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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Global Select Market on June 30, 2024, was $124,145,240.

The number of shares of Registrant's Common Stock outstanding as of March 24, 2025 was 37,572,250.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, on or before the date 120 days after the conclusion of the Registrant's fiscal year ended December 31, 2024 pursuant to Regulation 14A in connection with the Registrant's 2025 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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Special Note Regarding Forward Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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, cash equivalents and restricted cash 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, cash equivalents and restricted cash;
- 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 ("IND") 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 orphan drug designation, for our product candidates;
- our plans relating to the further development and manufacturing of our product candidates, including for additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available;
- our plan to rely on third parties to conduct and support preclinical and clinical development;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;

- the impact of any global health emergencies or other related disruptions on our business;
- unfavorable macroeconomic conditions or market volatility resulting from global economic conditions or geopolitical developments, including supply chain issues, inflationary pressures, market volatility, international tariffs, trade protection measures, economic sanctions, economic slowdowns or recessions, acts of war, and civil and political unrest; 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 Annual Report on Form 10-K, 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 Annual Report on Form 10-K by these cautionary statements.

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 Annual Report on Form 10-K and should be carefully considered, together with other information in this Annual Report on Form 10-K and our other filings with the U.S. Securities and Exchange Commission (SEC), before making investment decisions regarding our common stock.

- We have a limited operating history, limited experience in conducting clinical trials, 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 development activities are focused on the development of novel covalent small-molecule therapies to treat patients with diabetes and obesity, and the approach we are taking to discover and develop such product candidates is novel, may never lead to marketable products and may not ultimately represent a significant or viable 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 early in our development efforts and are substantially dependent on our product candidates, icovamenib (formerly BMF-219) and BMF-500. If we are unable to advance icovamenib, BMF-500 or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize icovamenib, 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 obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business.
- The results of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration (FDA) or other

comparable foreign regulatory authorities. Successful preclinical studies and clinical trials cannot provide assurance of successful commercialization.

- 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 be volatile, and you may not be able to resell shares of our common stock at or above the price you paid.

PART I

Item 1. Business

Overview

We are a clinical-stage diabetes and obesity medicines company focused on the discovery and development of oral covalent small molecule drugs to treat patients with metabolic diseases. We aim to cure.

A covalent small molecule drug is a synthetic compound that forms a permanent bond to its target protein and offers potential advantages over conventional non-covalent drugs, including greater target selectivity, lower systemic drug exposure, and the ability to drive a deeper, more durable response. Leveraging our extensive expertise in covalent chemistry and development, we built our proprietary FUSION™ System discovery platform to advance a pipeline of novel small molecule product candidates. Our lead clinical program's drug candidate, icovamenib, is currently being developed as an orally bioavailable, and selective covalent inhibitor of menin in two clinical and multiple preclinical studies, investigating icovamenib's potential in type 1 and type 2 diabetes, as well as its impact in obesity.

After working closely together at Pharmacyclics, Inc. (formerly Nasdaq: PCYC) (Pharmacyclics), our former Chief Executive Officer, Thomas Butler, and Chief Operating Officer and President, Ramses Erdtmann, founded Biomea Fusion, Inc. (the Company, we, our, or us) in 2017 with the shared vision and goal of developing targeted therapies for patients. Today, we have grown to approximately 80 employees, and has built a management team with significant experience both in precision medicine and in progressing drug candidates from early-stage research to clinical trials and ultimately to regulatory approval and commercialization. We have cultivated in-house expertise in medicinal chemistry, biology, translational medicine, computational biology, and chemistry, in vitro and in vivo pharmacology, biomarker development, and manufacturing. We have also established internal expertise and synergies in clinical development, clinical operations, pharmacovigilance, clinical pharmacology, regulatory affairs, and quality control. Members of the team have held various positions at several renowned biotechnology companies including Gilead Sciences, Inc. (Nasdaq: GILD), Genentech, Inc., Pharmacyclics, AbbVie Inc. (NYSE: ABBV), Celera Genomics, Johnson and Johnson, Inc. (NYSE: JNJ), and others. The team includes the co-inventors of the covalent inhibitors Imbruvica, Remdesivir, and Harvoni. We are supported by our experienced Board, broad scientific advisory board of renowned experts in diabetes and obesity, and a leading syndicate of investors.

Management Update
In March 2025, the Company announced a leadership transition, appointing Board member Mick Hitchcock, Ph.D., as Interim Chief Executive Officer, succeeding Thomas Butler. Dr. Michael J. M. Hitchcock, Ph.D. (Mick) has served as a member of the Company's board since March 2021. Dr. Hitchcock is currently a Past Chair of the University of Nevada, Reno (UNR) Foundation and Adjunct Professor of Microbiology at UNR Medical School, a position in which he has served since July 2016. Dr. Hitchcock's career in pharmaceutical research and development initially began with Bristol-Myers Squibb, where he served in several infectious disease research and project planning roles from 1980 through 1993. He joined Gilead Sciences, Inc. in 1993 and during his 27 years with the Company, he held a variety of positions, including vice president roles with responsibility for project and portfolio management, alliance management, strategic planning, medical affairs and specific areas of research. He also served as Senior Advisor at Gilead from 2009 through November 2019. During his career, he was involved in the development and commercialization of a number of anti-infective agents, primarily antivirals for treatment of HIV, HBV, influenza, CMV and other viral diseases. Dr. Hitchcock holds a Ph.D. in microbiology from the University of Melbourne, Australia and B.Sc. and M.Sc. degrees in biochemistry from the University of Manchester Institute of Science and Technology, England. He also conducted post-doctoral research at Georgetown University and NIH prior to joining industry.

OUR PROGRAMS

Our current pipeline and potentially addressable patient population

Icovamenib

Our lead product candidate, icovamenib, 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 icovamenib for the treatment of menin regulated or dependent diseases such as type 1 and type 2 diabetes.

Dual Potential Mechanism of Action

Icovamenib has demonstrated a generally well-tolerated safety profile in preclinical and early-stage clinical studies. Mechanistic studies support two potential modes of action: (i) increasing beta cell mass and function, thereby enhancing insulin synthesis and secretion, and (ii) upregulating glucagon-like peptide-1 (GLP-1) receptor expression, which may contribute to improved glycemic control and metabolic benefits.

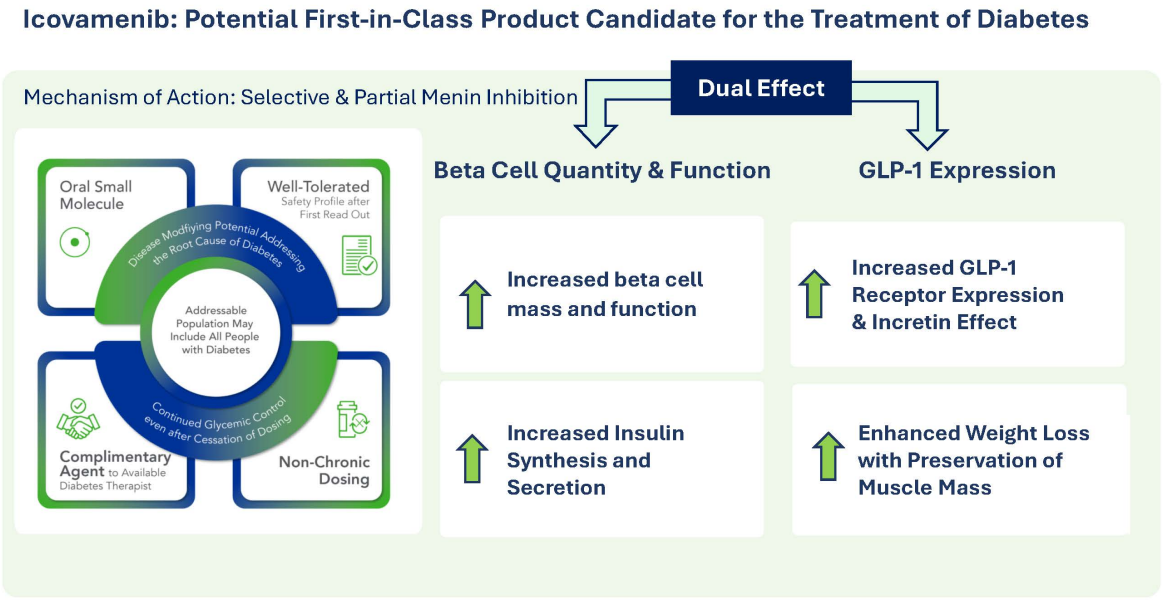
(i) Beta Cell Quantity and Function

Icovamenib is designed to increase beta cell mass and function, addressing a fundamental deficiency in patients with diabetes. Through its proposed mechanism of action, icovamenib has been observed in non-clinical and early-stage clinical studies to promote glucose-regulated beta cell proliferation and enhance insulin synthesis and secretion. By inducing controlled beta cell regeneration, this approach aims to restore endogenous insulin production and provide a durable glycemic benefit.

(ii) GLP-1 Receptor Expression

In addition to its effects on beta cell mass and function, icovamenib has been shown to upregulate GLP-1 receptor expression in preclinical studies, which may enhance incretin signaling and improve glucose metabolism. Non-clinical data suggest that this upregulation could contribute to metabolic benefits, including improved glycemic control and potential weight loss.

Due to the long half-life of beta cells, icovamenib is not intended as a chronic therapy for insulin deficient diabetes, but rather as a 12-week treatment designed to produce lasting effects beyond the period of active administration.



We are currently investigating icovamenib in diabetes in our ongoing Phase II clinical trial COVALENT-111, for patients with type 2 diabetes, and our ongoing Phase II clinical trial COVALENT-112, for 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, which is mediated by autoimmune dysfunction leading to destruction of the beta cells, and type 2 diabetes, which is 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, the 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 controlled inhibition of menin could lead to replenishment 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.

