash, rights or other property) or cause an award to accelerate in full prior to the change in control, such award will continue in effect or be assumed or substituted by the acquirer. The administrator may also make appropriate adjustments to awards under the 2020 Plan and is authorized to provide for the acceleration, cash- out, termination, assumption, substitution or conversion of such awards in the event of a change in control or certain other unusual or nonrecurring events or transactions.

Amendment and termination. The administrator may terminate or amend the 2020 Plan at any time and from time to time. However, we must generally obtain stockholder approval to the extent required by applicable law.

Director compensation

Historically, we have not had a formalized non-employee director compensation program, we did not compensation our non-employee directors for their service on our board of directors and we did not pay director fees to our directors who are our employees. However, we provide reimbursement to our non-employee directors for their reasonable expenses incurred in attending meetings of our board of directors and committees of our board of directors. None of our non-employee directors received any compensation or equity awards in 2020 for their service on our board. As of the year ended December 31, 2020, none of our non-employee directors held any options to purchase our common stock or other equity awards

We intend to approve and implement a compensation policy for our non-employee directors to be effective on the consummation of this offering.

Certain relationships and related party transactions

The following includes a summary of transactions since January 1, 2018 and any currently proposed transactions to which we were or are expected to be a participant in which (i) the amount involved exceeded or will exceed $120,000, and (ii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any affiliate or member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled “Executive and director compensation.”

Certain transactions with A2A Pharmaceuticals, Inc. and Biomea Healthcare, LLC

Between August 2017 and June 2020, A2A Pharmaceuticals, Inc. and Biomea Healthcare, LLC contributed a combined $3.1 million to the company in exchange for 1,074,980 shares of our common stock. Each of Mr. Butler, our Chief Executive Officer, Co-Founder and a member of our board of directors, and Mr. Erdtmann, our President, Co-Founder and a member of our board of directors, own a controlling interest in Biomea Healthcare, LLC, and Mr. Stergiopoulos, M.D., a member of our board of directors, is an affiliate of A2A Pharmaceuticals Inc.

Series A convertible preferred stock financing

In December 2020, we entered into a Series A convertible preferred stock purchase agreement with various investors, pursuant to which we issued an aggregate of 799,200 shares of Series A convertible preferred stock at $70.07 per share for gross proceeds of approximately $56.0 million in two closings. The first closing occurred in December 2020, at which time we issued 795,688 shares of our Series A convertible preferred stock for gross proceeds of approximately $55.8 million. The second closing also occurred in December 2020, at which time we issued an additional 3,512 shares of our Series A convertible preferred stock for gross proceeds of approximately $0.25 million.

The table below sets forth the number of shares of our Series A convertible preferred stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members. Each share of Series A convertible preferred stock in the table below will convert into one share of our common stock upon the completion of this offering.

Name[1]	Series A convertible preferred stock (#)	Aggregate cash purchase price ($)
Entities affiliated with Cormorant Asset Management[2]	256,886	18,000,000
Entities affiliated with Tavistock Group[3]	142,714	10,000,000
Aisling Capital V, LP[4]	57,086	4,000,000
Point Sur Investors LLC[5]	28,543	2,000,000
Clifton Capital LP[6]	14,271	1,000,000

(1) For additional information regarding these stockholders and their equity holdings, see the section titled “Principal stockholders.”

(2) Entities affiliated with Cormorant Asset Management became beneficial owners of (in the aggregate) more than 5% of our outstanding capital stock upon the closing of the Series A convertible preferred stock financing. Ms. Bihua Chen was designated to serve as a member of our board of directors by Cormorant Asset Management effective immediately upon the consummation of such financing. Ms. Chen is the founder and managing partner of Cormorant Asset Management.

(3) Entities affiliated with Tavistock Group became beneficial owners of (in the aggregate) more than 5% of our outstanding capital stock upon the closing of the Series A convertible preferred stock financing.

(4) Dr. Aguiar was designated to serve as a member of our board of directors by Aisling Capital V, LP effective immediately upon the consummation of the Series A convertible preferred stock financing. Dr. Aguiar is a partner at Aisling Capital.

(5) Point Sur Investors LLC is affiliated with Mr. Thomas Butler and Mr. Ramses Erdtmann, who are both currently, and were at the time of the Series A convertible preferred stock financing, members of our board of directors. Mr. Butler and Mr. Erdtmann are both partners at Point Sur Investors.

(6) Mr. John Kwon is currently, and was at the time of the Series A convertible preferred stock financing, a member of our board of directors. Mr. Kwon was designated to serve as a member of our board of directors by Clifton Capital LP. Mr. Kwon is a partner at Clifton Capital LP.

Common stock financing

In June 2020, we entered into a series of purchase agreements with various investors, pursuant to which we issued an aggregate of 268,745 shares of common stock at $37.21 per share for gross proceeds of approximately $10.0 million in two closings. The first closing occurred in June 2020, at which time we issued 251,277 shares of our common stock for gross proceeds of approximately $9.4 million. The second closing occurred in October 2020, at which time we issued an additional 17,468 shares of our common stock for gross proceeds of approximately $0.7 million.

The table below sets forth the number of shares of our common stock purchased by our executive officers, directors, holders of more than 5% of our capital stock and their affiliated entities or immediate family members.

Name[1]	Common stock (#)	Aggregate cash purchase price ($)
Clifton Capital LP[2]	86,672	3,000,000
John Kwon[2]	10,184	352,500

(1) For additional information regarding these stockholders and their equity holdings, see the section titled “Principal stockholders.”

(2) Mr. John Kwon is currently, and was at the time of the common unit financing, a member of our board of directors. Mr. Kwon was designated to serve as a member of our board of directors by Clifton Capital LP. Mr. Kwon is a partner at Clifton Capital LP.

Investors’ rights agreement

In December 2020, we entered into an investors’ rights agreement with the purchasers of our outstanding convertible preferred stock, including entities with which our directors, Eric Aguiar, Bihuan Chen and John Kwon are affiliated. Following the consummation of this offering, the holders of approximately shares of our common stock, including the shares of common stock issuable upon the conversion of our Series A convertible preferred stock, are entitled to rights with respect to the registration of their shares under the Securities Act. For a more detailed description of these registration rights, see the section titled “Description of capital stock—Registration rights.” The investors’ rights agreement also provides for a right of first offer in favor of certain holders of convertible preferred stock with regard to certain issuances of our capital stock. The rights of first offer will not apply to, and will terminate immediately prior to the consummation of, this offering.

