REFINITIV

DELTA REPORT

10-Q

BIOMEA FUSION, INC.

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

The following comparison report has been automatically generated

TOTAL DELTAS	942
CHANGES	148
DELETIONS	369
ADDITIONS	425

REFINITIV

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, March 31, 2023 2024

OR

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

For the transition period from to

Commission File Number: 001-40335

Biomea Fusion, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-2520134**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
900 Middlefield Road, 4th Floor Redwood City, California	**94063**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 980-9099

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	BMEA	The Nasdaq Global Select Market

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

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

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

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

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

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

As of October 23, 2023 April 26, 2024, the registrant had 35,705,786 35,944,584 shares of common stock, $0.0001 par value per share, outstanding.

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Special Note Regarding Forward Looking Statements

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 and investments 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 investments; equivalents;
- 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, clinical trials and investigational new drug applications (INDs) and other regulatory submissions;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates and the ability of our FUSION™ System to generate additional product candidates with such characteristics;
- the timing, progress and focus of our ongoing and future clinical trials, and the reporting of data from those 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;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to commercializing our product candidates, if approved;
- our estimates of the patient populations addressable by our product candidates, if approved, and the number of participants that will enroll in our ongoing and planned clinical trials;
- 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 orphar drug designation, for our product candidates;
- our plans relating to the further development and manufacturing of our product candidates, including for additional indications tha 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 any pandemics or other related disruptions on our business;
- unfavorable global economic conditions, including inflationary pressures, market volatility, acts of war and civil and political unres 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 Quarterly Report on Form 10-Q, 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. We qualify all of the forward-looking statements in this Quarterly Report on Form 10-Q by these cautionary statements.

Biomea Fusion, Inc., the Biomea logo and our other registered or common law trademarks, trade names or service marks appearing in this Quarterly Report on Form 10-Q are owned by us. This Quarterly Report on Form 10-Q contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report on Form 10-Q, including logos, artwork and other visual displays, generally appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Summary Risk Factors

The following is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address every aspect of our risk factors, all of the risks that we face, or other factors not presently known to us or that we currently believe are immaterial. Additional discussion of the risks summarized in these summary risk factors, and other risks that we face, can be found under the heading “Risk Factors” in this Quarterly Report on Form 10-Q and should be carefully considered, together with other information in this Quarterly Report on Form 10-Q and our other filings with the Securities and Exchange Commission, or SEC, before making investment decisions regarding our common stock.

- We have a limited operating history, have not completed the clinical development of any product candidates, 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 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 activities are focused on the development of novel covalent small-molecule therapies, initially targeted at menin, to treat patients with genetically-defined cancers and metabolic diseases, 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 product candidates, BMF-219 and BMF-500 If we are unable to advance BMF-219, BMF-500 or any of our future product candidates through clinical development, obtain

regulatory approval and ultimately commercialize BMF-219, BMF-500 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 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 obtai 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 a limited operating history, have not 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 limited experience as a company in conducting clinical trials and have not successfully completed the clinical development of any product candidates to date.
- Adverse global economic conditions, including supply chain issues, and inflationary pressures could materially adversely impact our business, results of operations, and financial condition, including our preclinical studies and clinical trials.

- 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.
- The price of our stock may has been and is likely to continue to be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Biomea Fusion, Inc.

Condensed Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Assets				
Current assets:				
Cash and cash equivalents	$ 199,090	$ 111,899	$ 144,918	$ 176,866
Short-term investments	—	1,150		
Prepaid expenses and other current assets	3,414	4,770	2,648	2,315
Total current assets	202,504	117,819	147,566	179,181
Property and equipment, net	5,575	5,841	4,806	5,159
Operating lease right-of-use assets	11,810	2,151	9,013	9,714
Restricted cash	369	351	369	370
Other assets	4,829	3,145	6,740	5,503
Total assets	$ 225,087	$ 129,307	$ 168,494	$ 199,927
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	$ 3,194	$ 6,826	$ 4,709	$ 6,851
Accrued expenses and other current liabilities	10,191	11,657	17,379	13,543
Operating lease liabilities, current	2,825	618	3,166	2,466
Total current liabilities	16,210	19,101	25,254	22,860
Operating lease liabilities, non-current	9,265	1,667	7,926	7,830
Total liabilities	25,475	20,768	33,180	30,690
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—		

Common stock, $0.0001 par value; 300,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 35,698,847 and 29,561,554 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4	3		
Preferred stock, $0.0001 par value; 10,000,000 authorized as of March 31, 2024 and December 31, 2023; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023			—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 35,933,586 and 35,866,610 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			4	4
Additional paid-in capital	413,549	240,107	423,196	418,058
Accumulated other comprehensive income	—	(1)	—	—
Accumulated deficit	(213,941)	(131,570)	(287,886)	(248,825)
Total stockholders' equity	199,612	108,539	135,314	169,237
Total liabilities and stockholders' equity	$ 225,087	$ 129,307	$ 168,494	$ 199,927

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

Biomea Fusion, Inc.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Operating expenses:						
Research and development	$ 25,347	$ 18,242	$ 71,680	$ 42,174	$ 33,776	$ 24,395
General and administrative	5,772	5,242	17,127	15,184	7,283	5,636
Total operating expenses	31,119	23,484	88,807	57,358	41,059	30,031
Loss from operations	(31,119)	(23,484)	(88,807)	(57,358)	(41,059)	(30,031)
Interest and other income, net	2,690	594	6,436	844	1,998	980
Net loss	$ (28,429)	$ (22,890)	$ (82,371)	$ (56,514)	$ (39,061)	$ (29,051)
Other comprehensive loss:						
Unrealized gain (loss) on investments, net	—	4	—	(3)	—	1
Comprehensive loss	$ (28,429)	$ (22,886)	$ (82,371)	$ (56,517)	$ (39,061)	$ (29,050)
Net loss per common share, basic and diluted	$ (0.80)	$ (0.78)	$ (2.46)	$ (1.93)	$ (1.09)	$ (0.98)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	35,653,988	29,319,042	33,551,808	29,214,549	35,890,370	29,586,468

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

Condensed Statements of Stockholders’ Equity

(Unaudited)

(in thousands, except share amounts)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	29,561,554	$ 3	$ 240,107	$ (1)	$ (131,570)	$ 108,539

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2023	35,866,610	$ 4	$ 418,058	$ —	$ (248,825)	$ 169,237
Issuance of restricted stock	44,226	—	—	—	—	—

Exercise of stock options	4,504,701	—	4,007	—	—	4,007	22,750	—	116	—	—	116
Issuance of restricted stock	4,507,909	—	—	—	—	—						
Stock-based compensation expense	—	—	3,223	—	—	3,223	—	—	5,022	—	—	5,022
Unrealized gain (loss) on investments, net	—	—	—	1	—	1						
Net loss	—	—	—	—	(29,005)	(29,005)	—	—	—	—	(39,061)	(39,061)
Balance at March 31, 2023	29,651,524	$ 3	$ 7,234	$ —	$ (16,080)	$ 8,231						

Issuance of common stock from public offering, net of offering costs	5,750,000	$ 1	$ 216,000	$—	$—	216,001
Exercise of stock options	156,000	—	1,406,000	—	—	1,406,000
Issuance of restricted stock	508,000	—	—	—	—	—
Purchases under employee stock purchase plan	152,000	—	2,601,000	—	—	2,601,002
Stock-based compensation expense	—	—	3,463,000	—	—	3,463,000
Unrealized gain (loss) on investments, net	—	—	—	—	—	—

					(24,891)	(24,891)
Net loss	—	—	—	—	(1)	(1)
Balance at June 30, 2023	35,630,276	$ 4	409,815,185	$ —	$ (2)	$ 5
Exercise of stock options	23,493	—	138	—	—	138
Issuance of restricted stock	45,078	—	—	—	—	—
Stock-based compensation expense	—	—	3,589	—	—	3,589
Unrealized loss on investments	—	—	—	—	—	—
					(28,442)	(28,442)
Net loss	—	—	—	—	(9)	(9)

Balance at September 30, 2023	35,956,789	$ 4	$ 9	$ —	$ (1)	$ 2
Balance at March 31, 2024	35,933,586	$ 4	$ 423,196	$ —	$ (287,886)	$ 135,314

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	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity
Balance at December 31, 2022	29,561,554	$ 3	$ 240,107	$ (1)	$ (131,570)	$ 108,539
Exercise of stock options	44,501	—	407	—	—	407
Issuance of restricted stock	45,079	—	—	—	—	—
Stock-based compensation expense	—	—	3,233	—	—	3,233
Unrealized gain (loss) on investments, net	—	—	—	1	—	1
Net loss	—	—	—	—	(29,051)	(29,051)
Balance at March 31, 2023	29,651,134	$ 3	$ 243,747	$ —	$ (160,621)	$ 83,129

Biomea Fusion, Inc.

Condensed Statements of Stockholders' Equity

(Unaudited)

(in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Gain (Loss)	Deficit	Equity

Balance at December 31, 2021	29,115,421	$ 3	$ 228,532	$ (10)	$ (49,742)	$ 178,783
Exercise of stock options	6,044	—	31	—	—	31
Issuance of restricted stock	47,216	—	—	—	—	—
Stock-based compensation expense	—	—	2,330	—	—	2,330
Unrealized gain (loss) on investments, net	—	—	—	(13)	—	(13)
Net loss	—	—	—	—	(16,366)	(16,366)
Balance at March 31, 2022	29,168,681	$ 3	$ 230,893	$ (23)	$ (66,108)	$ 164,765
Exercise of stock options	9,366	—	62	—	—	62
Issuance of restricted stock	47,216	—	—	—	—	—
Purchases under employee stock purchase plan	54,868	—	256			256
Stock-based compensation expense	—	—	2,559	—	—	2,559
Unrealized gain (loss) on investments, net	—	—	—	6	—	6
Net loss	—	—	—	—	(17,258)	(17,258)
Balance at June 30, 2022	29,280,131	$ 3	$ 233,770	$ (17)	$ (83,366)	$ 150,390
Exercise of stock options	61,405	—	400	—	—	400
Issuance of restricted stock	47,217	—	—	—	—	—
Stock-based compensation expense	—	—	2,731	—	—	2,731
Unrealized gain (loss) on investments, net	—	—	—	4	—	4
Net loss	—	—	—	—	(22,890)	(22,890)
Balance at September 30, 2022	29,388,753	$ 3	$ 236,901	$ (13)	$ (106,256)	$ 130,635

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

Biomea Fusion, Inc.

Condensed Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Operating Activities				
Net loss	$ (82,371)	$ (56,514)	$ (39,061)	$ (29,051)
Adjustments to reconcile net loss to net cash used in operating activities				
Depreciation expense	1,095	510	420	293
Non-cash operating lease expense	1,976	426	999	612
Stock-based compensation expense	10,267	7,620	5,022	3,233
Net amortization of premiums and accretion of discounts on investments	1	136	—	1
Changes in operating assets and liabilities:				
Prepaid expenses and other current assets	1,356	(2,358)	(333)	2,345
Other assets	(1,684)	747	(1,236)	(744)
Accounts payable	(1,099)	(13)	(2,176)	665
Accrued expenses and other current liabilities	(1,466)	7,649	3,836	(823)
Operating lease liabilities	(1,830)	(419)	499	(575)
Net cash used in operating activities	(73,755)	(42,216)	(32,030)	(24,044)
Investing Activities				
Purchase of property and equipment	(3,362)	(318)	(35)	(2,906)
Purchase of investments	—	—		
Maturities of investments	1,150	28,360	—	1,150
Net cash provided by (used in) investing activities	(2,212)	28,042		
Net cash used in investing activities			(35)	(1,756)
Financing Activities				
Proceeds from issuance of common stock from public offering, net of offering costs	161,803	—		
Proceeds from stock option exercise and purchases under the employee stock purchase plan	1,373	749		

Proceeds from stock option exercise			116	201
Net cash provided by financing activities	163,176	749	116	201
Net increase (decrease) in cash, cash equivalents, and restricted cash	87,209	(13,425)		
Net decrease in cash, cash equivalents, and restricted cash			(31,949)	(25,599)
Cash, cash equivalents, and restricted cash at the beginning of the period	112,250	146,087	177,236	112,250
Cash, cash equivalents, and restricted cash at the end of the period	$ 199,459	$ 132,662	$ 145,287	$ 86,651
Non-cash financing and investing activities:				
Acquisition of operating lease right-of-use assets	$ 11,639	$ —	$ —	$ 11,639
Acquisition of property and equipment in accounts payable and accrued liabilities	$ 4	$ 276	$ 34	$ 375
Reconciliation of cash and cash equivalents and restricted cash:				
Reconciliation of cash and cash equivalents, and restricted cash:				
Cash and cash equivalents	$ 199,090	$ 132,311	$ 144,918	$ 86,300
Restricted cash	369	351	369	351
Total cash and cash equivalents and restricted cash	$ 199,459	$ 132,662		
Total cash and cash equivalents, and restricted cash			$ 145,287	$ 86,651

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

Notes to Unaudited Condensed Financial Statements

Note 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 unaudited condensed 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 clinical-stage biopharmaceutical company dedicated to discovering and developing novel covalent small molecules to treat and improve the lives of patients with genetically defined cancers and metabolic diseases. Since its inception in 2017, the Company has built its proprietary FUSION™ System platform to design and develop a pipeline of novel covalent product candidates.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2022 December 31, 2023 has been derived from the audited financial statements at that date but does not include all of the information required by GAAP for complete financial statements. These unaudited condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments which are necessary for a fair statement of the Company's financial information. The unaudited interim results of operations for the three and nine months ended September 30, 2023 March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2023 December 31, 2024 or for any other interim period or for any other future year.