We are also exploring the potential benefits icovamenib can provide to patients with diabetes or obesity who are either newly dosed with a glucagon-like peptide-1 receptor (GLP-1R)-based therapy or failing on a GLP-1R-based therapy. In non-clinical studies, icovamenib when dosed in combination with semaglutide showed an additional 11.5% body weight reduction and 43% increase in lean muscle mass compared to semaglutide alone in the Zucker Diabetic Fatty (ZDF) rat model. The combination with semaglutide approximately doubled C-peptide production per unit of glucose compared to semaglutide alone, leading to a 60% improved reduction of fasting blood glucose. In ex vivo human islet experiments icovamenib enhanced the activity of GLP-1R-based therapies, leading to a substantial increase in insulin secretion. In addition, topline data from the COVALENT-111 study showed that 12 weeks of daily icovamenib in patients uncontrolled on a GLP-1R-based therapy (n=10) led to a mean HbA1c reduction of 0.84% at week 26.

BMF-650

GLP-1 is a naturally occurring incretin hormone that plays a vital role in glucose homeostasis and appetite regulation. GLP-1 receptor agonists (GLP-1 RAs) are a class of medications that bind to and activate GLP-1 receptors, mimicking the effects of native GLP-1. These agents have demonstrated robust clinical efficacy in improving glycemic control, promoting weight loss, and enhancing insulin sensitivity in individuals with type 2 diabetes and obesity.

BMF-650, is an investigational next-generation, oral small-molecule GLP-1 RA, developed by our team. BMF-650 demonstrated positive early preclinical activity, including improved glucose-stimulated insulin secretion, reduction in blood glucose concentration, and appetite suppression in cynomolgus monkeys. Preclinical studies to evaluate the properties of BMF-650 in comparison to a leading oral GLP-1 RA showed that BMF-650 exhibited higher bioavailability and a less variable pharmacokinetic profile, which may translate to improved tolerability and support successful dose escalation in patients. In cynomolgus monkey studies, BMF-650 showed significant improvements in glucose-stimulated insulin secretion, in line with findings from human donor islet experiments. BMF-650 also demonstrated superior glucose control. Appetite suppression studies demonstrated that daily oral BMF-650 dosing significantly reduced food intake during peak drug concentration, with sustained effects throughout the day for a six-day study period. These findings highlight BMF-650's potential as an oral treatment for diabetes and obesity. Our strategy with BMF-650 is centered on flat pharmacokinetics and an increase in area under the curve (AUC) to drive development of a potential best-in-class, oral, small molecule GLP-1.

BMF-650 is advancing through IND enabling studies. With its unique pharmacokinetic profile and enhanced bioavailability, we believe BMF-650 has the potential to provide a best-in-class therapeutic option for diabetes and obesity. Submission of the IND application for BMF-650 is planned for the second half of 2025.

RECENT DEVELOPMENT UPDATES

COVALENT-111 (Type 2 Diabetes)

COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study evaluating icovamenib in healthy adults and adults with type 2 diabetes. In December 2024, we reported that the study successfully met its primary endpoint, demonstrating statistically significant reductions in HbA1c at Week 26 compared to placebo after only 12 weeks of dosing. Best response was achieved in beta cell deficient patients on one or more antidiabetic agents at baseline, showing a placebo-adjusted mean reduction of 1.47% in HbA1c at Week 26 with statistical significance, after only 12 weeks of dosing icovamenib with 100 mg once daily. Overall, icovamenib was generally well-tolerated, with no adverse-event related discontinuations, no hypoglycemic events and no study drug-related serious adverse events. The Expansion Phase (Phase IIb) of the study is ongoing, with final 52-week results anticipated in the second half of 2025.

COVALENT-112 (Type 1 Diabetes)

COVALENT-112 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study evaluating icovamenib in healthy adults and adults with type 1 diabetes. The study's primary endpoint assesses the mean change from baseline in stimulated C-peptide AUC at Week 12. The former clinical hold imposed in June 2024 and lifted in September 2024, had a more profound impact on the COVALENT-112 study in type 1 diabetes, where over 90% of the targeted patient population was not able to complete dosing due to the clinical hold. We are therefore planning to continue enrollment in the COVALENT-112 study so that we can provide a more complete update in this patient population.

FDA Clinical Hold Resolution

In June 2024, the FDA imposed a clinical hold on the Phase I/II trials of icovamenib in type 1 and type 2 diabetes due to observations from the escalation phase, when higher dosages of icovamenib were tested. In September 2024, following submission to the FDA of an in-depth review of additional safety data showing that the concerning elevated lab values occurred at 200 mg and 400 mg starting doses, not at 100 mg or lower, and none of the elevated lab values translated to serious liver injury or impairment, and 30 days later, the FDA issued a full lift of the clinical hold. The expansion phase continued as planned at the 100 mg starting dose.

Expansion into Obesity Treatment

In October 2024, we advanced BMF-650, an investigational next-generation, oral small-molecule GLP-1 RA, for the treatment of diabetes and obesity. IND-enabling studies are ongoing, and submission of the IND application for BMF-650 is planned for the second half of 2025.

Oncology Programs Discontinuation

In January 2025, we announced our strategic decision to transition into a diabetes and obesity medicines company. Based on the most recent clinical trial results, the strategic focus for icovamenib will be in metabolic disorders. We plan to conclude our studies exploring icovamenib's potential in oncology and explore partnerships to further advance our oncology assets (i.e. BMF-500), while concentrating internal resources on metabolic disorders. As part of this transition, we have discontinued our oncology programs, including COVALENT-101 (hematologic malignancies) and COVALENT-102 (solid tumors), and are concluding our study COVALENT-103 (BMF-500 for acute leukemia).

Our Strategy – We Aim to Cure

We are committed to pioneering innovative therapies that address the underlying causes of metabolic diseases, with a primary focus on diabetes and obesity. Our strategy is driven by a patient-centric approach, leveraging our expertise in covalent drug development and our proprietary FUSION™ System to create novel, potential first-in-class therapies that provide durable clinical benefits in these disease settings.

Our strategy is to identify key cellular regulators of metabolic homeostasis and molecular drivers of diabetes and other metabolic diseases, then to design, optimize, and develop covalent inhibitors that have the potential to produce clinically differentiated therapeutic profiles with an aim to cure. We focus on restoring beta cell function and improving glucose metabolism through precise targeting of the key pathways involved in diabetes progression. We seek to recognize the clinical value of precision targeting of malfunctioning proteins through optimized covalent inhibition.

Guided by the FUSION™ system, we design covalent small molecule drug candidates to work in a two-step process. First, an inhibitor reversibly associates with the target protein, bringing its chemical warhead in proximity to a reactive amino acid residue of the target protein. In the second step, a permanent covalent bond is formed between the inhibitor and the target protein. Conventional reversible inhibitors differ from covalent inhibitors in that they do not involve the second step. The covalent "lock-and-key", when optimized, can result in small molecule candidates with high selectivity for their targets, limited off-target activity, potentially generating a large therapeutic window. The only way then for the disease-driving functional protein to return is through de novo synthesis. This allows the drug candidate to potentially be dosed in short bursts without requiring constant systemic drug exposure as may be required by more conventional reversible drug candidates. In addition, conventional reversible small molecule drug candidates may bind to multiple targets, which can lead to poor selectivity and cause unintended side effects. We believe the covalent approach affords an added degree of selectivity, since "innocent" targets are not exposed to the drug for any longer than necessary.

Key Strategic Priorities

- **Advance Icovamenib as a Disease-Modifying Therapy for Diabetes and Obesity:**

  Icovamenib, a potentially first-in-class covalent menin inhibitor, has demonstrated the potential to restore beta cell function, and mass to improve glycemic control. We are prioritizing the development of icovamenib initially for two key patient populations:

- **Severe Insulin Deficient Diabetes Patients (SIDD):** Representing approximately 14 million of type 2 diabetes in the United States and European Union (EU), and more than 50 million patients in Asian countries. This population of patients exhibit the highest unmet medical need, experiencing high treatment failure rates, rapid progression to insulin-dependency, and poor cardiovascular outcomes.

- **Combination with GLP-1R Based Therapies:** Icovamenib has been shown to enhance the activity of GLP-1 Rs in preclinical studies, leading to superior glucose control, weight loss, and muscle preservation. We plan to initiate a late-stage clinical trial evaluating icovamenib as an adjunct to GLP-1R-based therapies in subjects who remain uncontrolled or who are newly treated with a GLP-1R-based therapy.

- **Expand the Metabolic Pipeline with BMF-650:** BMF-650, our next-generation oral GLP-1 RA, is advancing through IND-enabling studies. With its unique pharmacokinetic profile and enhanced bioavailability, BMF-650 has the potential to provide a best-in-class therapeutic option for diabetes and obesity. Submission of the IND application for BMF-650 is planned for the second half of 2025.

- **Evaluate Opportunities to Enhance the Potential of our Programs in Collaboration with Third Parties.** We own full worldwide development and commercialization rights to each of our programs. In the future, we may selectively enter into collaborations where we believe there is an opportunity to speed up clinical development or enhance the commercialization potential of our product candidates. We intend to commercialize our product candidates in key markets either alone or with partners in order to maximize the worldwide commercial potential of our programs.

- **Maintain our Entrepreneurial Outlook, Scientifically Rigorous Approach, and Culture of Tireless Commitment to Patients**. We will continue to apply transformative science in the development of novel targeted therapies for patients suffering from metabolic diseases with limited therapeutic options. We intend to continue building our team of qualified individuals who share our commitment to collaboration and scientific rigor in the development of novel covalent product candidates that may have the potential to treat patients with metabolic diseases.