Voting agreement

In December 2020, we entered into a voting agreement with certain holders of our common stock and convertible preferred stock. Upon the consummation of this offering, the voting agreement will terminate. For a description of the voting agreement, see the section titled “Management—Board composition—Voting arrangements.”

Right of first refusal and co-sale agreement

In December 2020, we entered into a right of first refusal and co-sale agreement with certain holders of our common stock and convertible preferred stock. This agreement provides for rights of first refusal and co-sale

relating to the shares of our common stock held by the parties to the agreement. Immediately prior to the consummation of this offering, the right of first refusal and co-sale agreement will terminate.

Executive officer and director compensation

See the section titled “Executive and director compensation” for information regarding the compensation of our named executive officers.

Employment agreements

We have entered into offer letter agreements with our executive officers that, among other things, provide for certain compensatory and change in control benefits, as well as severance benefits. For a description of these agreements with our named executive officers, see the section titled “Executive and director compensation— Executive compensation arrangements.”

Indemnification agreements

We have entered into indemnification agreements with certain of our current directors and officers, and intend to enter into new indemnification agreements with each of our current directors and officers before the completion of this offering. Our amended and restated certificate of incorporation and our amended and restated bylaws provide that we will indemnify our directors and officers to the fullest extent permitted by applicable law. See the section titled “Management—Limitation on liability and indemnification matters.”

Policies and procedures for related person transactions

Prior to the consummation of this offering, our board of directors will adopt a written related person transaction policy, to be effective upon the consummation of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including without limitation purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including but not limited to whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction with an unrelated third party and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

Principal stockholders

The following table sets forth, as of January 31, 2021, information regarding beneficial ownership of our capital stock by:

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

The percentage ownership information under the column titled “Before offering” is based on 2,236,186 shares of common stock outstanding as of January 31, 2021 assuming the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 799,200 shares of common stock upon the completion of this offering. The percentage ownership information under the column titled “After Offering” is based on the sale of shares of common stock in this offering. The percentage ownership information assumes no exercise of the underwriters’ option to purchase additional shares. In addition, the following table does not reflect any shares of common stock that may be purchased in this offering.

Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power of that security. In addition, shares of common stock issuable upon the exercise of stock options or warrants that are currently exercisable or exercisable within 60 days of January 31, 2021 are included in the following table. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants 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. The information contained in the following table does not necessarily indicate beneficial ownership for any other purpose. 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, subject to applicable community property laws.

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Biomea Fusion, Inc., 726 Main Street, Redwood City, California 94063.

Name of beneficial owner	Number of shares beneficially owned (#)	Percentage of shares beneficially owned: Before offering (%)	Percentage of shares beneficially owned: After offering (%)
Greater than 5% Stockholders:			
Biomea Healthcare, LLC(1)	493,817	22.1	
A2A Pharmaceuticals Inc.(2)	493,817	22.1	
Entities affiliated with Cormorant Asset Management(3)	256,886	11.5	
Entities affiliated with Tavistock Group(4)	142,714	6.4	
Named Executive Officers and Directors:			
Thomas Butler(5)	296,834	13.2	
Ramses Erdtmann(6)	266,929	11.9	
Sunny Lee Ryan(7)	7,314	*	
Eric Aguiar, M.D.(8)	57,086	2.6	
Bihua Chen(9)	256,886	11.5	
John Kwon(10)	10,184	*	
Sotirios Stergiopoulos, M.D.(11)	493,817	22.1	
All executive officers and directors as a group (seven persons)(12)	1,389,050		

* Represents beneficial ownership of less than 1%.

(1) Consists of 493,817 shares of our common stock. Each of Mr. Butler, our Chief Executive Officer, Co-Founder and a member of our board of directors, and Mr. Erdtmann, our President, Co-Founder and a member of our board of directors, own a controlling interest in Biomea Healthcare, LLC and may be deemed to share voting and dispositive power over shares held by Biomea Healthcare, LLC. The principal address for Biomea Healthcare, LLC is 1073 Arlington Blvd., El Cerrito, California 94530.

(2) Consists of 493,817 shares of our common stock. Mr. Stergiopoulos, M.D., is an affiliate of A2A Pharmaceuticals Inc. The board of directors of A2A Pharmaceuticals Inc. has sole voting and investment control and power over such securities. The principal address for A2A Pharmaceuticals Inc. is 180 Varick Street, New York, New York 10014.

(3) Consists of (i) 194,257 shares of our common stock issuable upon conversion of our Series A preferred stock directly held by Cormorant Private Healthcare Fund III, LP, (ii) 58,493 shares of our common stock issuable upon conversion of our Series A preferred stock directly held by Cormorant Global Healthcare Master Fund, LP and (iii) 4,136 shares of our common stock issuable upon conversion of our Series A preferred stock directly held by CRMA SPV, L.P. Cormorant Asset Management LP is the investment manager to Cormorant Private Healthcare Fund III, LP, Cormorant Global Healthcare Master Fund, LP and CRMA SPV, L.P., and, in such capacity, exercises shared voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management and may be deemed to beneficially own such securities. Bihua Chen serves as the managing member of Cormorant Asset Management LP and as such shares voting and dispositive power over the securities held by the entities affiliated with Cormorant Asset Management. The principal address for the Cormorant Asset Management LP entities is 200 Clarendon Street 52nd Floor, Boston, Massachusetts 02116.

(4) Consists of (i) 134,435 shares of our common stock issuable upon conversion of our Series A preferred stock directly held by Boxer Capital, LLC (“Boxer Capital”), for which Boxer Capital, Boxer Asset Management Inc. (“Boxer Management”) and Joe Lewis hold shared voting power and shared dispositive power, and (ii) 8,279 shares of our common stock issuable upon conversion of our Series A preferred stock directly held by MVA Investors, LLC (“MVA Investors”), for which MVA Investors and Aaron Davis hold shared voting power and shared dispositive power. Boxer Management is the managing member and majority owner of Boxer Capital. Joe Lewis is the sole indirect beneficial owner of and controls Boxer Management. MVA Investors is the independent, personal investment vehicle of certain employees of Boxer Capital. Aaron Davis is a member of and has voting and dispositive power over securities held by MVA Investors. The principal address for Boxer Capital, MVA Investors and Aaron Davis is 12860 El Camino Real, Suite 300, San Diego, CA 92130. The principal address of Boxer Management and Joe Lewis is Cay House, EP Taylor Drive N7776, Lyford Cay, New Providence, Bahamas.