The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2022 December 31, 2023, included in the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024.

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 $213.9 287.9 million at September 30, 2023 March 31, 2024. As of September 30, 2023 March 31, 2024, the Company had cash, cash equivalents, and restricted cash and investments of $199.5 145.3 million. Management believes that the existing financial resources are not sufficient to continue operating activities for at least one year past the issuance date of these unaudited condensed financial statements. The Company's ability to continue as a going concern will require the Company to raise additional capital to fund the Company's operations through public or private equity offering, debt financings, collaborations and licensing arrangements or other sources. There can be no assurance that additional financing will be available

to the Company or that such financing, if available, will be available on terms acceptable to the Company. Accordingly, there is substantial doubt about the Company's ability to continue as a going concern.

The Company has historically financed its operations primarily through the sale of convertible preferred stock and common stock and the issuance of unsecured promissory notes. To date, none of the Company's product candidates have been approved for sale, and the Company has not generated any revenue since inception. Management expects operating losses to continue and increase for the foreseeable future, as the Company continues clinical development activities for its lead product candidate and advances the preclinical and clinical development of other product candidates. The Company's prospects are subject to risks, expenses and uncertainties frequently encountered by companies in the biotechnology industry as discussed below. There can be no assurance that in the event the Company requires additional financing, such financing will be available on terms which are favorable or at all. Failure to generate sufficient cash flows from operations, raise additional capital or reduce certain discretionary spending would have a material adverse effect on the Company's ability to achieve its intended business objectives.

Note 2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of these unaudited condensed financial statements in conformity with U.S. GAAP requires management There have been no significant changes to make estimates and assumptions that affect the amounts reported significant accounting policies during the three months ended March 31, 2024, as compared to those included in the financial statements and accompanying notes. On an ongoing basis, Company's Annual Report on Form 10-K filed with the Company evaluates its estimates, including, but not limited to, those related to clinical and preclinical accruals, manufacturing accruals, fair value of common stock, stock-based compensation, operating lease right-of-use (ROU) assets and liabilities and income taxes. The Company bases its estimates SEC on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates. March 28, 2024.

Segments

Recent Accounting Pronouncements - Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, Improvements to Reportable Segment Disclosures ("ASU 2023-07") which is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses, including for single reportable segment entities. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted.

The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company operates and manages its business as one reportable and operating segment, which is currently evaluating the business of developing covalent small molecule drugs to treat patients with genetically defined cancers and metabolic diseases. 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 disclosure requirements related to the United States of America.

Concentration of Credit Risk and Other Risks and Uncertainties*new standard.*

In December 2023, the Financial instruments that potentially subject Accounting Standards Board issued Accounting Standards Update ("ASU") 2023-09, "Income Taxes - Improvements to Income Tax Disclosures" requiring enhancements and further transparency to certain income tax disclosures, most notably the Company to a concentration of credit risk, consist primarily of cash, cash equivalents tax rate reconciliation and investments. The Company maintains bank deposits in federally insured financial institutions and these deposits may exceed federally insured limits. The Company invests in money market funds, U.S. Treasury securities, U.S. government agency securities, corporate notes, commercial paper, and asset backed securities. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash and cash equivalents and issuers of investments to the extent recorded in the balance sheet. The Company's investment policy limits investments to money market funds, certain types of debt securities issued by the U.S. Government and its agencies, corporate notes and commercial paper, and places restrictions on the credit ratings, maturities and concentration by type and issuer. The Company has not experienced any losses on its deposits of cash, cash equivalents and investments.
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 preclinical studies, clinical trials and achievement of milestones, uncertainty of regulatory approval of the Company's existing and potential product candidates, uncertainty of market acceptance of the Company's product candidates (if approved), competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole source suppliers and changes in the Company's operating expenses as a result of these uncertainties and other factors, such as inflation. 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.

Cash, Cash Equivalents, and Restricted Cash

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. Cash equivalents consist of amounts invested in money market accounts and are stated at fair value. Restricted cash consists of two stand-by letters of credit issued to the Company's landlord in connection with two of the Company's leases.

Investments

The Company adopted ASU 2016-13, Measurement of Credit Losses on Financial Instruments, on January 1, 2023. Investments consist of money market funds, U.S. Treasury Securities, and corporate notes. The Company's investments have been classified

and accounted for as available-for-sale securities. Fixed income securities consist of U.S. Treasury securities, U.S. government agency securities, corporate debt securities, commercial paper and asset backed securities. The specific identification method is used to determine the cost basis of fixed income securities sold. These securities are recorded on the balance sheets at fair value and reported in cash equivalents, short-term investments, or long-term investments. The Company classifies its investments with the remaining effective maturities of twelve months or less from the balance sheet date as short-term; otherwise, they are classified as long-term on the balance sheet.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or it is more likely than not that it will be required to sell the security before recovery of its amortized cost basis. If either of the criteria regarding intent or requirement to sell is met, the security's amortized cost basis is written down to fair value and recognized in interest and other income, net in the statement of operations. If neither criterion is met, the Company evaluates whether the decline in fair value is related to credit-related factors or other factors. In making this assessment, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security is compared to the amortized cost basis of the security. If the present value of cash flows expected to be

collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss on the condensed balance sheet, limited by the amount that the fair value is less than the amortized cost basis. Credit-related impairment losses, limited by the amount that the fair value is less than the amortized cost basis, are recorded through an allowance for credit losses in interest and other income, net in the statement of operations.

Any unrealized losses from declines in fair value below the amortized cost basis as a result of non-credit factors are recognized in accumulated other comprehensive income (loss), net of tax as a separate component of stockholders' equity, along with unrealized gains. Realized gains and losses and declines in fair value, if any, on available-for-sale securities are included in interest and other income, net in the statement of operations.

For purposes of identifying and measuring credit-related impairments, the Company's policy is to exclude applicable accrued interest from both the fair value and amortized cost basis of the related security. The Company has elected to write-off uncollectible accrued interest receivable balances in a timely manner, which is defined by the Company as when interest due becomes 90 days delinquent. The accrued interest write-off will be recorded by reversing interest income. Accrued interest receivable is recorded to prepaid expenses and other current assets.

Property and Equipment, Net

Property and equipment are recorded at cost net of accumulated depreciation and amortization. Property and equipment are depreciated using the straight-line method over the estimated useful lives of the assets. The useful lives of property and equipment are as follows:

Computer equipment	3 years
Furniture and fixtures	5 years
Laboratory equipment	5 years
Leasehold improvements	Shorter of remaining lease term or estimated useful life

Upon retirement or sale of the assets, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is recorded to the statements of operations. Repairs and maintenance are expensed as incurred.

Leases

The Company determines if an arrangement is a lease at inception in accordance with Accounting Standard Codification 842, “Leases” (ASC 842). As of September 30, 2023, the Company's lease population consisted of real estate leases and the Company did not have any finance leases.
Operating leases are included in operating lease right-of-use assets, current operating lease liabilities and non-current operating lease liabilities on the Company’s balance sheet. ROU assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent the Company’s obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. The Company’s lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. The Company’s leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of those lease payments. The Company determines the incremental borrowing rate based on an analysis of corporate bond yields with a credit rating similar to the Company. The determination of the Company’s incremental borrowing rate requires management judgment including the development of a synthetic credit rating and cost of debt as the Company currently does not carry any debt. The Company believes that the estimates used in determining the incremental borrowing rate are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary. The operating lease ROU assets also include adjustments for prepayments and accrued lease payments and exclude lease incentives. Operating lease cost is recognized on a straight-line basis over the expected lease term. Variable lease costs represent payments that are dependent on usage, a rate or index. Variable lease cost primarily relates to common area maintenance charges. Lease agreements that include lease and non-lease components are accounted for as a single lease component. The Company has elected to apply the short-term lease exception for all lease agreements with a noncancelable term of less than twelve months.

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash

flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There was no impairment of long-lived assets during the three and nine months ended September 30, 2023 and 2022.

Research and Development Expenses

The Company expenses research and development costs as they are incurred. Research and development expenses consist primarily of: (i) personnel-related expenses, including salaries, benefits and stock-based compensation expense, for personnel in the Company's research and development functions; (ii) fees paid to third parties such as contractors, consultants and contract research organizations (CROs), for animal studies and other costs related to preclinical and clinical testing; (iii) costs related to acquiring and manufacturing research and clinical trial materials, including under agreements with third parties such as contract manufacturing organizations (CMOs), and other vendors; (iv) costs related to the preparation of regulatory submissions; (v) expenses related to laboratory supplies and services; and (vi) depreciation of equipment and facilities expenses.

Accrued Research and Development Expenses

The Company records accruals for estimated costs of research, preclinical studies, clinical trials, 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, investigator fees, 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 September 30, 2023, there have been no material differences from the Company's estimated accrued research and development expenses to actual expenses.

Stock-Based Compensation

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees, non-employees and directors based on estimated grant-date fair values. The Company uses the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period, and estimates the fair value of share-based awards to employees, non-employees and directors using the Black-Scholes option-pricing model. The Company accounts for forfeitures as they occur. The fair value of restricted stock awards is based on grant-date fair value. The fair value of each purchase under the employee stock purchase plan (ESPP) is estimated at the beginning of the offering period using the Black-Scholes option pricing model and recorded as expense over the service period using the straight-line method.

Income Taxes

The Company began providing for income taxes under the asset and liability method in December 2020 upon conversion from a limited liability company into a corporation. Current income tax expense or benefit represents the amount of income taxes expected to be payable or refundable for the current year. Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax basis of assets and liabilities and net operating loss and credit carryforwards and are measured using the enacted tax rates and laws that will be in effect when such items are expected to reverse. Deferred income tax assets are reduced, as necessary, by a valuation allowance when management determines it is more likely than not that some or all the tax benefits will not be realized.

The Company accounts for uncertain tax positions in accordance with ASC No. 740 *Income Taxes*. The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. Assessing an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit might change as new information becomes available.

The Company includes any penalties and interest expense related to income taxes as a component of income tax expense, as necessary.

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 each period presented.

Recent Accounting Pronouncements - Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss methodology, which will result in more timely recognition of credit losses. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. This ASU also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. paid. This ASU is effective for fiscal years beginning after December 15, 2022 December 15, 2024 on a prospective basis and interim periods within those fiscal years. retrospective application is permitted. The Company adopted ASU 2016-13 on January 1, 2023, using is currently evaluating the modified retrospective approach, and no cumulative effect adjustment to accumulated deficit was needed as impact of the adoption date. Additionally, no prior period amounts were adjusted and continue to be reported in accordance with the legacy other-than-temporary impairment model. The adoption of ASU 2016-13 did not have a material impact this standard on the Company's unaudited condensed financial statements. statements and related disclosures.

Note Note 3. Fair Value Measurement

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The following tables set forth the fair value of the Company's financial assets, which consist of cash equivalents and marketable

securities measured and recognized at fair value (in thousands):

	September 30, 2023				March 31, 2024				
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets included in cash and cash equivalents:										
Money market funds	Level 1	$ 196,838	$ —	$ —	$ 196,838	Level 1	$ 142,998	$ —	$ —	$ 142,998
Total		$ 196,838	$ —	$ —	$ 196,838		$ 142,998	$ —	$ —	$ 142,998

	December 31, 2022				
	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets included within cash and cash equivalents:					
Money market funds	Level 1	$ 105,684	$ —	$ —	$ 105,684
Financial assets included within short-term investments:					
Corporate notes	Level 2	1,151	—	(1)	1,150
Total		$ 106,835	$ —	$ (1)	$ 106,834

	December 31, 2023

	Fair Value Hierarchy Level	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Financial assets included in cash and cash equivalents:					
Money market funds	Level 1	$ 174,429	$ —	$ —	$ 174,429
Total		$ 174,429	$ —	$ —	$ 174,429

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Levels Levels1, 2 and 3 during the three and nine months ended September 30, 2023 March 31, 2024 and 2022. 2023. As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, there

were no financial instruments classified as Level 2 or Level 3. There have been no realized gains or losses recognized for the periods presented. Unrealized gains and losses are included in accumulated other comprehensive loss within stockholders' equity on the balance sheet.

As of September 30, 2023, there was There were no unrealized loss. As of December 31, 2022, all debt securities with an unrealized loss position have been in a loss position for less than one year. The aggregate fair value of debt securities in an unrealized loss position investments as of December 31, 2022 was $1.2 million with no individual securities in a significant unrealized loss position. The Company evaluated its securities for other-than-temporary impairment March 31, 2024 and December 31, 2023, as of December 31, 2022, and considered the decline in market value to be primarily attributable to current economic and market conditions and would not be required to sell the securities before recovery of the amortized cost basis. Based on this analysis, these marketable securities were not considered to be other-than-temporarily impaired as of December 31, 2022. As there were no unrealized losses as of September 30, 2023, such, no allowance for credit losses has been recognized as of September 30, 2023 March 31, 2024. During the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, the Company did not recognize any impairment losses related to investments.