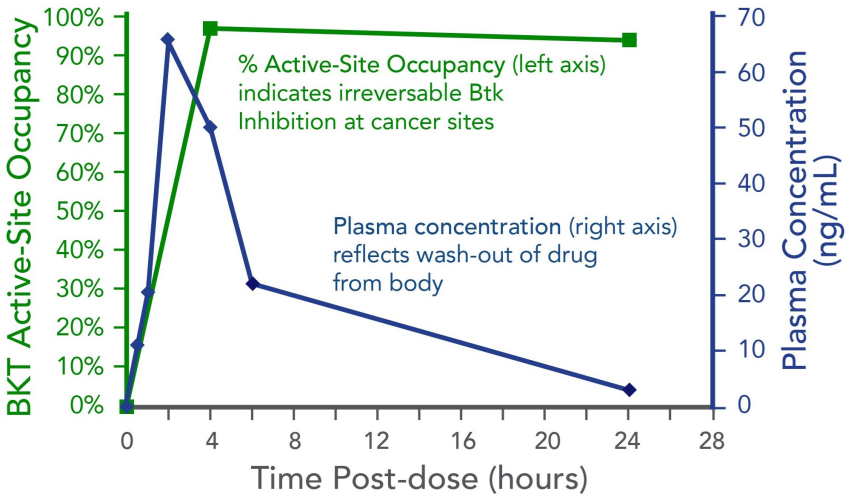
Background on Covalent Inhibition

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

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

Key Advantages of Covalent Drugs

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



Persistent site occupancy of a marketed, covalent inhibitor in the absence of sustained drug exposure

Beyond aspirin and the Bruton's tyrosine kinase covalent inhibitor ibrutinib (marketed as IMBRUVICA® for various B-cell malignancies and chronic graft versus host disease), a number of other covalent inhibitors have been approved by the FDA, including sofosbuvir (marketed as SOVALDI® for hepatitis C virus), tenofovir (marketed as VIREAD® for hepatitis B virus), osimertinib (marketed as TAGRISSO® for NSCLC), and bortezomib (marketed as VELCADE® for multiple myeloma and mantle cell lymphoma).

Challenges in Developing Covalent Drugs

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

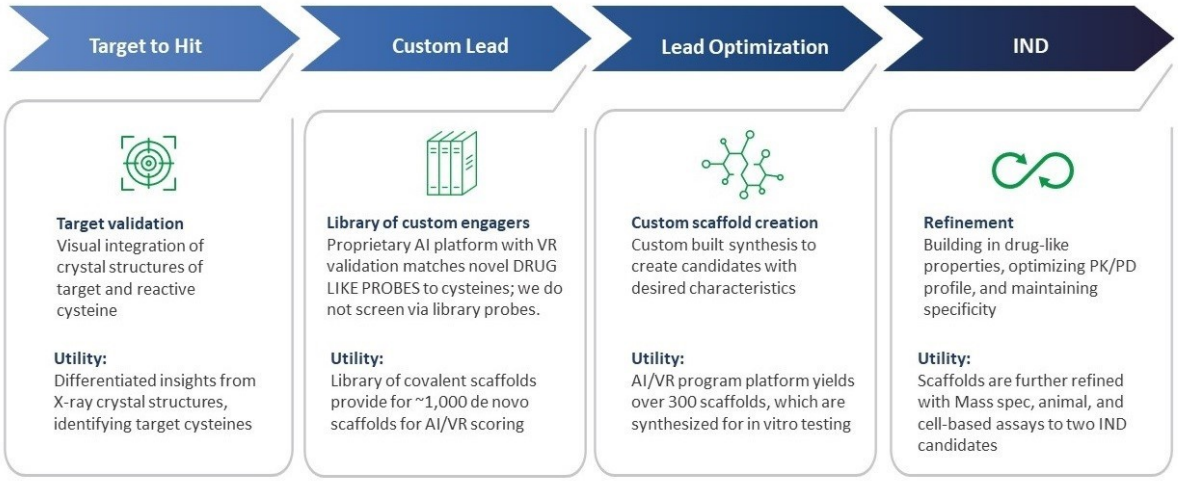
- **Complexity.** The discovery and development of covalent drugs requires significant structural knowledge and medicinal chemistry capabilities, including the ability to construct complex novel chemical scaffolds. In addition, not all disease-causing proteins have the properties necessary for the application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

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

FUSION™ System Discovery Platform

We believe that covalent small molecules have the potential to address the key limitations of existing reversible therapeutics and treat diseases where targeted therapies are not yet approved. Leveraging our extensive experience developing covalent drugs and covalent binding chemistry expertise, we built our proprietary FUSION™ System to enable the design and development of novel covalent small molecule product candidates against high-value drivers of disease. The system also has

the capability to create a novel non-covalent inhibitor, which we may advance depending on the target. We have described some of the differences between the FUSION™ System and traditional small molecule drug discovery approaches below:



The FUSION™ System leverages artificial intelligence (AI) and virtual reality (VR) matching and custom synthesis to develop novel drugs

Our FUSION™ System Discovery platform encompasses the following:

- **Target Selection Validation and AI/VR Matching**: We use our expertise in structural biology and covalent binding chemistry to identify both validated and novel targets that we believe may have a demonstrable and specific impact on disease and have particular structural characteristics that would be amenable to direct intervention with a covalent binder.
- **Custom Scaffold Creation:** We create novel chemical scaffolds using a computational platform to exploit the unique structural elements of a specific target protein. We then screen these scaffolds with in-house technologies to select the optimal candidates for further construction and design. This evaluation process is intended to increase the probability of having multiple targeted compounds that can advance through the discovery process and into the clinic.
- **Molecule Optimization/Refinement:** Using our proprietary suite of computational technologies, assays, analytical approaches, chemistry, and know-how we strive to maximize the potential selectivity, potency, safety, and convenience of our oral, covalent small molecule product candidates. We avoid compound library screening, which results in highly selective/specified scaffolds. This saves considerable time during the lead optimization step.

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

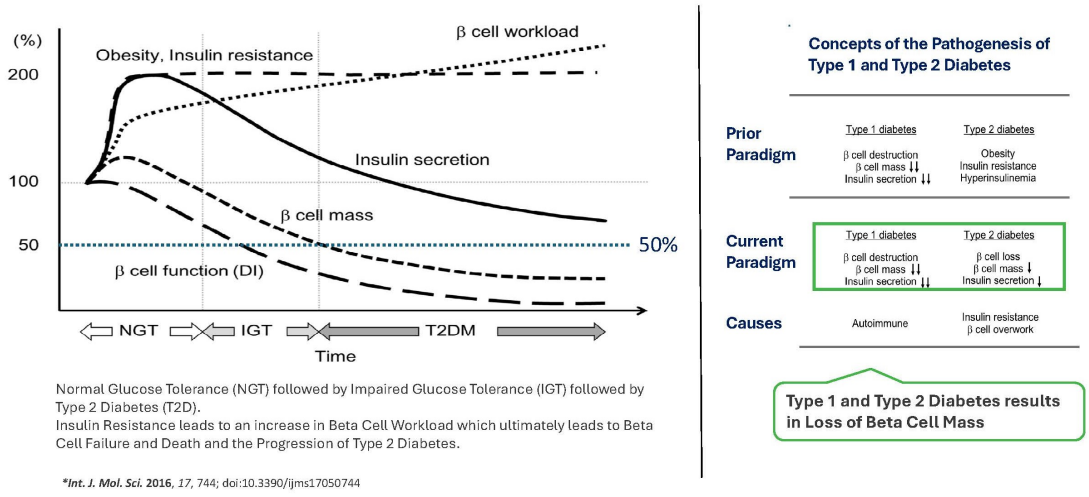
Our Initial Focus: Menin

Menin and Beta Cell Biology in Diabetes

Diabetes is a chronic metabolic disease that affects the body's ability to regulate blood sugar levels, leading to elevated glucose in the bloodstream. Over time, uncontrolled blood sugar can result in serious complications, including cardiovascular disease, kidney failure, nerve damage, and vision impairment. People with diabetes often have a reduced life expectancy compared to those without this disease. Diabetes is also a significant economic burden on the U.S. health care system, ranking as the 7th leading cause of death in the U.S. and accounting for approximately one out of every four dollars spent on healthcare in the country. According to a study published in The Lancet, worldwide over 800 million adults are estimated to live with diabetes. The CDC estimates about two in five of the adult population in the U.S. are now expected to develop diabetes during their lifetime. More than 38.4 million people of all ages (about 11% of the U.S. population) have diabetes today, while an additional 97.6 million adults (more than one in three) have pre-diabetes, blood sugars that are higher than normal but not high enough to be classified as diabetes.

Despite the availability of numerous treatment options, there remains a critical need for improved therapies that can modify disease progression rather than simply managing symptoms. The American Diabetes Association (ADA) categorizes diabetes based on etiology and onset. Type 1 diabetes is caused by an autoimmune attack on pancreatic beta cells leading to absolute insulin deficiency, including latent autoimmune diabetes of adulthood. Type 2 diabetes is characterized by progressive beta cell dysfunction and insulin resistance. The primary treatment objective is to achieve glycemic control, typically measured by reductions in HbA1c (glycated hemoglobin), a marker indicating average blood glucose over the past two to three months, to 6.5% or lower. Effective glycemic control is critical in preventing or delaying complications such as kidney disease, heart disease and nerve damage.

The loss of functional beta cell mass is a fundamental driver of disease progression in both type 1 diabetes and type 2 diabetes. Beta cells, located in the pancreas, are responsible for producing and secreting insulin, a hormone essential for glucose metabolism and regulation. In diabetes, beta cell dysfunction and depletion lead to impaired insulin secretion, resulting in hyperglycemia. Researchers suggest that menin, a regulatory protein, plays a key role in beta cell proliferation. Inhibiting menin may remove this restriction, allowing for the regeneration and restoration of functional beta cells.