(5) Consists of (i) 246,908 shares of our common stock described in footnote (1) above, (ii) 11,417 shares of our common stock directly held by Point Sur Investors LLC, (iii) 32,949 shares of our common stock issued pursuant to the grant of restricted stock awards and (iv) 5,560 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of January 31, 2021. Mr. Butler, our Chief Executive Officer, Co-Founder and a member of our board of directors, is employed as a Managing Member at Point Sur Investors LLC.

(6) Consists of (i) 246,908 shares of our common stock described in footnote (1) above, (ii) 11,417 shares of our common stock directly held by Point Sur Investors LLC, (iii) 7,734 shares of our common stock issued pursuant to the grant of restricted stock awards and (iv) 870 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of January 31, 2021. Mr. Erdtmann, our President, Co-Founder and a member of our board of directors, is as a Managing Member at Point Sur Investors LLC.

(7) Consists of 6,574 shares of our common stock issued under restricted stock awards and 740 shares of our common stock that may be acquired pursuant to the exercise of stock options issuable upon conversion within 60 days of January 31, 2021.

(8) Consists of 57,086 shares of common stock directly held by Aisling Capital V, LP. The principal address for Aisling Capital V, LP is 888 Seventh Avenue, 12th Floor, New York, NY 10106. Dr. Aguiar, a member of our board of directors, is employed as a Partner at Aisling Capital, which is investment manager of Aisling Capital V, LP. Dr. Aguiar disclaims beneficial ownership of all such shares except to the extent of his pecuniary interests therein.

(9) Consists of the shares described in footnote (3) above.

(10) Consists of 10,184 shares of our common stock. Mr. Kwon, a member of our board of directors, is employed as a Partner at Clifton Capital LP. Mr. Kwon disclaims ownership of any shares of common stock owned directly or indirectly by Clifton Capital LP.

(11) Consists of the shares described in footnote (2) above.

(12) Consists of (i) 1,381,880 shares held by our current directors and executive officers and (ii) 7,170 shares subject to options exercisable within 60 days of January 31, 2021.

Description of capital stock

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, the investors' rights agreement to which we and certain of our stockholders are parties and of the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and investors' rights agreement, copies of which have been filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation, 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.

Common stock

Outstanding shares

As of December 31, 2020, we had shares of common stock outstanding, held of record by stockholders, assuming the conversion of all of our outstanding shares of convertible preferred stock into shares of common stock in connection with the completion of this offering.

Voting rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66-2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights and preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully paid and nonassessable

All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred stock

Upon the completion of this offering, all of our currently outstanding shares of convertible preferred stock will convert into common stock and we will not have any shares of preferred stock outstanding. Immediately prior to the completion of this offering, our amended and restated certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. From and after the consummation 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 our 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.

Stock options

As of December 31, 2020, we had no outstanding options to purchase shares of our common stock. For additional information regarding terms of our equity incentive plans, see the section titled “Executive and director compensation—Equity incentive plans.”

Registration rights

Upon the completion of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our investors’ rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will terminate upon the earliest of (i) with respect to each stockholder, such date, on or after the completion of this offering, on which all registrable shares held by such stockholder may immediately be sold during any 90-day period pursuant to Rule 144 of the Securities Act (Rule 144), and (ii) the occurrence of a deemed liquidation event, as defined in our amended and restated certificate of incorporation, as currently in effect.

Demand registration rights

Upon the completion of this offering, holders of up to shares of our common stock issuable upon conversion of outstanding convertible preferred stock will be entitled to certain demand registration rights. Beginning 180 days following the effectiveness of the registration statement of which this prospectus is a part, certain major investors holding, collectively, 40% of registrable securities, or a lesser percent if the anticipated aggregate offering price exceeds $15.0 million, net of selling expenses, may request that we register all or a portion of their shares, subject to certain specified exceptions. If any of these holders exercises its demand registration rights, then holders of shares of our common stock issuable upon the shares of our convertible preferred stock in connection with this offering will be entitled to register their shares, subject to specified conditions and limitations in the corresponding offering.

Piggyback registration rights

In connection with this offering, holders of up to shares of our common stock issuable upon conversion of outstanding convertible preferred stock are entitled to their rights to notice of this offering and to include their shares of registrable securities in this offering. The requisite percentage of these stockholders are expected to waive all such stockholders' rights to notice of this offering and to include their shares of registrable securities in this offering. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

S-3 registration rights

Upon the completion of this offering, the holders of shares of our common stock issuable upon conversion of outstanding convertible preferred stock will initially be entitled to certain Form S-3 registration rights. Certain major investors holding at least 20% of registrable securities may, on not more than two registrations on Form S-3 within any 12-month period, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds $5.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Anti-takeover effects of provisions of delaware law and our amended and restated certificate of incorporation and amended and restated bylaws

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective immediately prior to the completion of this offering contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and

directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware anti-takeover statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed “interested stockholders” from engaging in a “business combination” with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Undesignated preferred stock

The ability to authorize undesignated preferred stock will make it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

Special stockholder meetings

Our amended and restated certificate of incorporation will provide that a special meeting of stockholders may be called at any time by our board of directors, but such special meetings may not be called by the stockholders or any other person or persons.

Requirements for advance notification of stockholder nominations and proposals

Our amended and restated bylaws will establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of stockholder action by written consent

Our amended and restated certificate of incorporation will eliminate the right of stockholders to act by written consent without a meeting.

Classified board; election and removal of directors; filling vacancies

Effective upon the consummation of this offering, our board of directors will be divided into three classes, divided as nearly as equal in number as possible. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation will provide for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66-2/3% of the voting power of the then outstanding voting stock. For more information on the classified board, see the section titled "Management—Board composition." Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders.

This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

Choice of forum

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws (as either may be amended from time to time); or any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide that the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware, or a Foreign Action, in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such

stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation and amended and restated bylaws will contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder.

Amendment of charter provisions

The amendment of any of the above provisions in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue undesignated preferred stock, would require approval by a stockholder vote by the holders of at least a 66-2/3% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitation on liability and indemnification

For a discussion of limitation on liability and indemnification, see the section titled "Management—Limitation on liability and indemnification matters."