Note 4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Laboratory equipment	$ 3,847	$ 2,331	$ 3,902	$ 3,852
Leasehold improvements	3,186	801	3,195	3,195
Computer equipment	130	130	146	130
Furniture and fixtures	409	325	409	409
Construction in progress	14	3,170	6	4
Total property and equipment, gross	7,586	6,757	7,658	7,590
Less: accumulated depreciation	(2,011)	(916)	(2,852)	(2,431)
Total property and equipment, net	$ 5,575	$ 5,841	$ 4,806	$ 5,159

Depreciation expense for the three and nine months ended September 30, 2023 March 31, 2024 was $0.4 million and $1.1 million, respectively. million. Depreciation expense for the three and nine months ended September 30, 2022 March 31, 2023 was $0.2 0.3 million and $0.5 million, respectively. million.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Accrued research and development materials and services	$ 4,984	$ 6,039	$ 14,054	$ 6,952
Accrued personnel expenses			2,430	5,956
Accrued professional services	294	208	669	443
Accrued personnel expenses	4,749	4,774		
Other	164	636	226	192
Total accrued expenses and other current liabilities	$ 10,191	$ 11,657	$ 17,379	$ 13,543

Note 5. Leases

Operating Leases

The Company leases its headquarters with its main offices and laboratory facilities in Redwood City and San Carlos, California. In September 2022, the Company entered into a thirty-month sublease agreement for office space located at 900 Middlefield Road, 4th Floor, Redwood City, California, pursuant to leases which commenced in January 2023 and expires expire in July 2025. In connection with the sublease, the Company made a security deposit of $2.1 million which is included in other assets on the

balance sheet at September 30, 2023. Upon commencement, the Company recognized a right-of-use asset and lease liability of $6.0 million, discounted at 11.5%, the Company's estimated incremental borrowing rate.

In November 2021, the Company entered into a four-year 2027 lease for additional lab space located at 1585 Industrial Road, , respectively. The San Carlos California which commenced in January 2023 and expires in January 2027. Under the provisions of the agreement, upon the commencement date, the term of the lab space located at 1599 Industrial Road, San Carlos, California (1599 lease), was also extended from April 2026 to January 2027. The lease included includes a renewal option for an additional five years until January 2032, which has been included in the determination of the right-of-use as of September 30, 2023 March 31, 2024.

In November 2023, the Company submitted a claim of approximately $1.5 million against tenant improvement allowance reimbursement in connection with its operating lease for lab space located at 1585 Industrial Road, San Carlos, California which was received in January 2024. Of the total reimbursement, approximately $0.4 million constitutes a loan required to be repaid in the form of additional lease payments over the remaining original lease term at an annual interest rate of 7%. As the term Upon receipt of the 1599 lease was extended, this did not result in a separate contract, accordingly, reimbursement, the Company remeasured the right-of-use asset and lease liability totaling to $7.8 million under one lease, discounted at 11.4%, the Company's estimated incremental borrowing rate. In addition, the Company is eligible for a tenant improvement allowance of up to $1.4 million, which will be accounted for as a lease incentive if utilized. There has been no lease incentive paid nor payable as of September 30, 2023. and related right-of-use asset.

The following table summarizes the lease costs and cash paid for the Company's leases (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Cash paid for operating lease liabilities	$ 986	$ 178	$ 2,870	$ 527	$ 640	$ 840
Operating lease costs	1,040	178	3,060	534	990	980
Short-term lease cost	—	773	—	2,285	—	—
Variable lease costs	358	72	925	217	381	245

The maturities of lease liabilities as of September 30, 2023 March 31, 2024 were as follows (in thousands):

Year Ending December 31,	Operating Lease Commitments	Operating Lease Commitments
2023 (remaining three months)	$ 986	
2024	4,054	
2024 (remaining nine months)		$ 3,154
2025	2,757	2,903
2026	1,380	1,525
2027	1,431	1,443
2028		1,474
Thereafter	6,300	4,827
Total future undiscounted lease payments	16,908	15,326
Less: Imputed interest	(4,818)	(4,234)
Total operating lease liabilities	$ 12,090	$ 11,092
Operating lease liabilities, current	2,825	3,166
Operating lease liabilities, non-current	9,265	7,926
Total operating lease liabilities	$ 12,090	$ 11,092

Supplemental balance sheet information related to leases was as follows:

	Three Months Ended March 31,	
	2024	2023
Weighted-average remaining lease term (in years) - operating leases	5.9	6.1
Weighted-average discount rate - operating leases	11.42%	11.43%

Note 6. Capital Structure

Common Stock

The Company's amended and restated certificate of incorporation authorizes the Company to issue up to 300,000,000 shares of common stock with a par value of $0.0001 per share and 10,000,000 shares of preferred stock with a par value of $0.0001 per share.

Common stockholders are entitled to dividends when and if declared by the Company's Board of Directors and after any preferred share dividends are fully paid. The holder of each share of common stock is entitled to one vote. As of September 30, 2023 March 31, 2024, no dividends have been declared.

The Company had reserved common stock, on an as-converted basis, for future issuance as follows:

	September 30	December 31

	September 30, 2023	December 31, 2022
Stock options, issued and outstanding	7,315,216	5,341,975
Stock options, authorized for future issuance	867,514	1,446,872
Employee stock purchase plan, available for future issuance	548,932	402,747
Restricted stock, issued and outstanding	156,999	292,236
Total	8,888,661	7,483,830

Public Offering

In April 2023, pursuant to a registration statement on Form S-3, the Company issued and sold 5,750,000 shares of common stock at a public offering price of $30.00 per share in an underwritten public offering. The net proceeds to the Company from the offering were approximately $161.8 million, after deducting underwriting discounts and commissions and offering costs of approximately $11.0 million.

Note 7. Stock-Based Compensation

The 2021 Equity Incentive Plan (the “2021 Plan”) provides for an increase of shares on the first day of each fiscal year beginning in 2022 and ending in 2031, equal to the lesser of (i) 5% of the Company’s common stock outstanding at December 31 of the immediately preceding year, or (ii) such number of shares as determined by the Company’s Board of Directors. Effective January 1, 2023 January 1, 2024, the number of shares of common stock available under the 2021 Equity Incentive (the “2021 Plan”) Plan increased by 1,493,437 1,798,926 shares pursuant to the evergreen provision of the 2021 Plan. provision. As of September 30, 2023 March 31, 2024, 867,514 770,983 shares of common stock remained available for issuance under the 2021 Plan. Effective January 1, 2024, the number of shares of common stock available under the 2021 Employee Stock Purchase Plan (the "ESPP") increased by 359,785 shares pursuant to the evergreen provision of the ESPP. As of

March 31, 2024, 811,671 shares of common stock remained available for issuance under the ESPP. As of March 31, 2024, 1,993,000 shares of common stock remained available for issuance under the 2023 Inducement Equity Plan as adopted in November 2023.

Stock-Based Compensation Expense

Total stock-based compensation expense related to the Company's equity incentive plan and employee stock purchase plan was recorded in the statements of operations and allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
Research and development	$ 1,778	$ 1,186	$ 4,902	$ 3,451	$ 2,546	$ 1,474
General and administrative	1,820	1,545	$ 5,365	4,169	2,476	1,759
Total stock-based compensation expense	$ 3,598	$ 2,731	$ 10,267	$ 7,620	$ 5,022	$ 3,233

As of September 30, 2023 March 31, 2024, there was $30.1 42.9 million of total unrecognized stock-based compensation expense which is expected to be recognized over a weighted-average period of 2.4 2.6 years.

The Company estimates the fair value of stock options using the Black-Scholes option pricing model and the fair value of these stock options was estimated using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Expected term in years	6.0	6.0	6.0	6.0
Expected volatility	82%	96%	80%	94%
Risk-free interest rate	4.4%	3.6%	3.7%	3.0%
Dividend yield	—	—	—	—
Weighted average fair value of share-based awards granted	$ 12.59	$ 8.81	$ 7.47	$ 4.91

Stock Options

The following table summarizes stock option activity:

Outstanding Options	Outstanding Options

	Shares	Weighted-Average Exercise	Weighted-Average Remaining Contractual Term (Years)	Shares	Weighted-Average Exercise	Weighted-Average Remaining Contractual Term (Years)
Balance, December 31, 2022	5,341,975	$ 8.79	8.6			
Balance, December 31, 2023				7,357,607	$ 9.34	8.1
Granted	2,304,295	10.54		1,838,510	14.60	
Exercised	(99,554)	7.65		(22,750)	5.09	
Cancelled	(231,500)	12.39		(4,082)	9.61	
Balance, September 30, 2023	7,315,216	9.24	8.4			
Exercisable, September 30, 2023	3,037,500	$ 8.82	7.9			
Balance, March 31, 2024				9,169,285	10.40	8.3
Exercisable, March 31, 2024				4,020,182	$ 9.08	7.6

Restricted Stock

The following table summarizes the restricted stock activity:

	Number of Restricted Stock Awards	Weighted-Average Grant Date Fair Value	Number of Restricted Stock Awards	Weighted-Average Grant Date Fair Value
Balance, December 31, 2022	292,236	$ 4.04		
Balance, December 31, 2023			111,920	$ 4.06
Granted	—	—	—	—
Released	(135,237)	4.02	(44,226)	4.03
Forfeited	—	—	(2,564)	3.96
Balance, September 30, 2023	156,999	$ 4.05		
Balance, March 31, 2024			65,130	$ 4.09

Note 8. Commitments and Contingencies

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant

judgment by the Company is required to determine both probability and the estimated amount. Management is currently not aware of any legal matters that could have a material adverse effect on its financial position, results of operations or cash flows.

Indemnification

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these arrangements is not determinable. The Company has never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, the Company believes the fair value of these agreements is not material.

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.

Note 9. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common stock outstanding for the period. For periods in which the Company generated a net loss, the Company does not include the potential impact of dilutive securities in diluted net loss per share, as the impact of these items is anti-dilutive.
The following equity instruments were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for the periods presented:

	September 30,		March 31,	
	2023	2022	2024	2023
Stock options, issued and outstanding	7,315,216	5,189,839	9,169,285	6,949,081
Estimated shares issuable under the employee stock purchase plan	108,082	97,459	114,511	105,062
Restricted stock, issued and outstanding	156,999	352,265	65,130	247,157
Total	7,580,297	5,639,563	9,348,926	7,301,300

Note 10. Subsequent Events

None. 10

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery and development of novel oral covalent small molecule drugs to treat patients with metabolic diseases and genetically defined cancers and metabolic diseases. cancers. A covalent 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 non-covalent drugs, including greater target selectivity, lower drug exposure, and the ability to drive a deeper, more durable response. Leveraging our extensive expertise in covalent binding chemistry and development, we built our proprietary FUSION™ System discovery platform to advance a pipeline of novel covalent small molecule product candidates. Our goal is to utilize our capabilities and FUSION™ System to become the leader in developing covalent small molecules to maximize the depth and durability of clinical benefit when treating various diseases. To date we have announced two clinical development candidates, BMF-219 and BMF-500.

BMF-219

Our lead product candidate, BMF-219, is designed to be an orally bioavailable, potent, and selective covalent 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. Menin plays a key role in beta-cell proliferation and function, as previously demonstrated through increased beta-cell mass generation in *Men1* knockout mice (Ja et al., 2021). We are developing BMF-219 for the treatment of menin regulated or dependent diseases such as type 1 and type 2 diabetes as well as subtypes of liquid and solid tumors.

BMF-219 in Diabetes

We are currently investigating BMF-219 in diabetes in our ongoing Phase 1/2 clinical trial COVALENT-111 (patients with type 2 diabetes) and our ongoing Phase 2 clinical trial COVALENT-112 (patients with type 1 diabetes).

Loss of functional beta cell mass is a core component of the natural history in both types of diabetes – type 1 diabetes (mediated by autoimmune dysfunction) and type 2 diabetes (mediated by metabolic dysfunction). Beta cells are found in the pancreas and are responsible for the synthesis and secretion of insulin, a hormone that helps regulate the body's capacity to absorb, metabolize, and convert glucose for energy. In patients with diabetes, beta cell mass and function are diminished over time, leading to insufficient insulin secretion and hyperglycemia. Menin is thought to act as a brake on beta cell turnover / beta cell growth, supporting the notion that inhibition of menin could lead to the regeneration of normal healthy beta cells. Based on these and other scientific findings, we are exploring the potential for menin inhibition as a possible therapeutic approach to improve beta cell health and mass, and thus potentially treat an underlying driver of diabetes.