Diabetes progression of type 1 and type 2 driven by beta cell loss

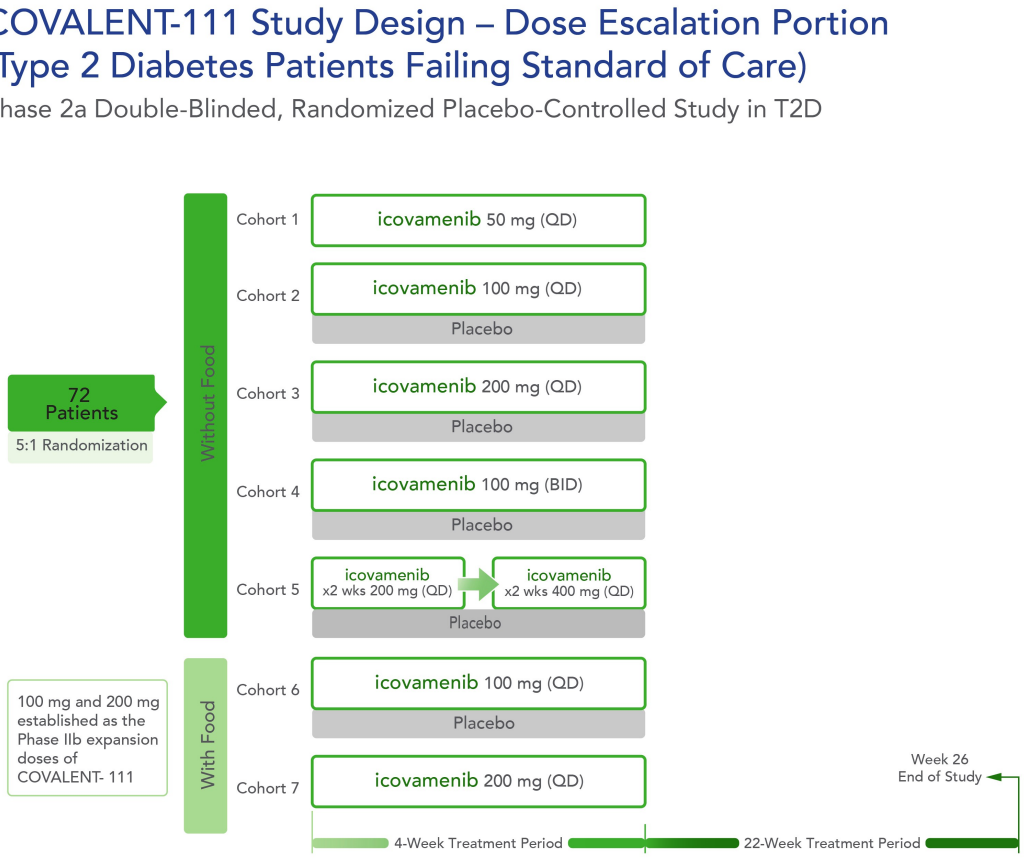
Icovamenib – Clinical Development in Diabetes

We are prioritizing the development of icovamenib as a potential therapeutic candidate for metabolic diseases, including type 2 diabetes. Our development strategy is informed by positive topline data from the Phase II COVALENT-111 study and preclinical in-vivo data indicating a potential synergistic effect with GLP-1 RA-based therapies.

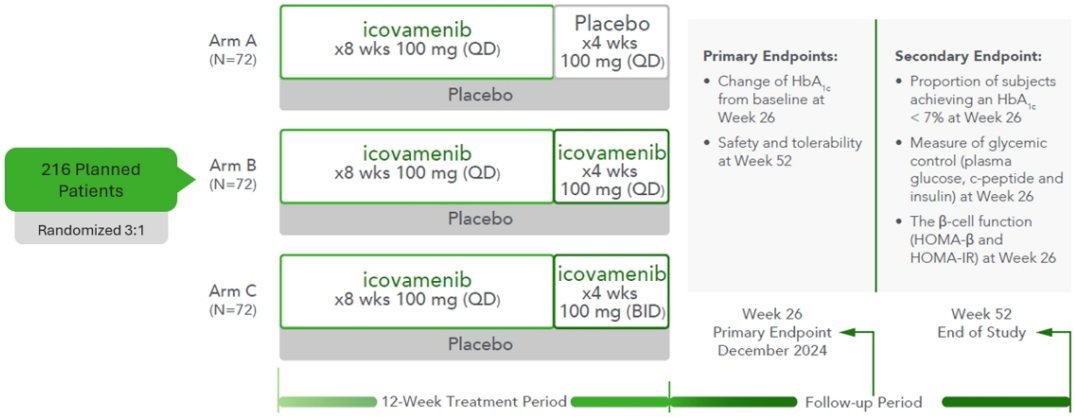
We are focusing our clinical development efforts initially on patients with severe insulin deficiency and patients currently receiving GLP-1 RA-based therapies to address the significant unmet medical need in these populations. Given its dual potential mechanism of action, which may include increasing beta cell mass and enhancing insulin synthesis, icovamenib is being evaluated as a potential disease-modifying treatment rather than a chronic therapeutic intervention. The Company remains committed to advancing its clinical program to assess icovamenib's ability to provide sustained glycemic control and improve metabolic outcomes. We believe this innovative strategy has the potential to transform diabetes treatment by addressing the root causes of the disease rather than solely managing symptoms.

COVALENT-111 Type 2 Diabetes Phase II Study

COVALENT-111 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study. In the completed Phase I portion of the trial, healthy volunteers were enrolled in single ascending dose cohorts to evaluate safety at the prospective dosing levels for patients with type 2 diabetes. Phase II consists of multiple ascending dose cohorts and includes adult patients with type 2 diabetes uncontrolled by standard of care medicines. The dose escalation phase evaluated icovamenib at multiple dose levels with and without food. Patients were only dosed for four weeks and then followed up for 22 weeks while off treatment.



Following the Escalation Phase of COVALENT-111, the study advanced into an Expansion Phase (n>200) consisting of multiple cohorts dosing type 2 diabetes patients for longer dose durations. The first three arms (Arm A, B, and C) of the Expansion Phase are evaluating icovamenib dosed over eight and 12 weeks at 100 mg and 200 mg with up to 40 weeks of follow-up, off treatment.

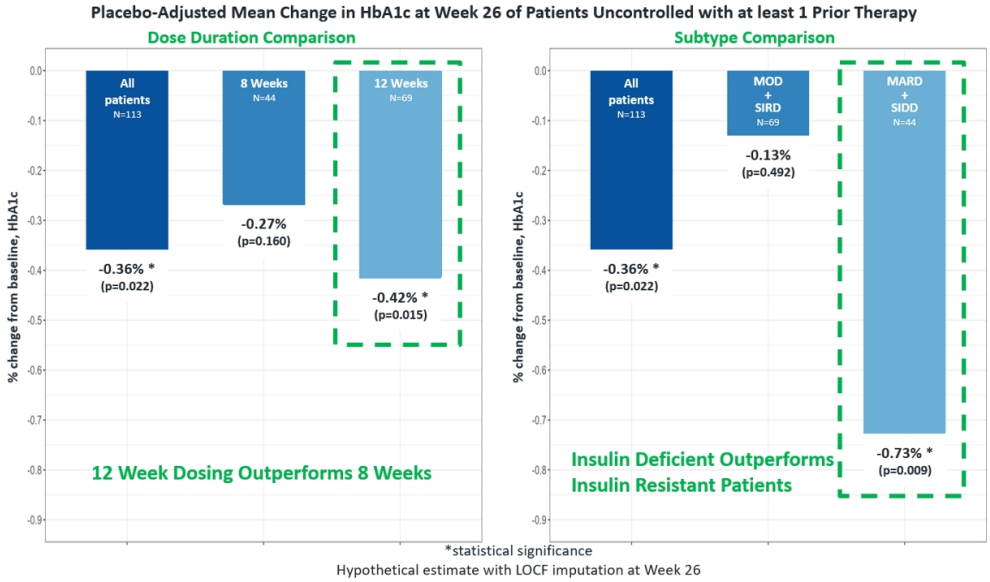


The modified intent-to-treat population was defined as all randomized participants who took at least one dose of study drug (N=225) or placebo. The study was interrupted by the FDA imposed clinical hold, and therefore some patients could not complete their dosing period. The topline efficacy analysis provided in December 2024 focused on those patients who had completed at least 80% of their assigned dosing schedule prior to the clinical hold, the Per Protocol Patient population, and included a post-hoc analysis of the subgroup who were treated with one or more anti-hyperglycemic therapies at baseline (n=168). From those patients N=113 were on study drug and N=55 were on placebo. In total 10% of all patients enrolled were on no background therapy, 69% were on metformin alone, 16% were on two therapies and 5% were on three therapies.

In per protocol patients who were “uncontrolled” with at least one medication at baseline (N=115), icovamenib showed a statically significant, placebo-adjusted 0.36% reduction in HbA1c, independent of dose strength. The dose duration comparison analyzed all 113 patients, and those treated for eight weeks (N=45 Arm A) versus those treated for 12 weeks (N=69 Arm B and C) showed a difference in HbA1c reduction of 0.27% versus 0.42% respectively. The longer duration of treatment resulted in greater HbA1c lowering, with a placebo-corrected statistically significant higher reduction.