Nasdaq global market listing

We have applied to list our common stock on the Nasdaq Global Market under the trading symbol "BMEA."

Transfer agent and registrar

Upon completion of this offering, the transfer agent and registrar for our common stock will be . The transfer agent and registrar's address is .

Shares eligible for future sale

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of our common stock, including shares issued upon the exercise of outstanding options, in the public market after the completion of this offering, or the perception that those sales may occur, could adversely affect the prevailing market price for our common stock from time to time or impair our ability to raise equity capital in the future. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after the completion of this offering due to contractual and legal restrictions on resale described below. Future sales of our common stock in the public market either before or after restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price of our common stock at such time and our ability to raise equity capital at a time and price we deem appropriate.

Sale of restricted shares

Based on the number of shares of our common stock outstanding as of December 31, 2020, upon the completion of this offering and (i) assuming the conversion of all of our outstanding convertible preferred stock into an aggregate of 799,200 shares of our common stock in connection with the completion of this offering, (ii) assuming no exercise of the underwriters' option to purchase additional shares of common stock and (iii) assuming no exercise of outstanding options, we will have outstanding an aggregate of approximately shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our "affiliates" as such term is defined in Rule 144, or subject to lock-up agreements. All remaining shares of common stock held by existing stockholders immediately prior to the consummation of this offering will be "restricted securities," as such term is defined in Rule 144. 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 of the Securities Act (Rule 701), which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701, based on the number of shares of our common stock outstanding (calculated as of December 31, 2020 on the basis of the assumptions described above), the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

Approximate number of shares	First date available for sale into public market
shares	181 days after the date of this prospectus, upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume, manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2021 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Rule 144

Under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, and we are current in our Exchange Act reporting at the time of sale, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the 90 days preceding a sale and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell those shares in the public market (subject to the lock-up agreement referred to below, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than "affiliates," then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to below, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our "affiliates," as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months, are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those shares of our common stock that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately shares of common stock immediately upon the completion of this offering (calculated as of December 31, 2020 on the basis of the assumptions described above); or
- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling shares on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and requirements related to the availability of current public information about us. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who acquired common stock from us in connection with a written compensatory stock or option plan or other written agreement in compliance with Rule 701 before the effective date of the registration statement of which this prospectus is a part (to the extent such common stock is not subject to a lock-up agreement) and who are not our "affiliates" as defined in Rule 144 during the immediately preceding 90 days, is entitled to rely on Rule 701 to resell such shares beginning 90 days after the date of this prospectus in reliance on Rule 144, but without complying with the notice, manner of sale, public information requirements or volume limitation

provisions of Rule 144. Persons who are our “affiliates” may resell those shares beginning 90 days after the date of this prospectus without compliance with minimum holding period requirements under Rule 144 (subject to the terms of the lock-up agreement referred to below, if applicable).

Lock-up and market standoff agreements

In connection with this offering, we, our directors, our executive officers and holders of substantially all of our securities have agreed, subject to certain limited exceptions, with the underwriters not to, among other things, directly or indirectly 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, make any short sale or otherwise transfer or dispose of any shares of our common stock or any securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives, and certain other limited exceptions. These agreements are described in the section titled “Underwriting.”

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors’ rights agreement, our standard form of option agreement, our standard form of restricted stock agreement and our standard form of restricted stock purchase agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

Registration rights

Upon the completion of this offering, the holders of up to 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 under “—Lock-up and market standoff agreements” 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, immediately upon the effectiveness of the registration statement of which this prospectus is a part. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. The requisite percentage of these stockholders will waive all such stockholders’ rights to notice of this offering and to include their shares of registrable securities in this offering. See the section titled “Description of capital stock—Registration rights.”

Equity incentive plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under our 2021 Plan and our ESPP. Such registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

Material U.S. federal income tax consequences to non-U.S. holders

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the "IRS"), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold 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 U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income, the alternative minimum tax provisions of the Code, or the special tax accounting rules under Section 451(b) of the Code. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, synthetic security, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies" and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATION PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL NON-INCOME TAX LAWS, INCLUDING ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a non-U.S. holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (i) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (ii) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend policy," we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions 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. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or other taxable disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to United States persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or other taxable disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI) by reason of our status as a U.S. real property holding corporation (USRPHC), at any time during the five-year period preceding such disposition (or the Non-U.S. Holders' holding period, if shorter), for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates applicable to United States persons. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information reporting and backup withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional withholding tax on payments made to foreign accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act (FATCA)) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (i) the foreign financial institution undertakes certain diligence and reporting obligations, (ii) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in (i) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

Underwriting

We are offering the shares of common stock described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC, Jefferies 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	
Jefferies LLC	
Piper Sandler & Co.	
Total	

The underwriters are committed to purchase all the shares of common stock 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 stock 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. After the initial offering of the shares to the public, if all of the shares of common stock 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 agreed to reimburse the underwriters for expenses relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. in an amount up to $.

A prospectus in electronic format may be made available on the web sites 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, subject to certain exceptions, (i) offer, pledge, announce the intention to sell, 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, hedge, 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, hedge, loan, disposition or filing, or (ii) enter into any swap, hedging, 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, Jefferies 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.

Our directors and executive officers, and substantially all of our securityholders (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, Jefferies 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, hedge, 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 of lock-up securities:

- (i) as bona fide gifts, or for bona fide estate planning purposes,
- (ii) by will, other testamentary document or intestacy,
- (iii) to any member of the lock-up party's immediate family or to any trust for the direct or indirect benefit of the lock-up party or any immediate family member, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust
- (iv) to a partnership, limited liability company or other entity of which the lock-up party and its immediate family members are the legal and beneficial owner of all of the outstanding equity securities or similar interests,
- (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 with the lock-up party or its affiliates or (B) as part of a distribution to members or stockholders of the lock-up party;
- (vii) by operation of law,
- (viii) to us from an employee, independent contractor, or other service provider upon death, disability or termination of employment or cessation of services, in each case, of such employee, independent contractor, or service provider,
- (ix) as part of a sale of lock-up securities acquired 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 of our 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 outstanding options, settlement of restricted stock units 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 such shares of common stock or warrants 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 (i) such plan does not provide for the transfer of lock-up securities during the restricted period and (ii) no filing by any party under the Exchange Act or other public announcement shall be required or made voluntarily in connection with such trading plan during the restricted period.