In October 2022, we announced completion of the Phase 1 portion of COVALENT-111, a Phase 1/2 clinical trial of BMF-219 in healthy volunteers and adults with type 2 diabetes in Canada. In December 2022, we announced FDA clearance of the IND for BMF-219 in type 2 diabetes, allowing us to expand the COVALENT-111 study to sites in the United States. In September 2023, we announced FDA and Health Canada clearance of the expansion cohorts of COVALENT-111, allowing us to evaluate BMF-219, administered at 100 mg and 200 mg, with dosing durations up to 12 weeks in adult type 2 diabetes patients. The expansion portion will consist of approximately 300 patients with 54 subjects treated with BMF-219 and 18 treated with placebo in each arm. We have reported several positive clinical data readouts from the escalation portion of Phase 2 study (COVALENT-111) in type 2 diabetes patients, supporting the disease-modifying potential of BMF-219 to address a root cause of diabetes: loss of healthy, insulin-producing beta cells. In March 2024, we reported clinical data from the dose escalation phase of COVALENT-111. After just a 4-week treatment period in type 2 diabetes patients who had previously failed standard of care (HbA1c ≥7.0% and ≤10.5%),

BMF-219 demonstrated continued glycemic control at 26 weeks, or five months, after cessation of dosing. A general dose response was observed from BMF-219 in type 2 diabetes patients supported by dose-dependent PK response. The 50 mg cohort had the lowest placebo adjusted mean percent change of A1c (-0.04%) while 200 mg with food cohorts achieved the highest change of A1c (-1.4%). A higher proportion of patients treated with once daily (QD) 200 mg (36%) achieved a durable glycemic response (≥1.0% HbA1c reduction) compared to 100 mg QD cohorts (20%) at Week 26 (22 weeks off treatment). Patients with >7 years duration of diabetes

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and failing dual- or triple-agent therapy (including GLP1 RA and/or SGLT2i) (n=2) also demonstrated improved glycemic control (HbA1c -0.4%, -1.1%, and -1.1% at Weeks 4, 12, and 26, respectively) with BMF-219 dosed at 200 mg with food. An increase in HOMA-B and C-peptide generally correlated with glycemic control, consistent with BMF-219's core mechanism of action: beta-cell proliferation and improved beta-cell function. Dose levels of 100 mg and 200 mg have been selected for the first 3 Arms of the Expansion Phase, which will dose patients up to 12 weeks (compared to 4 weeks in the Escalation Phase) and extended follow-up to Week 52. BMF-219 was generally well tolerated with no serious adverse events and no adverse event-related study discontinuations, and no symptomatic or clinically significant hypoglycemia. The dose expansion cohorts of COVALENT-111 are currently enrolling and initial 26-week data is expected to be announced in the second half of 2024.

In December 2023, we presented data from preclinical ex-vivo human islet experiments of BMF-219. Dependent on dose concentration and also dependent on dose duration, BMF-219 was observed to increase beta cell mass and function, as well as promote controlled proliferation and enhance insulin content in beta cells. Proliferation was observed only under elevated glucose conditions, which mimics diabetic levels, and with continuous drug exposure.

In October 2023, we announced FDA clearance of the IND for BMF-219 in type 1 diabetes mellitus, allowing us to initiate a Phase 2 clinical trial in approximately 150 patients with stage 3 type 1 diabetes (COVALENT-112) at two oral dose levels (50 subjects treated with BMF-219 and 25 treated with placebo for each dose level), 100 mg and 200 mg, for 12-weeks of treatment followed by a 40 week off-treatment period. The trial will also include an open label portion (n=40), enrolling participants in the U.S. and Canada with type 1 diabetes up to 15 years since diagnosis. In December 2023, we announced Health Canada clearance of Clinical Trial Application (CTA) for BMF-219 in type 1 diabetes.

In April 2024, we highlighted initial data from the first two Stage 3 type 1 diabetes patients dosed with BMF-219 in COVALENT-112, where both patients demonstrated early signs of clinical activity with improved measures correlated with beta-cell function. BMF-219 has been well tolerated by both patients. A 26-week follow-up data of the open label portion of Phase 2 COVALENT-112 study of 40 patients with type 1 diabetes dosed for 12 weeks with BMF-219 is expected in the second half of 2024.

BMF-219 in Oncology

Our current cleared INDs for We are currently investigating BMF-219 in oncology relate to in our ongoing Phase 1 clinical trial COVALENT-101 (patients with subtypes of leukemia and lymphoma lymphoma) and our ongoing Phase 1/1b clinical trial COVALENT-102 (patients with KRAS solid tumors).

In January 2022, we announced that we had initiated dosing in COVALENT-101, a Phase 1 clinical trial to explore the safety and efficacy of BMF-219 in patients with relapsed/refractory AML and acute lymphoblastic leukemia (ALL), including those with

MLL/KMT2A gene arrangements or NPM1 mutations. In 2022, we amended the IND to initiate additional cohorts in the COVALENT-101 study to explore the potential utility of BMF-219 across a range of menin-dependent hematologic malignancies including MM, DLBCL, and CLL.

In October 2022, we announced the initiation of a Phase 1/1b clinical trial of BMF-219 (COVALENT-102) in patients with unresectable, locally advanced, or metastatic non-small cell lung cancer (NSCLC), colorectal cancer (CRC) and pancreatic ductal adenocarcinoma (PDAC) with an activating KRAS mutation. Dose escalation completion and selection of the recommended Phase 2 dose are expected in 2024.

In July 2023, we also reported initial topline data from ongoing Phase 1 clinical trial (COVALENT-101) showcasing initial responses in relapsed/refractory AML patients with menin-dependent mutations. New data revealed 2 two Complete Responses (CRs) (1 CR, 1 CRi) out of 5 five relapsed/refractory AML patients carrying menin-dependent mutations treated at Dose Level 4. BMF-219, the first and only investigational covalent small-molecule menin inhibitor in clinical development to our knowledge, was generally well tolerated with no dose-limiting toxicities observed, and no QTc prolongation reported. Dose Level 4 exposure correlates with initial activity seen in BMF-219's preclinical studies. Safety profile of BMF-219 We believe that this data supports further dose escalation. Enrollment In December 2023, we reported the achievement of minimal residual disease negativity (MRD-neg) in first complete responder in a patient with AML. Within the total of 7 patients selected as evaluable for efficacy, 2 CRs were observed with a mean time to response of 1.8 months. We believe that pharmacodynamic data from a case study of an AML patient containing NUP98-NSD1 mutation further supports the proposed mechanism of action of BMF-219 as a menin inhibitor; in-line with preclinical models, BMF-219 downregulated key leukemogenic genes (e.g. HOXA9, MEIS1) as well as MEN1. BMF-219 was generally well tolerated with no dose-limiting toxicities observed and without adverse event (AE) related treatment discontinuations. Four participants experienced Differentiation Syndrome (DS) ≤ Grade 3, managed by cytoreductive therapy (hydroxyurea and steroids). Two participants recovered without dose modification or interruption, and none of the participants discontinued due to DS. Clinical data to date support protocol enhancements to COVALENT-101 to include focusing exclusively on patients with menin sensitive mutations such as MLL-r and NPM1 mutant acute leukemias and higher dose levels for CYP3A4 inhibitor Arm (Arm B). Dose Level 5 has commenced to explore escalation completion and selection of the optimal biological dose. recommended Phase 2 dose are expected in 2024.

BMF-219 in Diabetes Mellitus 12

Our current cleared INDs for BMF-219 in diabetes mellitus relate to COVALENT-111 (patients with type 2 diabetes mellitus) and COVALENT-112 (patients with type 1 diabetes mellitus).

Loss of functional beta cell mass is a core component of the natural history in both types of diabetes — type 1 diabetes mellitus (mediated by autoimmune dysfunction) and type 2 diabetes mellitus (mediated by metabolic dysfunction). Beta cells are found in the pancreas and are responsible for the synthesis and secretion of insulin, a hormone that helps regulate the body's capacity to absorb, metabolize, and convert glucose for energy. In patients with diabetes, beta cell mass and function are diminished, leading to

insufficient insulin secretion and hyperglycemia. Menin is thought to act as a brake on beta cell turnover / beta cell growth, supporting the notion that inhibition of menin could lead to the regeneration of normal healthy beta cells. Based on these and other scientific findings, we are exploring the potential for menin inhibition as a possible therapeutic approach to improve beta cell health and mass, and thus potentially treat an underlying driver of diabetes.

In October 2022, we announced completion of the Phase 1 portion of COVALENT-111, a Phase 1/2 clinical trial of BMF-219 in healthy volunteers and adults with type 2 diabetes mellitus in Canada. In December 2022, we announced FDA clearance of the IND for BMF-219 in type 2 diabetes mellitus, allowing us to expand the COVALENT-111 study to sites in the United States. In January 2023, we announced the dosing of the first patient with type 2 diabetes mellitus in the United States.

In March 2023, we reported initial clinical data from the Phase 2 portion of COVALENT-111. 40 patients were enrolled in the first three cohorts of COVALENT-111, with the first cohort (Cohort 1) comprising 16 healthy volunteers (HVs); 12 HVs were exposed to 100 mg BMF-219 once daily (QD) for two weeks and 4 HVs were exposed to placebo. In Cohorts 2 and 3, T2DM patients (n=12 per cohort with 10 patients treated with BMF-219 and 2 patients on placebo) received BMF-219 once daily for 4 weeks with or without food, respectively. In the two active treatment cohorts, enrolled patients had T2DM diagnosed for $\leq$15 years, were between the ages of 18 to 65, had been treated with lifestyle management together with up to three anti-diabetic medications, with a stable dose for at least two months prior to screening, had a BMI ≥25 and ≤40 kg/m2, and had poorly controlled diabetes (HbA1c ≥7.0% and ≤10%). At baseline, diabetic patients enrolled in the two active treatment cohorts, Cohorts 2 and 3, had a median A1c of 7.9 and 7.8%, respectively.

Active treatment Cohort 3 (BMF-219 without food) compared to Cohort 2 (BMF-219 with food) showed a positive dose-response pharmacokinetics relationship demonstrated by about a threefold median increase in C_{max} (ng/ml) and AUC (ng x h/ml) when BMF-219 was administered without food. This increase in BMF-219 systemic exposure was in line with the differences seen in the response rates between the two cohorts. Specifically, the change in HbA1c at four weeks for Cohort 3 patients (n=9) (the active group denominator in Cohort 3 is 9 because the week 4 sample for one patient was unable to process) on BMF-219 (100 mg, without food) showed a median A1c reduction of -1.0% and a 89% (8/9) response rate at four weeks, with 78% of subjects achieving a $\geq$0.5% reduction in A1c and 56% achieving a $\geq$1.0% reduction in A1c. Cohort 2 patients (n=10) on BMF-219 (100 mg, with food) showed a median A1c reduction of -0.3% and a 70% (7/10) response rate at 4 weeks, with 30% of subjects achieving a $\geq$0.5% to $\leq$1.0% reduction in A1c. Placebo patients (n=4) showed a median and mean A1c reduction between -0.1% and -0.15%.

We also reported on the tolerability profile of BMF-219 observed in Cohorts 1, 2, and 3 of COVALENT-111. BMF-219 was generally well tolerated; all patients completed the four-week treatment, and all patients continue in follow-up to assess the durability of the treatment effect. There were no dose reductions, serious adverse events, or severe adverse events. In the active treatment Cohorts 2 and 3 (100 mg QD, n=24) 7 of 20 patients treated with BMF-219 showed mild (Grade 1) Treatment Emergent AEs (TEAEs), 1 of 20 patients treated with BMF-219 showed a moderate (Grade 2) TEAE and 2 of 4 patients treated with placebo showed mild (Grade 1) TEAEs. No patients showed symptomatic hypoglycemia and no other TEAEs were observed. In the healthy volunteer (HV) Cohort 1 (100 mg QD, n=16), 2 of 12 subjects treated with BMF-219 and 1 of 4 subjects treated with placebo showed mild (Grade 1) TEAEs. No other TEAEs were observed.

In June 2023, we presented additional clinical data from the first two cohorts of patients with T2D enrolled in the Phase 2 portion of COVALENT-111. At Week 12, eight weeks after the last dose of BMF-219, patients who received BMF-219 in Cohort 2 and 3

had a mean HbA1c reduction of 0.1% and 1.0%, respectively. Specifically in Cohort 3 (100 mg BMF-219 QD without food for 4 weeks), 50% of patients (n=5/10) saw a continued improvement in HbA1c with a mean reduction in HbA1c of 1.49% at Week 12, compared to the mean reduction of 0.9% at the end of the dosing period at Week 4 (an additional 62% HbA1c reduction). 60% (n=6/10) of Cohort 3 patients achieved an HbA1c of 7% or below at the end of Week 12, compared to 30% (n=3/10) at the end of dosing period (Week 4) and 10% (n=1/10) at the end of Week 1. The average C-peptide expression for patients in Cohort 3 increased through Week 8. A similar increase in HOMA-B was observed, stabilizing at Week 8. As measured by continuous glucose monitoring (CGM), 7 of 10 (70%) of patients maintained or improved time in range while off treatment (between Week 4 and Week 12). As measured by CGM, 60% (n=6/10) of Cohort 2 patients maintained or improved time in range while off treatment (between Week 4 and Week 12). Placebo patients (n=4) in Cohorts 2 and 3 showed a mean HbA1c increase of 0.10% at Week 12. HVs in Cohort 1 showed minimal mean change (-0.1% to 0.1%) in HbA1c during 14 days of BMF-219 treatment and 6 weeks of follow-up.

Tolerability data during the off-treatment period was also presented. During the Week 4 to Week 12 off-treatment period, no severe or serious TEAEs were noted.

Dosing of patients in the 200 mg without food cohort was recently completed and is now in the follow-up period. The 200 mg with food cohort led to an increase in mild to moderate nausea compared to 200 mg without food. This cohort will be transitioned to 100 mg BID dosing. No other clinical symptoms or clinical concerns were observed in this dose level.