Each patient was classified into one of four identified phenotypes of type 2 diabetes based on their baseline characteristics prior to the readout. The various type 2 subtypes of diabetes are: Severe Insulin Deficient Diabetes (SIDD), Mild Obesity Diabetes (MOD), Mild Age Related Diabetes (MARD) and Severe Insulin Resistant Diabetes (SIRD). The statistical analysis plan prespecified each phenotype as well as the primary endpoint for analysis across each arm, prior to the recent readout of the Week 26 data. The identification of these subtypes was based on the specific algorithms specified by Ahlqvist E, et al. Lancet Diabetes Endocrinol. 2018;6:361-369. MOD and SIRD patients are generally considered insulin resistant and are identifiable by a higher BMI and higher homeostatic model assessment (HOMA) beta cell function (HOMA-β), indicating better beta cell functionality, versus MARD and SIDD patients who are generally considered insulin deficient with a lower BMI and a lower HOMA-β, indicating lower beta cell function. SIDD patients are known to present with the lowest c-peptide release and HOMA-β at baseline.

When comparing the per protocol patients who were considered “uncontrolled” (HbA1c >7.0%) in the various prespecified subtypes, COVALENT-111 study results after Week 26 showed that insulin deficient patients performed approximately six-fold better than those patients enrolled with insulin resistance. MOD and SIRD patients combined (N=69) showed a reduction in HbA1c of 0.13% versus the MARD and SIDD patients combined (N=44) who showed a combined reduction of 0.73% (statistically significant p=0.009), 14 weeks after completing treatment.



Comparing the various dosing arms (Arm A: dosing for eight weeks 100 mg once a day (QD)), Arm B: dosing for 12 weeks with 100 mg QD, Arm C: dosing for eight weeks with 100 mg QD and four weeks with 100 mg twice a day) the best performing Arm in the study was Arm B.

Summary Table of Efficacy Analysis

Targeted Patients - Insulin Deficient

		Number of Patients	Reduction in HbA1C	P Value	
ARM B & C	*All patients 12 weeks dosing*	69	-0.42%	0.015	*
ARM B & C	*SIDD/MARD (12 weeks)*	22	-0.84%	0.008	*
ARM B & C	*SIDD (12 weeks)*	11	-1.17%	0.038	*

		Number of Patients	Reduction in HbA1C	P Value	
ARM B	*All patients 12 weeks dosing*	37	-0.50%	0.012	*
ARM B	*SIDD/MARD (12 weeks)*	13	-1.05%	0.004	*
ARM B	*SIDD (12 weeks)*	7	-1.47%	0.022	*

** Statistically Significant*

Legend
Arm A: 8 weeks of dosing 100mg QD
Arm B: 12 weeks of dosing 100 mg QD
Arm C: 8 weeks of 100 mg QD + 4 weeks of 100 BID

MARD/SIDD: Mild Age-Related and Severe Insulin-Depleted Diabetes (Insulin deficient)
MOD/SIRD: Mild Obesity-Related Diabetes and Severe Insulin Resistance Diabetes (Insulin resistant)

Reviewing the prespecified subtypes with insulin deficiency (MARD and SIDD patients) in these two study arms (Arm B and C, dosing at 12 weeks), they had a statistically significant 0.84% mean reduction in HbA1c. These results are further improved when reviewing the most insulin deficient patients, SIDD patients, who had a statistically significant mean reduction in HbA1c at Week 26 of 1.17% in both study arms (Arm B and C). Among only the Arm B patients, with just 12 weeks of dosing 100 mg QD, the most insulin deficient patients (SIDD patients) showed even further improved responses up to a statistically significant mean reduction in HbA1c at Week 26 of 1.47%. These data suggest that 12 weeks of dosing, particularly in insulin deficient patients, has the potential to result in a robust improvement in glycemic control at Week 26.

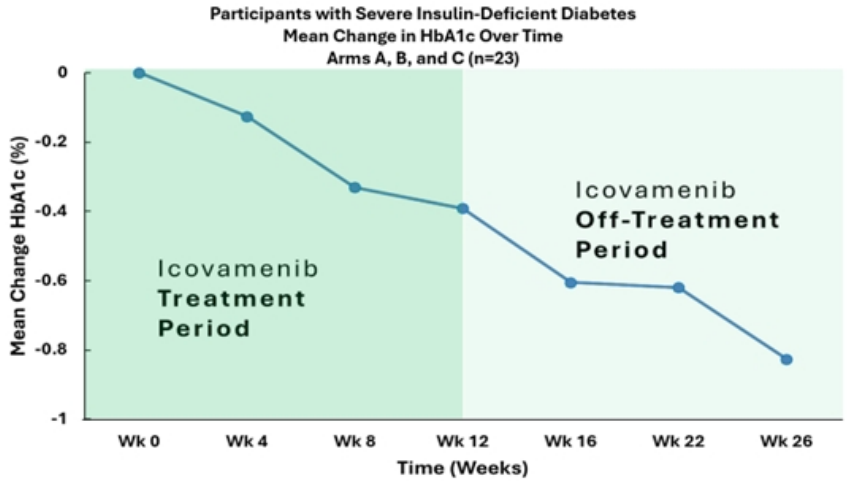
HbA1c Reduction Continued Over Time – Outside the Treatment Period

During the icovamenib 12-week treatment period, for both the combined 12-week arms (Arm B and C) and for Arm B alone, there were statistically significant reductions in HbA1c for all participants in those arms and greater improvements in HbA1c

in the insulin deficient patients. HbA1c levels reduced steadily, with a continued downward trajectory observed beyond Week 12. Notably, after the completion of treatment, during the off-treatment period, weeks 12 to 26, patients continued to experience reductions in HbA1c, suggesting a prolonged therapeutic effect.

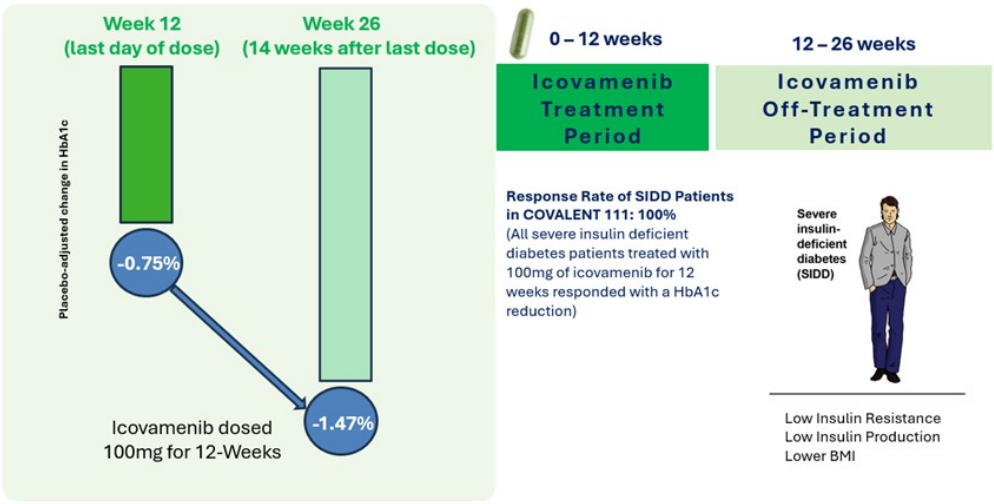
This response profile supports icovamenib's potential as a disease-modifying therapy for patients with insulin deficiency, with durable glycemic improvements even after treatment discontinuation.

Icovamenib Significantly Reduced HbA1c During the 12-Week Treatment Period and the Improvement Persisted through Week 26 (14 weeks after the final dose)



The placebo-adjusted mean change in HbA1c was -0.75% at Week 12 (end of treatment period). Notably, the HbA1c reduction continued to improve post-treatment, reaching -1.47% at Week 26, which represents 14 weeks after treatment cessation.

These findings suggest that icovamenib may provide a durable glycemic benefit beyond the treatment period, supporting its potential role as a disease-modifying therapy in patients with severe insulin deficiency who have limited treatment options. Further clinical evaluation is ongoing to assess the long-term impact of icovamenib on glycemic control.



Icovamenib was generally well-tolerated. There were no study drug-related serious adverse events reported, no treatment discontinuations nor study discontinuation due to adverse events and there were no deaths in icovamenib- or placebo-treated patients.

Overview of Adverse Events Through 26 Weeks (mITT Population, N=225)

Parameter	Arm A icovamenib (N=59)	Arm B icovamenib (N=54)	Arm C icovamenib (N=55)	Combined Arms icovamenib (N=168)	Combined Arms placebo (N=57)
Patients with ≥1 TEAE	18 (31)	19 (35)	13 (24)	50 (30)	18 (32)
SAEs	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Treatment Discontinuation due to AE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Study Discontinuation due to AE	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Deaths	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Data are n (%)
TEAE, treatment-emergent adverse event
SAE, serious adverse event related