J.P. Morgan Securities LLC, Jefferies 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 have applied to list our shares of common stock on the Nasdaq Global Market under the symbol “BMEA.”

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 shares of our common stock, or that the shares will trade in the public market at or above the initial public offering price.

Other relationships

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.

Notice to prospective investors in the 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 the shares may be offered to the public in that Relevant State at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

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

For the purposes of this provision, the expression 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.

Notice to prospective investors in the United Kingdom

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

(a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA.

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

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 (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 (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (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 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 (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 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.

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 Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth) (the “Corporations Act”);

- has not been, and will not be, lodged with the Australian Securities and Investments Commission (ASIC) as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, or Exempt Investors.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

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 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 (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (SFO) of Hong Kong and any rules made thereunder; or (b) 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 (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:

(a) 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 (SFA)) pursuant to Section 274 of the SFA;

(b) 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

(c) 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:

(a) 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

(b) 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.

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of the shares, the Company has determined, and hereby notifies all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are "prescribed capital markets products" (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to prospective investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority (CMA) pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to prospective investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of the Company. The shares may be offered to companies incorporated under the BVI Business Companies Act, 2004 (British Virgin Islands), or BVI Companies, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands.

Notice to prospective investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to prospective investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea and the decrees and regulations thereunder (FSCMA), and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea and the decrees and regulations thereunder (FETL). The shares have not been listed on any of the securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of the shares has been or will be registered with the Securities Commission of Malaysia (Commission), for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission; (ii) a holder of a Capital Markets Services License; (iii) a person who acquires the shares, as principal, if the offer is on terms that the shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction; (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual; (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months; (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months; (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts; (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies); (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010; (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010; and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of the shares is made by a holder of a Capital Markets Services License who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, no "*offer to the public*" (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted) (South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a "*registered prospectus*" (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1) (a) the offer, transfer, sale, renunciation or delivery is to:

(a) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;

(b) the South African Public Investment Corporation;

(c) persons or entities regulated by the Reserve Bank of South Africa;

(d) authorised financial service providers under South African law;

(e) financial institutions recognised as such under South African law;

(f) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or

(g) any combination of the person in (a) to (f); or

Section 96 (1) (b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as "advice" as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Legal matters

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Cooley LLP.

Experts

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

Where you can find additional information

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

You may read our SEC filings, including this Registration Statement, over the Internet at the SEC's website at www.sec.gov. Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for review at the SEC's website referred to above. We also maintain a website at www.biomeafusion.com, at which, following the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessible through our website is not a part of this prospectus or the registration statement of which it forms a part, and the inclusion of our website address in this prospectus is an inactive textual reference only.

Biomea Fusion, Inc.
Index to financial statements

Audited financial statements

Report of independent registered public accounting firm

To the stockholders and the Board of Directors of Biomea Fusion, Inc.

Opinion on the financial statements

We have audited the accompanying balance sheet of Biomea Fusion, Inc. (the “Company”) as of December 31, 2019, the related statement of operations, shareholders’ deficit, and cash flows, for the year ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and the results of its operations and its cash flows for the year ended December 31, 2019, 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 audit. 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 audit 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 audit 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 audit, 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Francisco, CA
February 12, 2021

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

Financial statements

Biomea Fusion, Inc.
Balance sheet
(in thousands, except share and per share amounts)

	December 31, 2019
Assets	
Current assets:	
Cash	$ 239
Prepaid expenses and other current assets	26
Total current assets	265
Total assets	$ 265
Liabilities and Stockholders' Deficit	
Current liabilities:	
Accounts payable	$ 271
Accrued liabilities	15
Total current liabilities	286
Total liabilities	$ 286
Commitments and contingencies (Note 5)	
Stockholders' deficit:	
Common stock; $0.0001 par value; 2,862,000 shares authorized as of December 31, 2019; 984,528 issued and outstanding as of December 31, 2019	-
Additional paid-in capital	2,830
Accumulated deficit	(2,851)
Total stockholders' deficit	(21)
Total liabilities and stockholders' deficit	$ 265

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

Biomea Fusion, Inc.
Statement of operations
(in thousands, except share and per share amounts)

	Year ended December 31, 2019
Operating expenses:	
Research and development	$ 1,092
General and administrative	103
Total operating expenses	1,195
Loss from operations	(1,195)
Other expense, net	(3)
Net loss and comprehensive loss	$ (1,198)
Net loss per common share, basic and diluted	$ (1.75)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	684,582

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

Biomea Fusion, Inc.
Statement of stockholders' deficit
(in thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' deficit
	Shares	Amount			
Balance at January 1, 2019	483,567	$ —	$ 1,390	$ (1,653)	$ (263)
Issuance of common stock	500,961	—	1,440	—	1,440
Net loss and comprehensive loss	—	—	—	(1,198)	(1,198)
Balance at December 31, 2019	984,528	$ —	$ 2,830	$ (2,851)	$ (21)

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

Biomea Fusion, Inc.
Statement of cash flows
(in thousands)

	Year ended December 31, 2019
Operating activities	
Net loss	$ (1,198)
Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	7
Accounts payable	(98)
Accrued liabilities	10
Net cash used in operating activities	(1,279)
Financing activities	
Proceeds from issuance of common stock	1,440
Net cash provided by financing activities	1,440
Net increase in cash	161
Cash at the beginning of the year	78
Cash at the end of the year	$ 239

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

Biomea Fusion, Inc.
Notes to financial statements

1. Organization

Organization

Biomea Fusion, Inc., (the “Company”), was established in the state of Delaware in August 2017 as Biomea Fusion, LLC. In December 2020, all outstanding membership interests in Biomea Fusion, LLC were converted into equity interests in the Company. The capitalization information included in these financial statements is consistently presented as if it is that of Biomea Fusion, Inc., even during the prior period when investors held their equity interests in Biomea Fusion, LLC.

The Company is a biopharmaceutical company focused on the discovery, development and commercialization of irreversible small molecules to treat patients with genetically defined cancers. Since its inception in 2017, the Company has built its proprietary FUSION System platform to design and develop a pipeline of novel irreversible therapies.

Basis of presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Liquidity and capital resources

The Company has incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $2.9 million at December 31, 2019. The Company has financed operations primarily through the issuance of common stock and has received aggregate investments of $2.5 million through December 31, 2019. As of December 31, 2019, the Company had a cash balance of $0.2 million.