In September 2023, we announced FDA and Health Canada clearance of the expansion cohorts of the ongoing Phase 2 clinical trial (COVALENT-111) in type 2 diabetes mellitus, allowing us to evaluate BMF-219, administered at 100 mg and 200 mg, with dosing durations up to 12 weeks in type 2 diabetes mellitus patients. The expansion portion will consist of approximately 300 patients. We also provided a high-level update on a total of 32 type 2 diabetes mellitus patients dosed for four weeks at 100 or 200 mg to date (10 active patients per arm, with dose levels 100 mg with food, 100 mg without (w/o) food, 200 mg w/o food, and 200 mg with food (n=2)). Compared to baseline, 84% of all patients dosed for four weeks with BMF-219 (n=32) in the escalation portion of COVALENT-111 showed a reduction in HbA1c at Week 4 and 74% at Week 12, two months after the final dose of BMF-219. During the 4-week dosing period, BMF-219 was generally well tolerated; there were no dose reductions, dose discontinuations, or severe or serious adverse events. Also, during the off-treatment period (Week 4 to Week 12), no severe or serious treatment emergent adverse events were noted.

In October 2023, we announced FDA clearance of the IND for BMF-219 in type 1 diabetes mellitus, allowing us to initiate a Phase 2 clinical trial in adults with type 1 diabetes mellitus (COVALENT-112) at two oral dose levels, 100 mg and 200 mg unfed, for 12-weeks of treatment followed by a 40 week off-treatment period.

BMF-500

Beyond Including the discovery and development of BMF-219, we are utilizing our novel FUSION™ FUSIONTM System to pioneer covalent treatments against other high-value genetic drivers of disease. In May 2022, we announced the nomination of our second development candidate, BMF-500, a third-generation oral covalent small molecule inhibitor of activating mutations of the FMS-like tyrosine kinase 3 (FLT3), which are the most frequent genetic alteration in AML and are associated with poor prognosis. We believe that, despite available therapies, the treatment of patients with FLT3-mutated AML continues to be considered a significant unmet medical need. In December 2022, we presented initial preclinical data at ASH the American Society of Hematology Annual Meeting (ASH) demonstrating BMF-500's picomolar affinity to activating FLT3 mutations including FLT3-ITD and various tyrosine kinase domain (TKD) mutations, multi-fold higher potency and increased cytotoxicity than commercially

available non-covalent FLT3 inhibitor gilteritinib, as well as complete tumor regression in mouse models of FLT3-ITD acute myeloid leukemia (AML) and maintenance of effect without the need for continued exposure. In May 2023, we announced FDA clearance of our IND to study BMF-500 in a Phase 1 study (COVALENT-103) examining safety and efficacy in patients with relapsed or refractory acute leukemia with FLT3 wild-type and FLT3 mutations, including those with MLLr/NPM1 mutations. In October 2023, we announced the first patient has been dosed with BMF-500 in relapsed or refractory acute leukemia. Dose escalation completion and selection of the recommended Phase 2 dose are expected in 2024.

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 September 30, 2023 March 31, 2024, we had an accumulated deficit of $213.9 million $287.9 million. We incurred net losses of $82.4 million $39.1 million and $56.5 million $29.1 million for the nine three months ended September 30, 2023 March 31, 2024 and 2022, 2023, respectively. 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 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 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 additional INDs;
- continue the conduct our ongoing preclinical studies and Phase 1 clinical development trial of BMF-219 for the treatment in variou types of patients with liquid and tumors, our planned Phase 1/1b clinical trial of BMF-219 in solid tumors as well as patients with type 1 and KRAS mutations, our Phase 1/2 clinical trial of BMF-219 in type 2 diabetes mellitus;
- explore the potential and our Phase 2 clinical utility trial of BMF-219 in other diabetic patient populations, including pre-diabetes;
- continue the clinical development of BMF-500, a covalent inhibitor of FLT3;
- continue our efforts to develop product candidates from our FUSION™ System discovery platform;type 1 diabetes;
- conduct preclinical studies and initiate and conduct 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.

We may need to raise additional capital in the future to fund our operations, including to conduct and complete clinical trials for our 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 currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates. All of our product candidates are small molecules and are manufactured in synthetic processes from available or custom synthesized starting materials. The chemistry is scalable and uses commonly available pharmaceutical 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

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not yet have a marketing or sales organization or commercial infrastructure. Accordingly, we will incur significant expenses to develop a marketing and sales organization and commercial infrastructure in advance of generating any product sales.

Components of Operating Results

Revenue

To date, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future.

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. depreciation.

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 BMF-500, and advance our 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 our ongoing preclinical development activities and clinical trials of BMF-219 and BMF-500 in various types of liquid cancer and solid tumors, as well as in type 2 diabetes mellitus, metabolic diseases, of any future preclinical development and clinical trials of our product candidates including BMF-500, and other research and development activities we may conduct; conduct, such as our Phase 1/2 clinical trial of BMF-219 in type 2 diabetes and Phase 2 clinical trial of BMF-219 in type 1 diabetes;

- uncertainties in clinical trial design and the interpretation of clinical trial data;
- per patient trial costs;
- the duration, scope and number of trials required for approval;
- the number of sites included in the trials;
- the number of patients who 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;
- 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, of 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 in light of adverse global market conditions; 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. products and product candidates. 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 and stock-based compensation expense 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 product candidates due to advances in our research and development programs.

Interest and Other Income, Net

Interest and other income, net consists primarily of interest earned on our investments and non-cash interest income (loss) related to accretion (amortization) of the discount (premium) on marketable securities.

Results of Operations

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

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

	Three Months Ended March 31,		
	2024	2023	$ Change
Operating expenses:			

Research and development	$ 33,776	$ 24,395	$ 9,381
General and administrative	7,283	5,636	1,647
Total operating expenses	41,059	30,031	11,028
Loss from operations	(41,059)	(30,031)	(11,028)
Interest and other income, net	1,998	980	1,018
Net loss	$ (39,061)	$ (29,051)	$ (10,010)

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	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	$ Change	2023	2022	$ Change
Operating expenses:						
Research and development	$ 25,347	$ 18,242	$ 7,105	$ 71,680	$ 42,174	$ 29,506
General and administrative	5,772	5,242	530	17,127	15,184	1,943
Total operating expenses	31,119	23,484	7,635	88,807	57,358	31,449
Loss from operations	(31,119)	(23,484)	(7,635)	(88,807)	(57,358)	(31,449)
Interest and other income, net	2,690	594	2,096	6,436	844	5,592
Net loss	$ (28,429)	$ (22,890)	$ (5,539)	$ (82,371)	$ (56,514)	$ (25,857)

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the periods indicated (in thousands):

Three Months Ended September 30,	Nine Months Ended September 30,	Three Months Ended March 31,

	2023	2022	$ Change	2023	2022	$ Change	2024	2023	$ Change
External costs	$ 15,811	$ 11,841	$ 3,970	$ 44,115	$ 24,460	$ 19,655	$ 22,240	$ 16,161	$ 6,079
Internal costs:									
Personnel-related expenses (including stock-based compensation)	7,353	4,920	2,433	21,440	13,572	7,868	9,507	6,377	3,130
Facilities and other allocated expenses	2,183	1,481	702	6,125	4,142	1,983	2,029	1,857	172
Total research and development expenses	$ 25,347	$ 18,242	$ 7,105	$ 71,680	$ 42,174	$ 29,506	$ 33,776	$ 24,395	$ 9,381

Research and development expenses increased by $7.1 million $9.4 million during the three months ended September 30, 2023 March 31, 2024 compared to the three months ended September 30, 2022 March 31, 2023. The increase of $4.0 million $6.1 million in external costs was primarily driven by an increase of $5.2 million $4.5 million related to clinical activities. The activities, an increase is offset by the decrease of $1.5 million $0.7 million in expenses related to manufacturing activities consultants and decrease an increase of $0.9 million $0.6 million related to preclinical activities primarily due to timing variations in execution of these activities. Personnel-related expenses, including stock-based compensation, increased by $2.4 million $3.1 million due to an increase in headcount. Depreciation and facilities increased by $0.7 million primarily due to new lease agreements for additional office and laboratory space in Redwood City and San Carlos which commenced in 2023.

Research and development expenses increased by $29.5 million during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. The increase of $19.7 million in external costs was primarily driven by an increase of $19.1 million related to clinical activities, $1.4 million related to manufacturing activities performed in relation to clinical

development of BMF-219 and BMF-500 and $1.2 million related to external consultants and advisors. The increase is offset by the decrease in preclinical related activities of $3.3 million. Personnel-related expenses, including stock-based compensation, increased by $7.9 million due to an increase in headcount. Depreciation and facilities increased by $2.0 million $0.2 million primarily due to new lease agreements for additional office and laboratory space in Redwood City and San Carlos which commenced in 2023.

General and Administrative Expenses

General and administrative expenses increased by $0.5 million $1.6 million during the three months ended September 30, 2023 March 31, 2024 compared to the three months ended September 30, 2022 and by $1.9 million during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 March 31, 2023. The increase in both periods was is primarily due to increased increase in personnel-related expenses, including stock-based compensation due to of $1.1 million, resulting from an increase in headcount. headcount, increase in legal costs of $0.4 million related to intellectual property related matters and increase in general external consultants cost.

Liquidity and Capital Resources

Liquidity

We have funded our operations primarily through the sale and issuance of shares of our common and convertible preferred stock and the issuance of unsecured promissory notes from inception through December 2020. In April 2021, we completed our IPO and issued an aggregate of 9,000,000 shares of our common stock at a price of $17.00 per share. Following the initial closing public offering (IPO), to date, we have used all of the IPO, an additional 823,532 shares were issued in connection with the partial exercise by the underwriters of their option to purchase additional

shares of common stock. Proceeds net proceeds from the IPO, and there was no material change in our actual use of the net of underwriting discounts and commissions and offering costs, were $152.8 million. proceeds from the IPO from that described in the final prospectus for our IPO.

On October 14, 2022, we filed a shelf registration statement on Form S-3 (the Shelf Registration Statement) with the SEC relating to the registration of up to an aggregate of $350.0 million in shares of our common stock, preferred stock, debt securities, warrants and units or any combination thereof. The Shelf Registration Statement was declared effective by the SEC on October 24, 2022. In April 2023, pursuant to the Shelf Registration Statement, we sold an aggregate of 5,750,000 shares of common stock at a price of $30.00 per share in an underwritten public offering for gross proceeds of $172.5 million, resulting in net proceeds of approximately $161.8 million after deducting underwriting discounts, commissions, and offering costs.

As of September 30, 2023 March 31, 2024, we had cash, cash equivalents, and restricted cash and investments of $199.5 million $145.3 million and an accumulated deficit of $213.9 million $287.9 million. Based on We have incurred substantial operating losses and have used cash in our operating activities since inception. Without any future financing, the current business operating plan we believe that our under the existing cash and cash equivalents, and restricted cash and investments as of March 31, 2024, will not be sufficient for us to fund our planned operations operating expenses and capital expenditure requirements for at least one year past twelve months following the issuance date of the unaudited condensed financial statements appearing elsewhere in this Quarterly Report statements. Our ability to continue as a going concern will require us to obtain additional financing to fund

our operations and there can be no assurance that additional financing will be available to us or that such financing, if available, will be available on Form 10-Q. terms acceptable to us. Accordingly, there is substantial doubt about our ability to continue as a going concern.

Future Funding Requirements

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 public or private or public equity or offerings, debt financings, collaborative collaborations and licensing arrangements or other arrangements with corporate sources, or through other sources of financing. sources. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and

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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, timing, progress, duration, costs and results of our clinical trials, drug discovery, preclinical development activities, ar 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
- our ability to establish and maintain strategic collaborations and other similar partnerships for the development and

commercialization of our product candidates; and

- the impact of the COVID-19 pandemic and adverse global economic conditions on our business, 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 other third parties rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

See the section of this Quarterly Report on Form 10-Q titled “Risk Factors” for additional risks associated with our substantial capital requirements.

Summary Statement of Cash Flows

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

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022	2024	2023
Net cash (used in) provided by:				
Operating activities	$ (73,755)	$ (42,216)	$ (32,030)	$ (24,044)
Investing activities	(2,212)	28,042	(35)	(1,756)
Financing activities	163,176	749	116	201
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 87,209	(13,425)		

Net decrease in cash, cash equivalents, and restricted cash	$ (31,949)	(25,599)

Net Cash Used in Operating Activities

Net cash used in operating activities was $73.8 million $32.0 million during the nine three months ended September 30, 2023 March 31, 2024 and consisted of a net loss of $82.4 million $39.1 million, offset by a decrease an increase in net assets of $4.7 million $0.6 million and non-cash adjustments of $13.3 million $6.4 million. The increase in net assets consisted primarily of an increase in prepaid expenses and other current assets of $0.3 million, an increase in other assets of $1.2 million, a decrease in accounts payable of $2.2 million offset by an increase in accrued expenses and other current liabilities of $3.8 million, and an increase in operating lease liabilities of $0.5 million. Non-cash adjustments consisted primarily of stock-based compensation expense of $5.0 million and operating lease expense of $1.0 million.

Net cash used in operating activities was $24.0 million during the three months ended March 31, 2023 and consisted of a net loss of $29.1 million, offset by an increase in net assets of $0.9 million and non-cash adjustments of $4.1 million. The increase in net assets consisted primarily of a decrease in prepaid expenses and other current assets of $1.4 million $2.3 million, decrease in accrued expenses and other current liabilities of $2.6 million and a decrease in operating lease liabilities of $1.8 million. The decrease is offset by an increase in other assets of $1.7 million $0.7 million, an increase in accounts payable of $0.7 million, and a decrease in accrued liabilities of $0.8 million. Non-cash adjustments consisted primarily of stock-based compensation expense of $10.2 million and operating lease expense of $2.0 million.