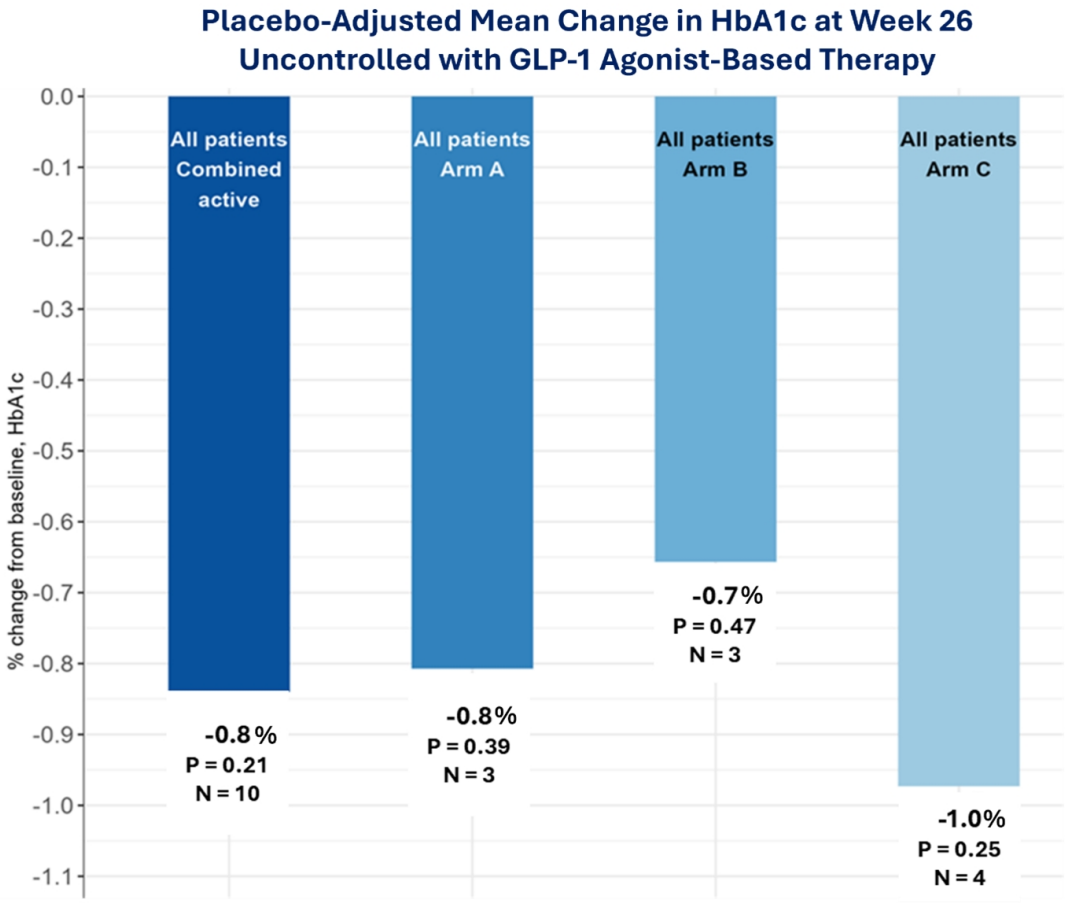
Safety and Tolerability (mITT Population, N=225)

Parameter	Arm A Icovamenib (N=59)	Arm B icovamenib (N=54)	Arm C icovamenib (N=55)	Combined Arms icovamenib (N=168)	Combined Arms placebo (N=57)
Diarrhea	4 (7)	2 (4)	1 (2)	7 (4)	0 (0)
Nausea	2 (3)	3 (6)	2 (4)	7 (4)	1 (2)
Hyperglycemia	1 (2)	4 (7)	1 (2)	6 (4)	3 (5)
Headache	0	3 (6)	1 (2)	4 (2)	3 (5)
ALT increase	2 (3)	0	2 (4)	4 (2)	0
AST increase	2 (3)	0	1 (2)	3 (2)	0

Data are n (%) of TEAE with ≥5% frequency in any arm and ALT or AST increase irrespective of incidence; mITT population (safe ty analysis set)
TEAE, treatment-emergent adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase

Diarrhea: In icovamenib arms, all 7 events were Grade 1.
Nausea: In icovamenib arms, 6 of 7 events were Grade 1 and 1 event was Grade 2 (Arm B). In placebo arm, the 1 event was Grade 1.
Hyperglycemia: In icovamenib and placebo arms, all events were Grade 2.
Headache: In icovamenib arms, 3 of the 4 events were Grade 1 and 1 event was Grade 2 (Arm B). In the placebo arm, 3 of the 4 events were Grade 1 and 1 event was Grade 2.
ALT increase: In the icovamenib arms, 3 of the 4 events were Grade 1 and 1 event was Grade 2 (Arm A).
AST increase: In the icovamenib arms, all 3 events were Grade 1.

In the COVALENT-111 study, in a post hoc analysis patients who were receiving GLP-1R based therapy at baseline exhibited a clinically meaningful 0.84% reduction in HbA1c following icovamenib administration across all dose levels. Notably, patients in Arm C achieved an even greater HbA1c reduction of 1.0%. These patients were considered “uncontrolled” at the time of enrollment (HbA1c > 7.0%) despite being on a GLP-1R based therapy. Additionally, they experienced up to 14% further reduction in body weight at Week 26.



We plan to initiate a late-stage development study evaluating icovamenib in SIDD subjects and a Phase II study evaluating icovamenib as an adjunct to GLP-1-based therapies in subjects who are either initiating a GLP-1 RA-based therapy or are uncontrolled on a GLP-1 RA-based therapy.

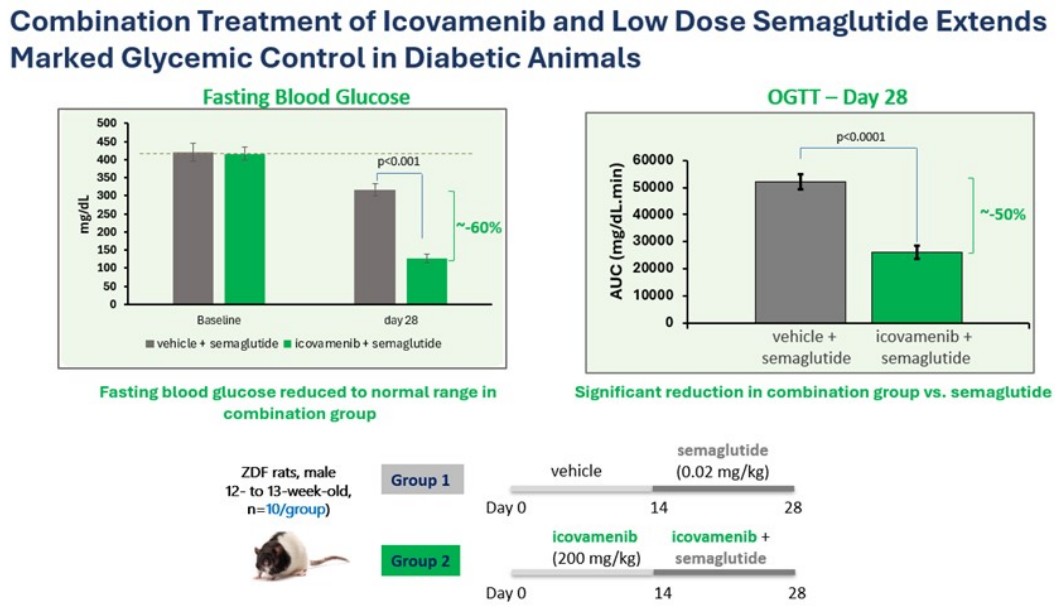
Further Preclinical Results of Icovamenib in Combination with Semaglutide

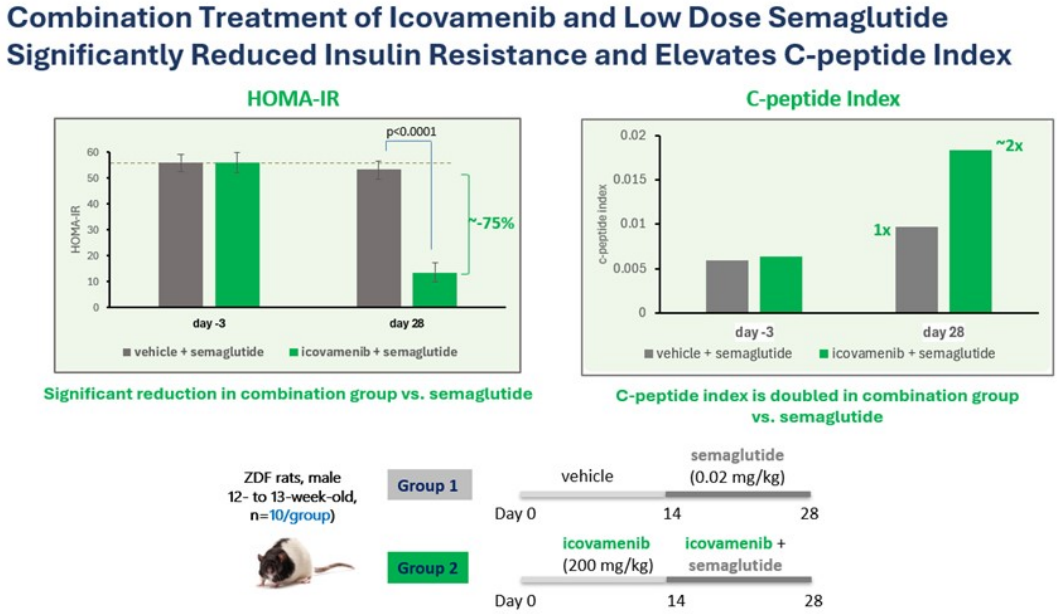
We conducted a preclinical study of two animal groups, one group of 10 ZDF rats dosed with icovamenib (day 1 through day 28) in combination with semaglutide (day 14 through day 28) and a second group of 10 ZDF rats dosed with semaglutide alone (day 14 through day 28). The ZDF rat is a type 2 diabetes animal model characterized by insulin resistance. This study evaluated the activity of icovamenib in combination with a GLP-1 RA (i.e., semaglutide) to assess key metabolic parameters in animal models including: improvements in C-peptide index, a marker of insulin secretion and glucose regulation, blood glucose, HbA1c, HOMA for insulin resistance (HOMA-IR) and HOMA-β, changes in body weight and composition, including fat and lean mass, and appetite suppression. Biomarkers were analyzed at multiple time points throughout a 28-day period.