In June and October 2020, the Company received net proceeds of $9.9 million from the sale and issuance of shares of its common stock. In December 2020, the Company received net proceeds of $55.7 million from the sale and issuance of shares of its Series A convertible preferred stock. As of December 31, 2020, the Company’s cash and cash equivalents balance totaled approximately $61.7 million. Due to the additional financing completed during 2020, management believes that its existing financial resources are sufficient to fund operating activities at least one year past the issuance date of these financial statements. Future capital requirements will depend on many factors, including the timing and extent of spending on research and development and the market acceptance of the Company’s product candidates.

Management plans to raise additional capital through private or public equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to the Company on acceptable terms or at all. The Company’s failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies.

2. Summary of significant accounting policies

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates, including, but not limited to, those related to accrued research and development expenses. The Company bases its estimates on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing clinical drug candidates for the treatment of cancer patients. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States.

Cash and cash equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash and cash equivalents.

Fair value of financial instruments

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued expenses, and are stated at their carrying value, which approximates fair value due to the short-term nature of these items.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk, consist primarily of cash. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents to the extent recorded in the balance sheet. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's future results of operations involve a number of other risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's potential product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole source suppliers. The Company's product candidates require approvals from the U.S. Food and Drug Administration and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company.

Research and development expenses

The Company's research and development expenses consist primarily of external and internal costs incurred in connection with the research and development of its research programs and product candidates.

External costs include:

- expenses incurred under agreements with third-party contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), research and development service providers, academic research institutions and consulting costs; and
- laboratory expenses, including supplies and services.

Internal costs include:

- personnel-related expenses, including salaries, benefits and stock-based compensation for personnel in research and product development roles; and
- facilities and other allocated expenses, including expenses for rent and facilities maintenance, and amortization.

The Company expenses research and development costs in the periods in which they are incurred. Nonrefundable advance payments for goods or services to be received in future periods for use in research and development activities are deferred and capitalized. The capitalized amounts are then expensed as the related goods are delivered and as services are performed. The Company tracks direct costs by stage of program, clinical or preclinical. However, it does not track indirect costs on a program specific or stage of program basis because these costs are deployed across multiple programs and, as such, are not separately classified.

Accrued research and development expenses

The Company records accruals for estimated costs of research, preclinical, and manufacturing development, which are significant components of research and development expenses. A substantial portion of the Company's ongoing research and development activities is conducted by third-party service providers, CROs and CMOs. The Company's contracts with the CROs and CMOs generally include fees such as initiation fees, reservation fees, costs related to animal studies and safety tests, verification run costs, materials and reagents expenses, taxes, etc. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to the Company under such contracts. The Company accrues the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. The Company determines the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion and actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. Through December 31, 2019, there have been no material differences from the Company's estimated accrued research and development expenses to actual expenses.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the accompanying statements of operations.

Comprehensive loss

There are no components of other comprehensive loss for the Company. Thus, comprehensive loss is the same as net loss for the period presented.

Net loss per share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are antidilutive given the net loss for the period presented.

Recent accounting pronouncements

The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"), and may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to
comply with new or revised financial accounting standards until private companies are required to comply with those standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards; and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts the Company from having to provide an auditor attestation of internal controls over financial reporting under Sarbanes-Oxley Act Section 404(b).

The Company will remain an EGC until the earliest of (i) the last day of the fiscal year in which it has total annual gross revenues of $1.07 billion or more, (ii) the last day of the fiscal year following the fifth anniversary of the completion of its IPO, (iii) the date on which it has issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which it is deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission ("SEC"), which generally is when it has more than $700 million in market value of its stock held by non-affiliates, has been a public company for at least 12 months and has filed one annual report on Form 10-K.

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position or results of operations upon adoption.

New accounting pronouncements to be adopted

In February 2016, the FASB issued Accounting Standard Update (ASU) No. 2016-02, *Leases ("Topic 842")*, which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. As a result of the Company having elected the extended transition period for complying with new or revised accounting standards pursuant to Section 107(b) of the JOBS Act, ASU No. 2016-02 is effective for the Company in the fiscal years beginning after December 15, 2021, with early adoption permitted. The Company expects to adopt the standard on January 1, 2020, which will result in the recognition of a right-of-use asset for leased facilities and recognition of a liability for the lease payments remaining on the lease on its balance sheet as of December 31, 2020 for a lease signed during 2020.

New accounting pronouncements recently adopted

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. This ASU simplifies the accounting for share-based awards to nonemployees by aligning it with the accounting

for share-based awards to employees, with certain exceptions. This ASU is effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. The Company early adopted this ASU as of January 1, 2019. The adoption of this ASU had an no impact on the Company's financial statements.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*. The standard replaces existing revenue recognition standards and significantly expands the disclosure requirements for revenue arrangements. The standard must be adopted using either a modified retrospective approach or a full retrospective approach for all periods presented. The Company adopted the standard as of January 1, 2019 under the full retrospective method. The Company does not have and has never had any contracts that are within the scope of ASU 2014-09 or its predecessor guidance, Accounting Standards Codification (ASC) 605, *Revenue Recognition*. Accordingly, adoption of the standard did not have an impact on the Company's financial statements. However, the adoption of this standard will impact the accounting for potential future revenue transactions.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation: Improvements to Employee Share-Based Payment Accounting*. The areas affected by this ASU include accounting for income taxes, classification of excess tax benefits on the statement of cash flows, minimum statutory tax withholding requirements, and classification of employee taxes paid on the statement of cash flows when an employer withholds shares for tax-withholding purposes. In addition, under this guidance, an entity can make an accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. The Company adopted this ASU and has elected to account for forfeitures as they occur rather than apply an estimated forfeiture rate to stock-based compensation expense. The adoption of this ASU had no impact on the Company's financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* that modifies how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted this ASU as of January 1, 2019. The adoption of this ASU had an immaterial impact on the Company's financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share: Distinguishing Liabilities from Equity; Derivatives and Hedging, (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. This ASU allows for the exclusion of a down round feature, when evaluating whether or not an instrument or embedded feature requires derivative classification. The Company early adopted this ASU as of January 1, 2019. The adoption of this ASU had no impact on the Company's financial statements.