Net cash used in operating activities was $42.2 million during the nine months ended September 30, 2022 and consisted of a net loss of $56.5 million offset by an increase in net assets of $5.6 million and non-cash adjustments of $8.7 million. The increase in net assets consisted primarily of an increase in accrued expenses and other current liabilities of $7.6 million and an increase in prepaid expenses and other current assets of $2.4 million. Non-cash adjustments consisted primarily of stock-based compensation expense of $7.6 million $3.2 million.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $2.2 million $0.03 million during the nine three months ended September 30, 2023 March 31, 2024 and was primarily related to the purchase of property and equipment partially offset by maturities of investments. equipment.

Net cash provided by used in investing activities was $28.0 million during $1.8 million for the nine three months ended September 30, 2022 March 31, 2023 and was primarily related to maturities the purchase of investments. property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $163.2 million $0.1 million during the nine three months ended September 30, 2023. Cash provided by financing activities was related March 31, 2024 and relates to $161.8 million net proceeds received from the public offering of our common stock and $1.4 million of proceeds received from stock option exercises and purchases under the employee stock purchase plan. exercises.

Net cash provided by financing activities was $0.7 million during $0.2 million for the nine three months ended September 30, 2022 and March 31, 2023. Cash provided by financing activities was related to proceeds received from stock option exercises and purchases under the employee stock purchase plan. exercises.

Contractual Obligations

As of September 30, 2023 March 31, 2024, there have been no material changes from the contractual obligations and commitments as of December 31, 2022 December 31, 2023 previously disclosed in our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024.

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.

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 unaudited condensed 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 unaudited condensed 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

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understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Our critical accounting policies are described in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" in our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. During the three months ended September 30, 2023 March 31, 2024, except as described in Note 2 to the unaudited condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. There was no material foreign currency risk for the quarter ended September 30, 2023 March 31, 2024. We held $199.5 million $145.3 million in cash, cash equivalents, and restricted cash and investments as of September 30, 2023 March 31, 2024. Cash equivalents consisted of money market funds. Restricted cash consisted of two stand-by letters of credit issued to our landlord in connection with the lab leases. We held no interest-bearing liabilities as of September 30, 2023 March 31, 2024. Historical fluctuations in interest rates have not been significant for us. Due to the short-term maturities of our cash equivalents, an immediate 10% relative change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, our principal executive officer and principal financial officer, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that as of such date our disclosure controls and procedures were effective at a reasonable assurance level (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (b) to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended September 30, 2023 March 31, 2024 identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

Our business is subject to various risks and uncertainties, including those described below, that we believe apply to our business and the industry in which we operate. You should carefully consider these risks, as well as the other information in this Quarterly Report on Form 10-Q, including our unaudited condensed financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business.

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 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 clinical-stage biotechnology company with a limited operating history with which investors can evaluate our business and prospects. We commenced operations in August 2017, have not 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, preparing for and initiating our first clinical trial, and establishing arrangements with third parties for the manufacture of initial quantities of product candidates. We currently have two product candidates, BMF-219 and BMF-500, under investigation in clinical trials, with the first patient recently dosed with BMF-500. BMF-500 in October 2023. Our remaining product candidates are in the discovery or preclinical development stage.

We have limited experience as a company in conducting clinical trials and have not successfully completed the clinical development of any product candidates to date. 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 early in our development efforts and have not yet completed the development of any of our product candidates. 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 sales of our common stock and convertible preferred stock.

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We have incurred significant net losses in each reporting period since we commenced operations in August 2017. Our net losses were $82.4 million $39.1 million and $56.5 million $29.1 million, for the nine three months ended September 30, 2023 March 31, 2024 and 2022 , respectively. 2023 ,respectively. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of $213.9 million $287.9 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 additional INDs;
- continue the clinical development of BMF-219 for the treatment of patients with liquid and solid tumors, as well as patients with type 1 and type 2 diabetes mellitus;

- explore the potential clinical utility of BMF-219 in other diabetic patient populations, including pre-diabetes;
- continue the clinical development of BMF-500, a covalent inhibitor of FLT3;
- continue our efforts to develop product candidates from our FUSION™ System discovery platform;
- conduct preclinical studies and initiate and conduct 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 and development 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. BMF-219, our lead product candidate, is in the early stage of clinical development. As such, we face significant translational risk as our product candidates advance further in clinical development, and promising results in preclinical studies or early clinical trials may not be replicated in later-stage 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, BMF-500 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 ongoing clinical

development of BMF-219 and BMF-500 and any 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 othe 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 various types of cancer;
- 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 therapies in our target indications, including cancer and metabolic diseases, 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 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 the discovery and development of novel covalent small molecules to treat patients with genetically defined cancers and metabolic diseases. 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 BMF-500 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

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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 metabolic disease treatment landscape or in the pharmaceutical, biopharmaceutical or biotechnology industry more generally, our business, financial condition and results of operations could be materially adversely affected.

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 and conduct 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 BMF-500, 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 ongoing and planned 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. We also expect to incur additional costs associated with our continuing operation as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of September 30, 2023 March 31, 2024, we had $199.5 million $145.3 million in cash, cash equivalents, and restricted cash, and investments. cash. Based on our current operating plan, we believe that our existing cash and cash equivalents, and restricted cash and investments as of March 31, 2024, without any future financing, will not be sufficient for the Company to fund our operations continue as a going concern for at least one year past from the issuance date of the unaudited condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. Our estimate as to how long we expect our existing capital resources 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 other 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, timing, progress, duration, costs and results of our clinical trials, drug discovery, preclinical development activities, and laboratory testing 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;
- our ability to establish and maintain strategic collaborations and other similar partnerships for the development and commercialization of our product candidates; and
- the impact of adverse global economic conditions 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, inflationary pressures, increases in interest rates and disruptions to and volatility in the credit and financial markets in the United States and worldwide or other factors.

There is substantial doubt about our ability to continue as a going concern.

To date, we have not generated any revenues from product sales and have incurred significant operating losses in each year since our inception and we anticipate that losses may continue for the next several years or until such time as we can generate substantial revenues and achieve profitability. In connection with the preparation of this quarterly report for the period ended March 31, 2024, our management has concluded that there is substantial doubt as to whether we can continue as a going concern for the twelve months following the issuance of this quarterly report. Our ability to continue as a going concern is dependent upon raising capital to maintain current operations and continue research and development efforts. We plan to raise

additional capital to fund our operations through public or private equity offerings, debt financings, and/or potential collaborations and license arrangement or other sources. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that we will be able to obtain financing or enter into a collaboration on terms acceptable to us.

Based on our current operating plan, we will not be able to continue as a going concern over the next twelve months unless we raise additional capital by other means. These factors raise substantial doubt about our ability to continue as a going concern.

Recent volatility in capital markets and lower market prices for many securities may affect our ability to access new capital through sales of shares of our common stock or issuance of indebtedness, which may harm our liquidity, limit our ability to grow our business, pursue acquisitions or improve our operating infrastructure and restrict our ability to compete in our markets.

Our operations consume substantial amounts of cash, and we intend to continue to make significant investments to support our business growth, pursue the preclinical and clinical development of our product candidates, respond to business challenges or opportunities, retain or expand our current levels of personnel, enhance our operating infrastructure, and potentially acquire complementary businesses and technologies. Our future capital requirements may be significantly different from our current estimates and will depend on many factors, including the need to:

- finance unanticipated working capital requirements;
- develop or enhance our technological infrastructure and our existing research and development capabilities;
- pursue acquisitions or other strategic relationships; and
- respond to competitive pressures.

Accordingly, we may need to pursue equity or debt financings to meet our capital needs. With uncertainty in the capital markets and other factors, such financing may not be available on terms favorable to us or at all. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could require us to pay significant interest on borrowings or involve additional restrictive covenants relating to our capital-raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. Our inability to obtain adequate financing or financing on terms satisfactory to us could have a negative impact on our financial condition and we could face significant limitations on 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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have or may enter into credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions with which we have or may enter into financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;

- Delayed or lost access to working capital sources and/or delays, inability or reductions in our ability to enter into new credit facilities or access other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; or
- Potential or actual breach of financial covenants in any credit agreements or credit arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws and otherwise have a material adverse impact on our business.

Risks Related to Product Development

Our discovery and development activities are focused on the development of novel covalent small molecule therapies, initially targeted at menin, to treat patients with genetically-defined cancers and metabolic diseases, 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 covalent small molecule therapies for patients with genetically-defined cancers and metabolic diseases, with a particular focus on menin, is an emerging field. While there is scientific evidence to support the feasibility of developing covalent therapies, the significant complexity and potential safety and toxicity concerns associated with poorly designed covalent binders have historically discouraged drug developers from pursuing this drug class. In particular, a significant risk for toxicity is posed by these small-molecule covalent 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 since our inception 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 novel covalent small molecule product candidates will demonstrate the deep inactivation of their targets or offer greater therapeutic windows than conventional non-covalent drugs. It is possible that the targets we select, such as menin, could be effectively and safely treated by more frequent dosing of non-covalent drugs, which could limit the potential advantages or perceived benefits of our covalent inhibitor product candidates.

Furthermore, although we believe, based on our preclinical work and research on covalent binders generally, that highly selective covalent 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, our lead product candidate, BMF-219, is in clinical development, and we recently dosed the first patient with our second product candidate, BMF-500, in October 2023, following clearance of our IND by the FDA in May 2023. Our current data is primarily limited to clinical data in a relatively small patient population for BMF-219, as well as animal models and preclinical cell lines for BMF-219 and BMF-500. These results may not be replicated in larger clinical trials, or, in the case of preclinical data, translate into humans. As such, even if we are able to develop small-molecule therapy candidates that demonstrate positive results in preclinical studies or early-stage clinical trials, there can be no assurance that such product candidates will subsequently demonstrate significant clinical benefit *in vivo* or in larger trials or will 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 active and selective covalent inhibitor of menin, in certain menin-driven cancers and/or metabolic diseases, we may never successfully identify additional covalent binding product candidates to validated oncology or other targets through our FUSION™ System. Therefore, we do not know if our approach of treating patients with genetically-defined cancers and metabolic diseases 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 novel covalent small molecule product candidates and progress these product candidates through clinical development for the treatment of various cancers and metabolic diseases. Although our research and development efforts to date have resulted in our discovery and preclinical development of BMF-219, BMF-500 and other programs, BMF-219, BMF-500 and such other programs may not be safe or effective in our target indications, and we may not be able to further develop BMF-219, BMF-500 or 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 a covalent 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 covalent 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 covalent small molecule 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 covalent 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 product candidates, BMF-219 and BMF-500. If we are unable to advance BMF-219, BMF-500 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize BMF-219, BMF-500 or any other product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We are early in our development efforts. We have not yet successfully completed clinical testing of our lead product candidate, BMF-219, in human subjects for various types of solid tumors or liquid tumors or type 2 diabetes mellitus, or type 1 diabetes, or our second product candidate, BMF-500, in human subjects for relapsed or refractory acute leukemia with FLT3 wild-type and FLT3 mutations, including those with MLLr/NPM1 mutations. We have only just received IND clearance to pursue the clinical development of BMF-219 in human subjects with type 1 diabetes mellitus. 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, BMF-500, 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 th regulatory approval process, manufacturing supply or clinical trial requirements and timing due to a continued and prolonged public health emergencies such as 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, including our ongoing Phase 1 clinical trial of BMF-219 in various types of liquid tumors, our Phase 1/1b clinical trial of BMF-219 in various types of solid tumors, our Phase 1/2 clinical trial of BMF-219 in type 2 diabetes mellitus, our Phase 2 clinical trial of BMF-219 in type 1 diabetes mellitus, and our Phase 1

clinical trial of BMF-500 in relapsed or refractory acute leukemia with FLT3 wild-type and FLT3 mutations, including those with MLL1r / NPM1 mutations;

- whether BMF-219, BMF-500 or any other product candidates that we may identify and pursue will demonstrate safety, tolerability and efficacy profiles that are satisfactory to the FDA or any foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product candidates from applicable regulatory authorities;

- completion of any required post-marketing approval commitments to applicable regulatory authorities in order to maintain marketing authorization for any of our product candidates that receive regulatory approval;
- 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 therapies for cancer or metabolic diseases;
- 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 an 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 meet the FDA requirements. 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 have two product candidates, BMF-219 and BMF-500, under investigation in clinical trials, with the first patient

recently dosed with BMF-500. We cannot be certain of the timely completion or outcome of our preclinical studies and clinical trials and cannot predict if the FDA will allow our existing and proposed clinical programs to proceed or if the outcomes of our preclinical studies and clinical trials will ultimately support further development of our programs. Our lead product candidate, BMF-219, is in clinical development in selected liquid tumors, solid tumors, and type 1 and type 2 diabetes mellitus, and we cannot be sure that we will be able to submit INDs or similar applications with respect to additional indications or 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 trials;

- timely completion of preclinical laboratory tests, animal studies and formulation studies in accordance with the FDA's GLP requirements and other applicable regulations;
- approval by an independent 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 ir 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 protoc 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 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;

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- 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 continued and prolonged public health emergencies such as 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.