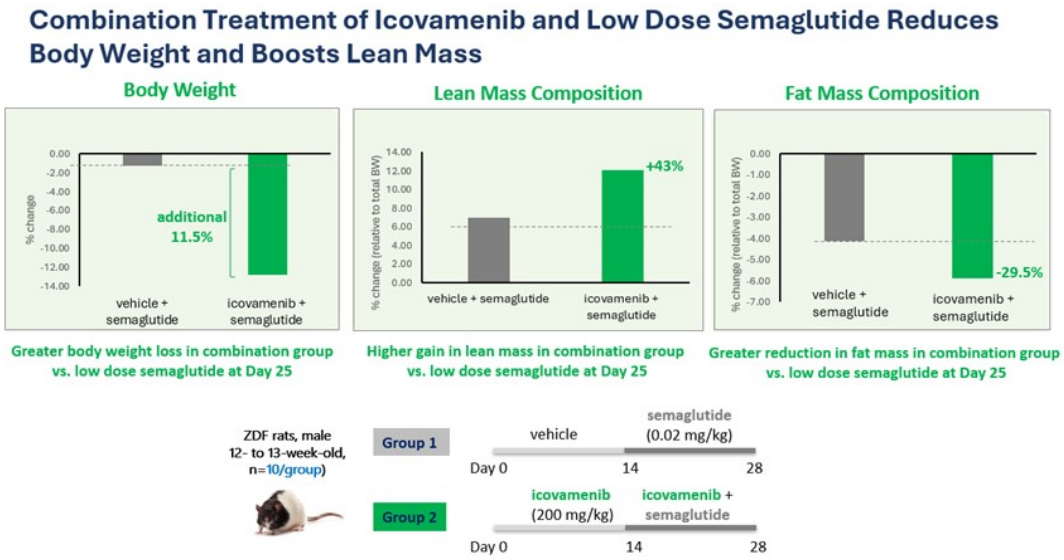
An approximately 60% reduction in fasting blood glucose level and an approximately 50% reduction in AUC during the Oral Glucose Tolerance Test (OGTT) were observed with the icovamenib combination therapy versus semaglutide alone, indicating improved glucose metabolism ($p<0.0001$). The HbA1c reduction on Day 28 was greater with the combination therapy (>1%) compared to semaglutide alone ($p<0.05$). Insulin resistance as measured by HOMA-IR was reduced by approximately 75% with combination therapy compared to semaglutide alone ($p<0.001$). Combination treatment also improved beta cell function as measured by HOMA-β. Importantly, the combination therapy reduced body weight by 11.5% and fat mass by 29.5% compared to semaglutide alone. A 43% increase in lean mass compared to semaglutide alone was observed with the combination therapy.

We believe these preclinical findings support the potential of icovamenib as a complementary therapy to GLP-1 RA based therapies in diabetes treatment. The combination demonstrated enhanced glycemic control, improved insulin sensitivity, and superior weight loss benefits while preserving muscle mass, suggesting a differentiated metabolic effect.

We continue to advance the clinical development of icovamenib and plan to further assess its activity in combination with GLP-1 RA-based therapies in future clinical studies.







COVALENT-112 Type 1 Diabetes Phase II Study

COVALENT-112 is a multi-site, randomized, double-blind, placebo-controlled Phase I/II study evaluating icovamenib in healthy adults and adults with type 1 diabetes. The study's primary endpoint assesses the mean change from baseline in stimulated C-peptide AUC at Week 12. The former clinical hold imposed in June 2024 and lifted in September 2024, had a more profound impact on the ongoing Phase II COVALENT -112 study in type 1 diabetes, where over 90% of the targeted patient population were not able to complete dosing due to the clinical hold. We are therefore planning to continue enrollment in the COVALENT-112 study so we can provide a more complete update in this patient population in 2025.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages. In addition, we believe we are currently the only company in the United States developing irreversible covalent binders specifically against menin. More broadly, we define ourselves as targeted drug developers focused on irreversible covalent drugs and as such expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

These companies may be or may become interested in discovery and development of irreversible 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 irreversible covalent binding against protein targets of interest to us.

To our knowledge, there are no clinical-stage programs that aim to specifically regenerate insulin-producing beta cells in the islets by targeting menin for diabetes. There are over 60 approved agents and therapies being utilized to address diabetes. Such approved agents and therapies are intended to provide specific benefits to patients; however, we are not aware of any successfully addressing the root cause of diabetes, a depleted pool of functional beta cells. Several programs are targeting beta cell proliferation, including DYRK1A inhibitors. However, in addition to specific safety challenges, studies have shown that this approach may not only proliferate beta cells but also other pancreatic cells, which would not necessarily improve the ratio of alpha to beta cells in the pancreas.

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

Intellectual Property

We seek to protect the intellectual property and proprietary technology that we consider important to our business, including by pursuing patent applications that cover our product candidates and methods of using the same, as well as other relevant inventions and improvements that we believe to be commercially important to the development of our business. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position. Our commercial success depends, in part, on our ability to obtain, maintain, enforce and protect our intellectual property and other proprietary rights for the technology, inventions and improvements we consider important to our business, and to defend any patents we may own or in-license in the future, prevent others from infringing any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid and enforceable patents and proprietary rights of third parties. As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our product candidates and technologies will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our pending provisional and Patent Cooperation Treaty (PCT) applications, and any patent applications that we may in the future file or license from third parties, may not result in the issuance of patents and any issued patents we may obtain do not guarantee us the right to practice our technology or commercialize our product candidates. The PCT is a treaty with more than 150 contracting states that makes it possible to seek patent protection across multiple states by filing a single “international” application. We also cannot predict the breadth of claims that may be allowed or enforced in any patents we may own or in-license in the future. Any issued patents that we may own or in-license in the future may be challenged, invalidated, circumvented or have the scope of their claims narrowed. In addition, because of the extensive time required for clinical development and regulatory review of a product candidate we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide.

The term of individual patents depends upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office (USPTO) in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent claiming a new drug product may also be eligible for a limited patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The extension period granted on a patent covering a product is typically one-half the time between the effective date of a clinical investigation involving human beings is begun and the submission date of a new drug application (NDA), plus the time between the submission date of a NDA and the ultimate approval date. The extension period cannot be longer than five years and the total patent term, including the extension period, must not exceed 14 years following FDA approval. Only one patent applicable to an approved product is eligible for the extension, and only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended. A patent that covers multiple products for which extension is sought can only be extended in connection with one of the approvals. The USPTO reviews the application for any patent term extension or restoration in consultation with the FDA. In the future, if any of our product candidates receive approval by the FDA, we expect to apply for a patent term extension on an issued patents covering the product, depending upon the length of the

clinical studies for the product and other factors. Outside the U.S., similar applications for patent term extensions or supplementary protection certificates are available in a limited number of countries. We expect to apply for such coverage where available. There can be no assurance that the USPTO or any other patent office outside the U.S. will approve any of our applications for patent term extensions or supplementary protection certificates. There can be no assurance that patents will issue from our current or future pending patent applications, or that we will benefit from any patent term extension or favorable adjustments to the terms of any patents we may own or in-license in the future. In addition, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products, if approved, for an adequate amount of time.

As of December 31, 2024, we owned four issued U.S. patents, more than sixty U.S. and outside U.S. pending patent applications, directed to compositions of matter, methods of treatment, and methods of making with respect to our product candidates, including icovamenib and BMF-500.

Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO or other foreign jurisdiction are often significantly narrowed by the time they issue, if they issue at all. Any of our pending PCT patent applications are not eligible to become issued patents until, among other things, we file national stage patent applications within 30 months in the countries in which we seek patent protection. If we do not timely file any national stage patent applications, we may lose our priority date with respect to our PCT patent applications and any patent protection on the inventions disclosed in such PCT patent applications. Our provisional patent applications may never result in issued patents and are not eligible to become issued patents until, among other things, we file a non-provisional and/or PCT patent application within 12 months of filing the related provisional patent application. If we do not timely file non-provisional or PCT patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. While we intend to timely file non-provisional and PCT patent applications relating to our provisional patent applications, and we intend to timely file national stage patent applications relating to our PCT patent applications, we cannot predict whether any of our current or future patent applications related to icovamenib, or any of our other product candidates, will issue as patents. If we do not successfully obtain patent protection, or, even if we do obtain patent protection, if the scope of the patent protection we obtain our product candidates or technology is not sufficiently broad, we will be unable to prevent others from using our technology or from developing or commercializing technology and products similar or identical to ours or other competing products and technologies. Additionally, even if any of our patent applications issue as patents, the patents covering our proprietary technologies and our product candidates would be expected to expire between 2039 to 2042.

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

License and Partnership Agreements

As of December 31, 2024, we did not have any license or partnership agreements related to any of our programs. As these programs and our business evolve, we may consider entering into a potential license or partnership and may explore partnerships to further advance our oncology assets while concentrating our internal resources on metabolic disorders. A potential partnership could provide non-dilutive funding and access to additional capabilities and expertise that a partner could provide to enhance the overall probability of program success.

Manufacturing

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

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. We believe that such an organization will be able to address the community of oncologists who are the key specialists in treating the patient populations for which our product candidates are being developed. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval. We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Government Regulation

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

U.S. Drug Development Process

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

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

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

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or participants are being exposed to an unacceptable health risk.

Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to participants. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- Phase I: The product candidate is initially introduced into healthy human subjects or participants with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase II: The product candidate is administered to a limited participant population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase III clinical trials.
- Phase III: The product candidate is administered to an expanded participant population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

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

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

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

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

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by independent investigators. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality and purity. Under the Prescription Drug User Fee Act (PDUFA) guidelines that are currently in effect, the FDA has a goal of ten months from the filing date to complete a standard review of an NDA for a drug that is a new molecular entity. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted.

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

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

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

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a risk evaluation and mitigation strategy (REMS) to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use (ETASU), such as restricted distribution methods, patient registries, and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without a REMS, if required. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more Phase IV post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

In addition, the Pediatric Research Equity Act (PREA) requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, fails to keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the Fast Track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. A Fast Track product may also be eligible for rolling review, where the FDA may consider for review portions of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the portions of the NDA, the FDA agrees to accept portions of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first portions of the NDA.