3. Balance sheet components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

(in thousands)		December 31, 2019
Prepaid expenses and receivables	$	11
Security deposits		15
Total prepaid expenses and other current assets	$	26

Accrued liabilities

Accrued liabilities consisted of the following:

(in thousands)	December 31, 2019
Accrued research and development materials and services	$ 6
Accrued professional services	9
Total accrued liabilities	$ 15

4. Capital structure

Common stock

The Company is authorized to issue 2,862,000 shares of common stock, par value $0.0001 per share. As of December 31, 2019, there were 984,528 shares of common stock outstanding. Common stockholders are entitled to dividends when and if declared by the Company's Board of Directors and after any convertible preferred share dividends are fully paid. The holder of each share of common stock is entitled to one vote. As of December 31, 2019, the Company had no preferred shares outstanding and never declared a dividend. There were no options to purchase common stock outstanding as of December 31, 2019.

The Company has financed operations primarily through the issuance of common stock and has received aggregate cash proceeds of $2.5 million through December 31, 2019. In June and October 2020, the Company received aggregate net proceeds of $9.9 million from the sale and issuance of shares of its common stock. In December 2020, the Company received net proceeds of $55.7 million from the sale and issuance of shares of its Series A convertible preferred stock. Prior to the December 2020 Series A convertible preferred stock financing, there were no shares of convertible preferred stock outstanding. See Note 9 for further information.

In December 2020, all of the outstanding membership interests in Biomea Fusion LLC were exchanged for equity interests in Biomea Fusion, Inc. in a statutory conversion under Delaware law. All of the share information referenced throughout the financial statements and notes to the financial statements have been retroactively adjusted to reflect the change in capital structure. As an LLC, the net losses of the Company were recorded by the members for tax purposes, and therefore there were no Biomea Fusion, Inc. net loss carryforwards as of December 31, 2019. There was a net difference of $167,000 between the tax basis and the reported amounts of the Company's assets and liabilities as of December 31, 2019.

5. Commitments and contingencies

Operating leases

The Company leases its lab space located in San Carlos, California under a month-to-month cancellable lease agreement that ended in September 2020. Rent expense for the year ended December 31, 2019, was $90,000. Future lease payments under this lease are $40,000 in 2020.

Legal proceedings

From time to time, the Company may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the year ended December 31, 2019, and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

Indemnification

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend an indemnified party for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. The Company has never incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require the Company to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by Delaware corporate law. The Company currently has directors' and officers' insurance.

6. Related party transactions

During the year ended December 31, 2019, A2A Pharmaceuticals and Biomea Healthcare, LLC invested a combined $1.4 million in the Company in exchange for 500,961 shares of the Company's common stock. Biomea Healthcare, LLC's initial investment of $0.2 million was in the form of expenses paid by Biomea Healthcare, LLC on behalf of the Company. As of December 31, 2019, the Company had an outstanding receivable balance from Biomea Healthcare, LLC of $9,000.

7. Net loss per share

The following table sets forth the computation of the basic and diluted net loss per share:

(in thousands, except share and per share numbers)	Year ended December 31, 2019
Numerator:	
Net loss	$ (1,198)
Denominator:	
Weighted-average common shares outstanding	684,582
Net loss per common share, basic and diluted	$ (1.75)

8. Subsequent events

Management has reviewed and evaluated material subsequent events from the balance sheet date of December 31, 2019, through the date the financial statements were available to be issued on February 12, 2021. No subsequent events have been identified for disclosure, other than those matters noted below.

In June and October 2020, the Company issued an aggregate of 268,745 shares of its common stock, par value $0.0001, in exchange for $9.9 million in net proceeds.

In December 2020, the Company issued 799,200 shares of its Series A convertible preferred stock, par value $0.0001, in exchange for $55.7 million in net proceeds.

In connection with the Series A convertible preferred stock offering referenced above, on December 21, 2020, the Company amended and restated its Articles of Incorporation to increase the authorized shares of preferred

stock to 799,200 shares. Each of the Series A convertible preferred shares may be converted into common stock at the original issuance price of $70.07 per share on a one-for-one basis. In the event of any liquidation, dissolution, or winding up of the Company, either voluntary or involuntary, the holders of preferred shares then outstanding shall be entitled to receive prior to any payments to holders of common stock the greater of the original issuance price or such amount per share as would have been payable had all the shares of Series A preferred stock been converted into common stock immediately prior to the liquidation event. In addition, the Series A stockholders, voting together as a group, were granted the right to elect 2 board members, and the common stockholders are entitled to elect 3 directors.

Since December 31, 2019, the Company has issued 93,262 restricted common stock awards to employees that vest quarterly on a straight-line basis over 48 months.

In January 2021, the Company granted options to employees and consultants to purchase 103,074 shares of common stock at a fair market value of $45.41 per share.

In February 2021, the Company entered into an 8-month sublease agreement with Level Home, Inc. for additional office space located in Redwood City, California.

On March 11, 2020, the World Health Organization declared a novel strain of the coronavirus disease (“COVID-19”), a global pandemic. Management continues to monitor and evaluate the impact of COVID-19 on an ongoing basis. The extent to which the pandemic will impact the Company’s future results of operations, cash flows and financial condition will depend on outside developments, which are highly uncertain and unpredictable, including new information which may emerge concerning the severity and duration of the pandemic and the actions taken by governmental authorities and the Company to contain it or treat its impact.

On March 27, 2020, the Coronavirus Air, Relief, and Economic Security Act (“CARES Act”) was signed into law. The CARES Act temporarily eliminates limitation (as enacted under the Tax Cuts and Jobs Act of 2017) for NOL deductions for 2018-2020 tax years and reinstated NOL carrybacks for the 2018-2020 tax years. Moreover, the CARES Act also temporarily increases the business interest deduction limitations from 30% to 50% of adjusted taxable income for the 2019 and 2020 taxable year. Lastly, the Tax Act technical correction classifies qualified improvement property as 15-year recovery period, allowing the bonus deprecation deduction to be claimed for such property retroactively as if it was included in the Tax Act at the time of the enactment.

Under the CARES Act, the Company will receive tax relief from the ability to carry back NOLs generated in tax years 2018-2020, as well as the technical corrections on qualified improvement property to allow the bonus depreciation deduction. The Company continues to examine the impact that the CARES Act may have on its business.