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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 or BMF-500 will perform in clinical trials as BMF-219 or BMF-500 have 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.

Any future pandemic, epidemic, or outbreak of an infectious disease similar to the COVID-19 pandemic could materially adversely impact our business, results of operations, and financial condition, including our preclinical studies and clinical trials.

The COVID-19 pandemic and government responses created disruptions in global supply chains, resulted in significant travel and work restrictions in many regions and caused a strain on healthcare resources, and have continued to adversely impact many industries.

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 continued 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 emergency 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 or any future pandemic, epidemic, or outbreak of an infectious disease similar to the COVID-19 pandemic, we have experienced, and may continue to experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- 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 ongoing and planned clinical trials;
- delays or difficulties in enrolling and retaining patients in our ongoing and planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinic 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 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.

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 ongoing and 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, particularly certain cancer indications, 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 ongoing and planned 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 or other methods of treatment 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 pursuing;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinica trials;
- delays in or temporary suspension of the enrollment of patients in our planned clinical trials due to a continued and prolonged public health emergency such as 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 healt conditions, 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.

Type 2 diabetes mellitus is a highly heterogeneous disease, there are over sixty approved therapies being utilized in treating diabetes at various stages of the disease progression, with early lines of therapies largely genericized. There is also a significant industry pipeline of potentially emerging new treatments all addressing patients either in front line or as a follow-on treatment either in monotherapy or in combination.

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. There is no guarantee, however, that our product candidates that we may

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identify and pursue, even if approved as a second or subsequent line of therapy, would be approved for an earlier line of therapy, and, prior to seeking any such approvals, we may have to conduct additional clinical trials.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. Our future success may depend in part on our ability to maintain a competitive position with our FUSION™ system platform. If we fail to stay at the forefront of technological change in utilizing our platform to create and develop product

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candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and platform. While we believe that BMF-219, BMF-500, our discovery platform, knowledge, and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including commercial biopharmaceutical enterprises, academic institutions, government agencies and private and public research institutions. Many of our competitors, either alone or with their collaborators, have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and

effectiveness of our products, the timing and scope of marketing approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Any drug candidates that we successfully develop and commercialize will likely compete with existing therapies and new therapies that may become available in the future.

The incidence and prevalence for target patient populations of BMF-219 and BMF-500 are based on estimates and third-party sources. If the market opportunities for BMF-219, BMF-500 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 and BMF-500 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, BMF-500 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. In addition, we believe we are currently the only company in the United States developing covalent small molecule product candidates specifically targeted against menin. More broadly, we define ourselves as targeted drug developers focused on covalent small molecule therapeutics 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 covalent 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 covalent binding against protein targets of interest to us.

In particular with respect to our oncology franchise, we are aware of Kura Oncology's KO-539 and Syndax Pharmaceuticals' SNDX-5613, both of which target menin through the use of non-covalent inhibition. Both KO-539 and SNDX-5613 are in clinical development and have

demonstrated Phase 1 results that support continued development into pivotal studies and validate menin as a therapeutic target. Other clinical programs have been reported by Daiichi Sankyo (DS-1594), Janssen Pharmaceuticals (JNJ-75276617) and Sumitomo Pharma Oncology (DSP-5336). Additionally, other preclinical programs have been reported by Bayer (BAY-155), 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 and metabolic diseases. 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, BMF-500 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 the section of our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024 titled “Business—Competition.”

Our covalent small molecule 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.

As is the case with many oncology drugs, it is likely that there may be significant side effects associated with their use. BMF-219, BMF-500 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 non-covalent 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

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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, BMF-500 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 clinical trials of BMF-219 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 have announced or published, and may continue to 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

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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. 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.

Any future pandemic, epidemic, or outbreak of an infectious disease similar to the COVID-19 pandemic could materially adversely impact our business, results of operations, and financial condition, including our preclinical studies and clinical trials.

The COVID-19 pandemic and government responses created disruptions in global supply chains, resulted in significant travel and work restrictions in many regions and caused a strain on healthcare resources, and have continued to adversely impact many industries.

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 continued 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 emergency 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 or other future pandemic, epidemic or outbreak of an infectious disease, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- 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 ongoing and planned clinical trials;
- delays or difficulties in enrolling and retaining patients in our ongoing and planned clinical trials;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinic 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 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.

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 approved 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. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024 titled “Business—Coverage Government Regulation —Coverage and Reimbursement.”

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

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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 us 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. 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, any future pandemics or as required by clinical sites, IRBs, the 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 product 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 produc 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 othe 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 A condition or disease we are conducting or plan to conduct clinical trials for may not be a rare disease or condition that is eligible for orphan drug designation or 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 of 200,000 or more 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

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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 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 in instances of supply issues.

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 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.

A Breakthrough Therapy designation or Fast Track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development, regulatory review or approval process, and each designation does not increase the likelihood that any of our product candidates will receive regulatory approval in the United States.

We may seek Breakthrough Therapy designation for some of our product candidates. A Breakthrough Therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as Breakthrough Therapies by the FDA may also be eligible for

priority review and accelerated approval. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to therapies considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more

of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

We may seek Fast Track designations for some of our product candidates. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the drug or biologic demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

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

We may seek accelerated approval of our current or future product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful

advantage over available therapies. In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA requires that a sponsor of a drug or biologic receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence. Under FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA currently requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product. Thus, even if we seek to utilize the accelerated approval pathway, we may not be able to obtain accelerated approval and, even if we do, we may not experience a faster development, regulatory review or approval process for that product. In addition, receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

We may seek priority review designation for one or more of our other product candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. We may request priority review for our product candidates. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular product candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily result in an expedited regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

We may seek approval of our product candidate into RTOR (Real-time oncology review). This program may not lead to a faster regulatory review or approval process and does not increase the likelihood that our product candidate(s) will receive marketing approval. Participation in RTOR is voluntary. Our acceptance into RTOR does not guarantee or influence approval of our application, which is subject to the same statutory and regulatory requirements for approval as applications that are not included in RTOR. Although early approvals have occurred with applications selected for RTOR, this may not be the case for our application even if it is

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selected for RTOR. If at any time the FDA determines our participation in RTOR, if selected, is no longer appropriate, the FDA may rescind our acceptance and instruct us to follow routine submission procedures for marketing approval.

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.

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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.

If a prolonged government shutdown occurs, or if global health concerns 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, 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, tracking and tracing requirements, good laboratory practice requirements, and good clinical practice requirements, for any clinical trials that we conduct post-approval. Additionally, under FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed. 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. 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. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024 titled "Business—Healthcare Government Regulation —Healthcare Reform."

In August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in

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Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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.

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, 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, 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

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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.

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 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. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024 titled “Business—Government Regulation—Other Healthcare Laws.”

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. 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.

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.

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.

For example, 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 HITECH, and their respective implementing regulations. Compliance with HIPAA and HITECH may require us to modify our data processing policies and to incur substantial costs and expenses.

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.

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 and Chairman of the Board of Directors, Thomas Butler, and Chief Operating Officer and President, Ramses Erdtmann. We will need to hire additional personnel 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

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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 September 30, 2023 March 31, 2024, we had 103 110 full-time employees, including 78 83 employees engaged in research and development activities.

In order to successfully implement our development and commercialization plans and strategies, and as we continue to operate as a public company, we expect to need additional managerial clinical, regulatory, 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, BMF-500 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, BMF-500 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, BMF-500 or 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, BMF-500 or any 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, BMF-500 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 current U.S. tax law, our federal NOLs generated in taxable years beginning after December 31, 2020 may be carried forward indefinitely, but such deductibility is limited to 80% of current year taxable income.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (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 shifts in our stock ownership, some of which are outside our control. We have performed a Section 382 study and concluded that 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.

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

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development performed in the U.S. and outside the U.S. will be capitalized and amortized, which may have an adverse effect on our cash flow. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our shareholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law.

A portion of our chemistry-based product development and sourcing of certain manufacturing raw materials for our product candidates takes place outside the United States 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 to support the development of our product candidates. Any disruption in production or inability of our manufacturers outside the United States 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 outside the United States, 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 other foreign governments, political unrest or unstable economic conditions in these jurisdictions. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. In addition, legislative proposals (for example, the BIOSECURE Act and related legislation) are pending that, if enacted, could negatively impact U.S. funding for certain biotechnology providers having relationships with foreign adversaries or which pose a threat to national security. Third parties upon

whom we rely are identified and impacted by these legislative proposals and while the potential downstream adverse impacts are unknown, they may include disruptions in carrying out their contractual duties or meeting expected deadlines and, as a result, delays in the manufacture and development of our product candidates. 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 in the future, on 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. If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

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

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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 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, qualified personnel, their equipment and facilities and any applicable licenses or approvals. 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 an 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 at acceptable prices, or at all, 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, qualified personnel, their equipment and facilities and any applicable licenses or approvals.

In addition, from time to time we have relied upon, and may continue to rely upon, third-party contract manufacturers that are based in jurisdictions outside the United States. Legislative proposals are pending that, if enacted, could negatively impact U.S. funding for certain biotechnology providers having relationships with foreign adversaries or which pose a threat to national security. If any of our third-party manufacturers are impacted by these legislative proposals, the potential downstream adverse impacts on us are unknown but may include supply chain disruptions or delays.

Our business could be materially adversely affected by any 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, be able to supply materials or services to us at cost that are acceptable to us, 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

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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

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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 rene 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 on a combination of patent applications, 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.

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 product candidates and any future products. 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 be 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.

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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

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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

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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 lawsuits 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 t 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

The price of our stock has been and is likely to continue to be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

The trading price of our common stock has been and 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 herein, these factors include:

- the timing, progress, costs and results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, progress 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;
- our ability to develop our product candidates for the treatment of type 1 and type 2 diabetes mellitus or other metabolic diseases;
- 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 menin inhibitors 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;
- 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;
- inflationary pressures and general economic, political, industry and market conditions; 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 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.

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 preferences 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.

A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. A significant portion of our outstanding shares of common stock are held by a small number of stockholders, including our directors, officers and significant stockholders. Sales by our stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock.

We have also registered or intend to register all shares of our common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. As a result, these shares will be available for sale in the public market subject to vesting arrangements and exercise of options, and restrictions under applicable securities laws. In addition, our directors, executive officers and certain affiliates have established or may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to

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be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We will need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders. In October 2022, we filed a registration statement on Form S-3 relating to the registration of our common stock, preferred stock, debt securities, warrants and units or any combination thereof. In November 2022, we entered into an “at-the-market” offering program, or ATM, which provides for the offering, issuance and sale by us of shares of our common stock from time to time for aggregate gross proceeds of up to $100 million in sales deemed to be “at-the-market offerings” as defined by the Securities Act of 1933, as amended. Although we have not yet sold or issued any shares of common stock pursuant to the ATM, in April 2023, we sold 5,750,000 shares of common stock at $30.00 per share for gross proceeds of $172.5 million under the registration statement on Form S-3. Any additional sales or issuances of securities pursuant to this registration statement or otherwise may result in dilution to our stockholders and may cause the market price of our stock to decline. Furthermore, new investors purchasing securities that we may issue and sell in the future could obtain rights superior to the rights of our existing stockholders.

We are also authorized to grant stock options and other equity-based awards to our employees, directors and consultants pursuant to our 2021 Incentive Award Plan, or Incentive Plan. The number of shares available for future grant under the Incentive Plan will automatically increase each year on January 1, from January 1, 2022 to January 1, 2031, by the lesser of (A) five percent of the shares of Common Stock outstanding on the last day of the immediately preceding fiscal year and (B) such smaller number of shares as determined by the Board or the Committee (as defined in the Incentive Plan). We have also reserved shares of common stock for issuance pursuant to our 2021 Employee Stock Purchase Plan, or ESPP, which number of shares will automatically increase each year on January 1, from January 1, 2022 to January 1, 2031, by the lesser of (i) one percent of the shares of Common Stock outstanding on the last day of the immediately preceding fiscal year and (ii) such number of shares as may be determined by the Board (as defined in the ESPP); provided, however, no more than 4,500,000 shares may be issued under the ESPP. Currently, we plan to register any increase in the number of shares available for issuance under the Incentive Plan and the ESPP promptly following the effectiveness of any such increase. If our board of directors elects to increase the number of shares available for future grant under the Incentive Plan or the ESPP, our stockholders may experience additional dilution, and our stock price may fall.

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.

Our executive officers, directors and their respective affiliates beneficially own approximately 27% 28% of our outstanding voting stock as of September 30, 2023 March 31, 2024. In particular, Thomas Butler and Ramses Erdtmann are executive officers and directors and are affiliates of Point Sur Investors Fund I, LP and Point Sur Investors LLC, and Bihua Chen is a director and an affiliate of the entities affiliated with Cormorant Asset Management. 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.

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 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, 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 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 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 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 or causes of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this report. 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

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such claims or make such lawsuits more costly for stockholders, 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 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 and our indemnification agreements that we have entered into with our directors and officers 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.

General Risk Factors

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, 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, 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 current and 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.

We will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which 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, under the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the SEC has adopted significant corporate governance and executive compensation related rules and regulations, such as “say on pay” and proxy access. While emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years from the pricing of the

IPO, we 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.

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 controls 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 is required to report upon the effectiveness of our internal controls over financial reporting. When we lose our status as an "emerging growth company," as defined in the JOBS Act, and become a large accelerated filer, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls 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 controls 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 controls 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 controls over financial reporting in the future. Any failure to maintain internal controls 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 controls 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 controls over financial reporting once that firm begins 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 Global Select Market, the SEC, or other regulatory authorities. Failure to remedy any material weakness or significant deficiencies in our internal controls 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.

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 operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act the regulations of the Nasdaq Global Select 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 controls 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. We are required to 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, and we may experience difficulty in meeting these reporting requirements in a timely manner.

We expect that we will need to hire additional accounting, finance, and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements which may result in substantial costs. Any disruptions or

difficulties in implementing or using our finance and accounting systems 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 controls 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 the Nasdaq Global Select Market, the SEC or other regulatory authorities.

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

We are 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. For additional information, see the section of our Annual Report on Form 10-K filed with the SEC on March 28, 2023 March 28, 2024 titled “Financial Statements and Supplementary Data—Notes to Financial Statements—Recent Accounting Pronouncements.”

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:

- 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 an the financial statements;
- reduced disclosure obligations regarding executive compensation 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

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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 $1.235 billion in annual revenue; (ii) the date we qualify as a “large accelerated filer,” with at least $700 million of equity

securities held by non-affiliates; (iii) the date on which we have issued more than $1 billion in non-convertible debt securities during the prior three-year period; and (iv) December 31, 2026.
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 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.

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.
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, uncertainty about economic stability and changes in fiscal policy, including higher interest rates. 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.

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. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. We may also face increased cybersecurity risks due to our reliance on internet technology and

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the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We or third parties related to us may also experience security breaches, incidents, or compromises that may remain undetected for an extended period. Further, we have outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Sensitive Information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may also be vulnerable to disruptions in service and unauthorized access to or misuse of our confidential or proprietary information. Sensitive Information.

Further, 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). 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, misuse 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, incidents, or compromises 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) information and Sensitive 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, including litigation and governmental investigations and fines or penalties, 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. breach, incident, or compromise. 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 breach, incident or compromise were to result in a loss, destruction, misuse 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. incident, breach or compromise. 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.

Our business could be negatively impacted by corporate citizenship and environmental, social and corporate governance matters and/or our reporting of such matters.

There is an increasing focus from certain investors, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Geopolitical risks associated with the ongoing military conflict between Russia and Ukraine could have an adverse impact on our business, financial condition and results of operations, including our clinical trials.

In late February 2022, Russia commenced a military invasion of Ukraine, and sustained conflict and disruption in the region is likely. The uncertain nature, magnitude, and duration of hostilities stemming from the conflict in Ukraine, including the potential effects of sanctions limitations, retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations.

Sanctions imposed by the United States, European Union, and other countries in response to the conflict between Russia and Ukraine and the potential response to such sanctions may have an adverse impact our business, including our clinical trials, the financial markets and the global economy. As the conflict in Ukraine continues, there can be no certainty regarding whether such governments or other governments will impose additional sanctions, or other economic or military measures relating to Russia, which could further adversely affect market and economic conditions.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

(a) Unregistered Sales of Equity Securities

None.

(b) Use of Proceeds from Registered Securities

On April 15, 2021, our registration statement on Form S-1 (File No. 333-254793), was declared effective in connection with our IPO. There has been To date, we have used all of the net proceeds from the IPO, and there was no material change in the planned our actual use of the net proceeds from our the IPO as from that described in the registration statement on Form S-1. final prospectus for our IPO.

(c) Purchases of Equity Securities by Issuer and Affiliated Purchasers

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation, as currently in effect	8-K	4/20/2021	3.2	
3.2	Amended and Restated Bylaws, as currently in effect	8-K	4/20/2021	3.4	
4.1	Form of Common Stock Certificate	S-1/A	4/12/2021	4.2	
4.2	Description of Registrant's Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934	10-Q	5/27/2021	4.4	
4.3	Investors' Rights Agreement, dated December 18, 2020, by and among the Registrant and the investors listed therein	S-1	3/26/2021	10.1	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X

101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation, as currently in effect	8-K	4/20/2021	3.2	
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4.3	Investors' Rights Agreement, dated December 18, 2020, by and among the Registrant and the investors listed therein	S-1	3/26/2021	10.1	
10.1#	Offer Letter, dated July 24, 2023, by and between the Registrant and Juan Pablo Frias				X

31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	X

79 # Indicates a management compensation plan, contract or arrangement

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOMEA FUSION, INC.

Date: October 30, 2023 May 2, 2024

By: /s/ Thomas Butler

Thomas Butler

Principal Executive Officer

Date: October 30, 2023 May 2, 2024

By: /s/ Franco Valle

Franco Valle

Principal Financial and Accounting Officer

Exhibit 10.1

July 24, 2023
Juan Pablo Frias, MD

Dear Juan,

I am pleased to offer you employment with Biomea Fusion Inc. (the "Company"). The purpose of this letter is to set forth the terms of your proposed employment with the Company. If you indicate your agreement to the terms in this letter by signing the last page, this letter will constitute your employment agreement with the Company (the "Agreement").

1.**Employment and Duties.**

A.The Company will employ you as Chief Medical Officer, Head of Diabetes effective as of August 31, 2023. Your position will be full-time, and you will devote your full time and effort to the business and affairs of the Company. Full-Time duties to start no later than November 1, 2023. You will report directly to the Chief Executive Officer.

B.Your duties will be to establish and be responsible for strategic development and tactical implementation of the clinical studies for our research program in the diabetes space and other programs as assigned. This will include providing direct medical and physician oversite for phase I/II and proof of concept clinical trials, and clinician input into all aspects of discover and preclinical development, from target selection to preclinical and regulatory strategy, and tactics. The scope for the role is broad and requires an interest for working with many different tasks and duties. You will contribute to Biomea Fusion's success and will be interacting with senior leaders including the CEO routinely as duties are given you. You will perform the duties in good faith and to the best of your ability and will render all services which may be required of you in such position.

C.Your principal place of employment shall be 900 Middlefield Road, Redwood City, California; provided that, you may be required to travel on Company business during your employment.

2. **Compensation.**

A.Your initial base salary will be $500,000 per annum ("Base Salary"). Your Base Salary will be paid at periodic intervals, no less frequently than once per month, in accordance with the Company's payroll practices. The Company, however, retains the sole discretion to set salaries and other compensation at levels it deems appropriate.

B.The Company may, in its sole discretion, pay you a bonus. Your target bonus amount is 40% percent of your Base Salary. If the Company decides to pay you a bonus the Company will, in its sole discretion, determine the bonus amount and pay it at a time that the Company will, in its sole discretion, determine the bonus amount and pay it at a time that the Company will determine. The bonus is not earned until paid and no amount will be paid if your employment terminates for any reason prior to the payment date. Any bonus for the fiscal year in which employment begins will be prorated, based on the number of days you are employed by the Company. You must be employed by September 30th of the year in order to be eligible for a Bonus.

Biomea Fusion Inc.

900 Middlefield Road, 4th Floor, Redwood City, CA 94063

www.biomeafusion.com

Exhibit 10.1

C.Following your start of employment, and subject to Board approval, you will be granted an option to purchase 300,000 shares of the Company's Common Stock (the "Option"). Options typically are granted on approximately the 1st and the 15th day of each month for any new hire that has started since the previous grant date. The Company's options are granted at fair market value based on the closing price on the date of grant as quoted on the NASDAQ exchange and are governed by the terms and conditions of the Company's 2021 Incentive Award Plan and the associated option agreement. The Option will be subject to a four-year vesting schedule, under which l/l6th of the total will vest quarterly, after the date you begin employment.

D.The Company will deduct and withhold, from any and all compensation paid to you in connection with your employment, any and all applicable Federal, state and local income and employment withholding taxes and any other amounts required to be deducted or withheld by the Company Wider applicable statute or regulation.

3. **Expense Reimbursement**.

You will be entitled to reimbursement from the Company for all customary, ordinary and necessary business expenses incurred by you in the performance of your duties hereunder, provided you furnish the Company with vouchers, receipts and other details of such expenses within thirty (30) days after they are incurred. You must obtain written permission of your immediate superior before incurring any expense in excess of $2,000 (two thousand dollars).

4. **Fringe Benefits.**

A.You will be eligible to participate in any group life insurance plan, group medical and/or dental insurance plan, and other employee benefit plans, which are made available to employees of the Company and for which you qualify.

B.You will be eligible to participate in the Company's time-off policy. New employees are required to be employed for 30 days, prior to requesting time-off.

C.You will be entitled to 5 sick days annually in accordance with Company policy and accrue such sick days in accordance with such policy and applicable state or local law.

5. **Outside Employment and Competition During Employment Prohibited.**

A. During your employment with the Company: (i) you will devote your full working time and effort to the performance of your duties; and (ii) except as approved in writing by the Company's President and Chief Executive Officer, you will not directly or indirectly, whether for your own account or as an employee, consultant, or advisor, provide services to any business enterprise other than the Company.

B. Notwithstanding the provisions of Section 6(A), you will have the right to perform such incidental services as are necessary in connection with (i) your private passive investments, (ii) your charitable or community activities, and (iii) your participation in trade or professional organizations, but only to the extent such incidental services do not interfere with the performance of your services.

6. **Proprietary Information/Intellectual Property**.

Upon signing this Agreement, you will also sign and deliver to the Company the standard-form Proprietary Information and Inventions Assignment Agreement.

7. **Termination of Employment**.

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Exhibit 10.1

A.Your employment with the Company shall be at will. This means that either you or the Company may terminate your employment at any time, for any reason or no reason, without prior notice.

B.Upon termination of your employment for any reason, you agree that you shall be deemed to have resigned from all positions that you may hold as an officer or member of the Board of the Company or of any of its affiliates.

8. **Waiver of Jury Trial; Miscellaneous**

A.WAIVER OF TRIAL BY JURY: The parties to this Agreement waive any right to a trial by jury with regard to all claims arising under or concerning this Agreement to ensure expeditious resolution of such claims.

B.This Agreement, for all purposes, shall be construed in accordance with, and governed by, the laws of California without regard to conflicts of laws principles. The exclusive venue for all disputes arising under or concerning this Agreement shall be the state and federal courts with jurisdiction over San Mateo County, California.

C.Unless specifically provided herein, this Agreement contains all of the understandings and representations between you and the Company pertaining to the subject matter hereof and supersedes all prior and contemporaneous understandings, agreements, representations and warranties, both written and oral, with respect to such subject matter.

D.No provision of this Agreement may be amended or modified unless such amendment or modification is agreed to in a writing that specifically states the amendments and modifications and is signed by you and the Chief Executive Officer of the Company.

E.No waiver by either of the parties of any breach by the other party hereto of any condition or provision of this Agreement to be performed by the other party hereto shall be deemed a waiver of any similar or dissimilar provision or condition at the same or any prior or subsequent time, nor shall the failure of or delay by either of the parties in exercising any right, power, or privilege hereunder operate as a waiver thereof to preclude any other or further exercise thereof or the exercise of any other such right, power, or privilege.

F.This Agreement may be executed in separate counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. Facsimile, electronic, and .pdf signatures shall be considered original signatures for purposes of this Agreement.

9. **Background Check**

This offer is contingent upon a clear background check. You agree to assist as needed and to complete any documentation at the Company's request to meet this condition. Should your background check not be completed before your scheduled start date, the Company will permit you to start work provisionally, subject to a final clear background check. If the contingency for the background check is not met, then your employment will be terminated for Cause.

Please indicate your acceptance of the foregoing provisions of this employment agreement by signing the enclosed copy of this agreement and returning it to the Company. This offer, if not accepted, will expire within two days of the date of this offer letter.

Biomea Fusion Inc.

900 Middlefield Road, 4th Floor, Redwood City, CA 94063

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Exhibit 10.1

Very truly yours,

Biomea Fusion Inc.

By /s/ Thomas Butler

Thomas Butler

CEO

ACCEPTED BY AND AGREED TO

Signature: /s/ Juan Frias

Print Name: Juan P. Frias

Dated: July 31st, 2023

Biomea Fusion Inc.

900 Middlefield Road, 4th Floor, Redwood City, CA 94063

www.biomeafusion.com

Exhibit 31.1

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

I, Thomas Butler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Biomea Fusion, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleadi with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defin in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiarie made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by thi report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has mate affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons perforn the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2023 May 2, 2024

By: /s/ Thomas Butler

Thomas Butler

Principal Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Franco Valle, certify that:

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

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defin in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiarie made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by thi report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has mate affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons perforn the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2023 May 2, 2024

By: /s/ Franco Valle

Franco Valle

Principal Financial and Accounting Officer

Exhibit 32.1

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

In connection with the Quarterly Report of Biomea Fusion, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Date: October 30, 2023 May 2, 2024

By: /s/ Thomas Butler

Thomas Butler

Principal Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of Biomea Fusion, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

operations of the Company.

Date: October 30, 2023 May 2, 2024

By: /s/ Franco Valle

Franco Valle

Principal Financial and Accounting Officer

DISCLAIMER

THE INFORMATION CONTAINED IN THE REFINITIV CORPORATE DISCLOSURES DELTA REPORT™ IS A COMPARISON OF TWO FINANCIALS PERIODIC REPORTS. THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORT INCLUDING THE TEXT AND THE COMPARISON DATA AND TABLES. IN NO WAY DOES REFINITIV OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED IN THIS REPORT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S ACTUAL SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

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