On May 5, 2020, the Company entered into a promissory note with City National Bank, which provided a loan in the amount of $35,637 (“PPP Loan”) pursuant to the Paycheck Protection Program (“PPP”), administered by the Small Business Administration under the CARES Act. The PPP Loan has a two-year term and bears interest at a rate of 1% per annum. Monthly principal and interest payments are deferred for seven months after the date of disbursement. The PPP Loan may be prepaid at any time prior to maturity with no prepayment penalties. The PPP loan may be partially or wholly forgiven if the funds are used for certain qualifying expenses as described in the CARES Act. The Company has used the entire PPP loan amount for qualifying expenses and intends to repay the loan during the first quarter of 2021.

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Prospectus

J.P. Morgan **Jefferies** **Piper Sandler**

, 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 the underwriting discounts and commissions, payable by Biomea Fusion, Inc. (the Registrant), in connection with the sale of our common stock being registered. All amounts are estimates except for the Securities and Exchange Commission (SEC) registration fee, the Financial Industry Regulatory Authority (FINRA) filing fee and the Nasdaq Global Market (Nasdaq) listing fee.

Item	Amount paid or to be paid
SEC registration fee	$ *
FINRA filing fee	*
Nasdaq listing fee	*
Printing expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent's fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be filed by amendment.

Item 14. indemnification of directors and officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and amended and restated bylaws that limit or eliminate the personal liability of our 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, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for 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 payment of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that:

- we shall indemnify our directors and officers to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;

- we may indemnify our employees and agents to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we shall advance expenses to our directors and officers and may advance expenses of our employees and agents in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our amended and restated bylaws are not exclusive.

Our amended and restated certificate of incorporation and our amended and restated bylaws provide for the indemnification provisions described above and elsewhere herein. We have entered or will enter into, and intend to continue to enter into, separate indemnification agreements with our directors and officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against certain liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended (the Securities Act).

We have purchased and currently intend to maintain insurance on behalf of each and every person who is or was a director or officer of the company against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

The form of underwriting agreement for this initial public offering provides for indemnification by the underwriters of us and our officers and directors who sign this Registration Statement for specified liabilities, including matters arising under the Securities Act.

Item 15. recent sales of unregistered securities.

Since January 1, 2018, we have made the following sales of unregistered securities:

Equity Plan-Related Issuances

1. Since January 1, 2018, we have granted to our directors, employees and consultants options to purchase 103,074 shares of our common stock with a weighted-average per share exercise price of $45.41 under our 2020 Plan.

Sales of Preferred Stock and Common Units

2. Between January 2018 and June 2020, we issued and sold investor units, which were subsequently converted into an aggregate of 1,074,980 shares of common stock, to A2A Pharmaceutics, Inc. and Biomea Healthcare, LLC in exchange for $3.1 million contributed by the two parties.

3. In December 2020, we issued and sold an aggregate of 799,200 shares of Series A convertible preferred stock to 17 accredited investors at $70.07 per share for gross proceeds of approximately $56.0 million.

4. In June and October 2020, we issued and sold investor units, which were subsequently converted into an aggregate of 268,745 shares of common stock to 12 accredited investors at $37.21 per share for gross proceeds of approximately $10.0 million.

The offers, sales and issuances of the securities described in paragraph (1) was deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by

an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraphs (2) and (3) were deemed to be exempt under Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D under the Securities Act as a transaction by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access to information about us. No underwriters were involved in these transactions.

Item 16. exhibits and financial statement schedules.

(a) Exhibits.

The exhibits listed below are filed as part of this Registration Statement.

Exhibit number	Exhibit description	Incorporated by reference			Filed herewith
		Form	Date	Number	
1.1*	Form of Underwriting Agreement				
3.1*	Amended and Restated Certificate of Incorporation, as amended, currently in effect				
3.2*	Form of Amended and Restated Certificate of Incorporation, to be in effect immediately prior to the completion of this offering				
3.3*	Bylaws, currently in effect				
3.4*	Form of Amended and Restated Bylaws, to be in effect immediately prior to the completion of this offering				
4.1*	Reference is made to Exhibits 3.1 through 3.4				
4.2*	Form of Common Stock Certificate				
5.1*	Opinion of Latham & Watkins LLP				
10.1*	Investors' Rights Agreement, dated December 23, 2020, by and among the Registrant and the investors listed therein				
10.2*	Secondary Sublease, dated August 18, 2020, by and between the Registrant and Interactive Memories, Inc. d/b/a Mixbook				
10.3(a)#*	2020 Equity Incentive Plan				

Exhibit number	Exhibit description	Incorporated by reference			Filed herewith
		Form	Date	Number	
10.3(b)#*	Form of Stock Option Agreement under 2020 Equity Incentive Plan				
10.4(a)#*	2021 Incentive Award Plan				
10.4(b)#*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Incentive Award Plan				
10.4(c)#*	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2021 Incentive Award Plan				
10.4(d)#*	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Incentive Award Plan				
10.5#*	Employee Stock Purchase Plan				
10.6#*	Employment Agreement by and between the Registrant and Thomas Butler				
10.7#*	Employment Agreement by and between the Registrant and Ramses Erdtmann				
10.8#*	Employment Agreement by and between the Registrant and Sunny Lee Ryan				
10.9#*	Non-Employee Director Compensation Program				
10.10*	Form of Indemnification and Advancement Agreement for Directors and Officers				
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm				
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1)				
24.1*	Power of Attorney (reference is made to the signature page to the Registration Statement)				

* To be filed by amendment.

\# Indicates management contract or compensatory plan.

(b) Financial Statement Schedules.

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. undertakings.

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 of 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:

1. 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.

2. 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 of 1933, as amended, the registrant 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 Redwood City, State of California on , 2021.

BIOMEA FUSION, INC.

By _____
Thomas Butler
Chief Executive Officer

Power of attorney

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Thomas Butler and Sunny Lee Ryan, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Registration Statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this 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 exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, 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 or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
Thomas Butler	Chief Executive Officer and Director *(Principal Executive Officer)*	, 2021
Sunny Lee Ryan	Executive Vice President of Finance *(Principal Financial and Accounting Officer)*	, 2021
Eric Aguiar, M.D.	Director	, 2021
Bihua Chen	Director	, 2021
Ramses Erdtmann	Director	, 2021

Signature	Title	Date
John Kwon	Director	, 2021
Sotirios Stergiopoulos, M.D.	Director	, 2021