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

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

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

or other clinical benefit. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period.

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

Orphan Drug Designation and Exclusivity

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

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or in instances of drug supply issues. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other potential benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

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

Post-approval Requirements

Drug products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors and those supplying products, ingredients, and components are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market

studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

From time to time, legislation is drafted, introduced, passed in Congress and signed into law that could significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidances, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

Other United States Regulatory Matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare and Medicaid Services (CMS), other divisions of the Department of Health and Human Services (HHS), the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission (FTC), the Occupational Safety and Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of our future product candidates, some of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit restoration of the patent term of up to five years as compensation for patent term lost during the FDA regulatory review process. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. The patent-term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Regulatory exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated NDA (ANDA), or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

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

In addition, drugs can also obtain pediatric exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Other Healthcare Laws

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs;
- federal civil and criminal false claims laws, including the False Claims Act (FCA), which can be enforced through civil "qui tam" or "whistleblower" actions, and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty

of violating these statutes without actual knowledge of the statutes or specific intent to violate them in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), imposes requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards;
- the federal Physician Payment Sunshine Act, created under the Patient Protection and Affordable Care Act of 2010, as amended (ACA) and its implementing regulations, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- California's California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, which affords consumers expanded privacy protections. For example, the CCPA gives California residents expanded rights to access and require deletion of their personal information, opt-out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that may increase our risk to data breach class action litigation. The CCPA was expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 (CPRA) became fully operative. The CPRA, among other things, gives California residents the ability to limit use of certain sensitive personal information, further restrict the use of cross-contextual advertising, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, provide for increased penalties for CPRA violations concerning California residents under the age of 16, and establish a new California Privacy Protection Agency to implement and enforce the new law;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payors are increasingly reducing reimbursements for medical products, drugs and services.

Factors payors consider in determining reimbursement are based on whether the product is:

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

No uniform policy for coverage and reimbursement for products exists among third-party payors in the U.S. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

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

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (a requirement later replaced under the Inflation Reduction Act of 2022 (IRA) by the Medicare Part D manufacturer discount program); and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Both the Trump administration and Congress have indicated that they will continue to seek new legislative and executive measures to control drug costs. In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- The U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of two percent per fiscal year that remain in effect through 2031.
- The U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

- The American Rescue Plan Act of 2021 eliminates the statutory Medicaid drug rebate cap, previously set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers were further reduced starting in 2025 absent further legislation.
- The IRA also includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow 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, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. 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 effect of IRA on our business and the healthcare industry in general is not yet known.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Human Capital Resources

As of December 31, 2024, we had 106 full-time employees, 79 of whom were engaged in research and development activities. We believe we have good relationships with our employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement.

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

Corporate Information

We were established in the state of Delaware in August 2017 as Biomea Fusion, LLC. In December 2020, all outstanding membership interests in Biomea Fusion, LLC were converted into equity interests in the Company.

Our principal executive offices are located at 900 Middlefield Road, 4th Floor, Redwood City, California 94063, and our telephone number is (650) 980-9099. Our website address is www.biomeafusion.com. We do not incorporate the information on or accessible through our website into this Annual Report on Form 10-K, and you should not consider any information on, or that can be accessed through, our website a part of this Annual Report on Form 10-K.

Biomea Fusion, Inc., the Biomea logo, FUSION™ System and our other registered or common law trademarks, trade names or service marks appearing in this Annual Report on Form 10-K are owned by us. This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, 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.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy and information statements and amendments to reports filed pursuant to Sections 13(a), and 15(d) of the Securities Exchange Act of 1934, as amended (Exchange Act) are filed with the SEC. We are subject to the informational requirements of the Exchange Act and file or furnish reports, proxy statements and other information with the SEC. The SEC maintains an Internet site that contains

reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov. Such documents and other information filed by us with the SEC are available free of charge on the "Investors & Media" section of our website when such reports are available on the SEC's website. The contents of websites referred to above are not incorporated into this Annual Report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual references only.

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 Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could 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, limited experience in conducting clinical trials, 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 initial clinical trials, and establishing arrangements with third parties for the manufacture of initial quantities of product candidates. We currently have two product candidates, icovamenib and BMF-500, under investigation in clinical trials, with the first patient dosed with BMF-500 in October 2023. Our remaining product candidates, including BMF-650, 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.

We have incurred significant net losses in each reporting period since we commenced operations in August 2017. Our net losses were $138.4 million and $117.3 million, for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $387.3 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 icovamenib for the treatment of patients with type 1 and type 2 diabetes;
- explore the potential clinical utility of icovamenib in other metabolic disorders, including pre-diabetes and obesity;
- continue the clinical development of BMF-500, a covalent inhibitor of FMS-like tyrosine kinase 3 (FLT3);
- continue the preclinical development and initiate clinical development of BMF-650;
- 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. Icovamenib, our lead product candidate, is in the early stages 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. If approved, Icovamenib is not intended as a chronic therapy for insulin deficient diabetes, which could further limit our ability to achieve profitability. 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 icovamenib, BMF-500, BMF-650 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 and preclinical development of icovamenib and BMF-650 and any future product candidates;
- our ability to complete IND-enabling studies, and successfully submit and receive authorization to proceed under INDs or comparable regulatory applications;
- whether we are required by the FDA or other comparable foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA and comparable foreign regulatory authorities the safety, efficacy, consistent manufacturing quality, and acceptable risk-benefit profile of our small molecule product candidates or any future product candidates;
- the prevalence, duration, and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the timely receipt of necessary regulatory approvals from the FDA and comparable foreign regulatory authorities;
- the willingness of physicians, operators of clinics, and patients to utilize or adopt any of our product candidates or future product candidates over alternative or more conventional therapies;
- 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 diabetes and obesity, 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 adequate 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 diabetes and obesity. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between advancing our current product candidates and any future product candidates. Although we had previously pursued the development of icovamenib in cancer and metabolic diseases, in January 2025, we announced that our strategic focus for icovamenib will be in metabolic disorders and that we will conclude our studies exploring icovamenib's potential in oncology and explore partnerships to advance our oncology assets.

Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. In addition, if our determination to focus our internal resources on the development of icovamenib in metabolic disorders and seek partnerships to advance our oncology assets does not lead to clinical or commercial success, or we otherwise make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the diabetes or obesity 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 our current product candidates 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 December 31, 2024, we had $58.6 million in cash, cash equivalents and restricted cash. Based on our current operating plan, we believe that our existing cash and cash equivalents, and restricted cash as of December 31, 2024, without any future financing, will not be sufficient for us to continue as a going concern for at least one year from the issuance date of the financial statements appearing elsewhere in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K for the year ended December 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 Annual Report on Form 10-K. 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.

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 our current and projected business operations and our 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 diabetes and obesity, and the approach we are taking to discover and develop such product candidates 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 diabetes and obesity, 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.

Our lead product candidate, icovamenib, is in clinical development, and we dosed the first participant 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 icovamenib, as well as animal models and preclinical cell lines for icovamenib, BMF-500 and BMF-650. 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, icovamenib, which is designed to be a highly active and selective covalent inhibitor of menin, in diabetes and obesity, we may never successfully identify additional covalent binding product candidates to validated metabolic or other targets through our FUSION™ System. Therefore, we do not know if our approach of treating patients with diabetes and obesity, 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 diabetes and obesity. Although our research and development efforts to date have resulted in our discovery and preclinical development of icovamenib, BMF-500, BMF-650 and other programs, icovamenib, BMF-500, BMF-650 and such other programs may not be safe or effective in our target indications, and we may not be able to further develop icovamenib, BMF-500, BMF-650 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 icovamenib 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 early in our development efforts and are substantially dependent on our product candidates, icovamenib and BMF-500. If we are unable to advance icovamenib, BMF-500 or any other product candidates through clinical development, obtain regulatory approval and ultimately commercialize icovamenib, 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, icovamenib, in human subjects for various types of type 2 diabetes 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. 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 icovamenib, 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 the 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 I clinical trial of icovamenib in various types of liquid tumors, our Phase I/Ib clinical trial of icovamenib in various types of solid tumors, our Phase I/II clinical trial of icovamenib in type 2 diabetes, our Phase II clinical trial of icovamenib in type 1 diabetes, and our Phase I 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 icovamenib, 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 diabetes and obesity;
- 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. For example, in June 2024, we announced that the FDA had imposed a clinical hold on the Phase I/II clinical trials of icovamenib in type 2 and type 1 diabetes. We worked to diligently resolve the hold, and in September 2024, the FDA lifted the clinical hold. 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, icovamenib and BMF-500, under investigation in clinical trials. 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 continue 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, icovamenib, is in clinical development in type 1 and type 2 diabetes, 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 participants to participate in our clinical trials;
- delays in manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing;
- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- developments on trials conducted by competitors for related technology that raises FDA or foreign regulatory authority concerns about risk to patients of the technology broadly, or if the FDA or a foreign regulatory authority finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;

- delays in recruiting, screening and enrolling participants and delays caused by participants 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;
- 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.

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, such as the previous clinical hold imposed by the FDA on our INDs for icovamenib in type 1 and type 2 diabetes, which was lifted in September 2024, 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 icovamenib, BMF-500, or BMF-650 will perform in clinical trials as icovamenib, BMF-500, or BMF-650 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 participant, 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 global health emergency such as a 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.

As a result of any future global health emergency such as a pandemic, epidemic, or outbreak of an infectious disease, we have experienced, and may in the future 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 participants 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 clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial participant visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of participant 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 participants 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 participants to participate in these trials through completion of such trials as required by the FDA or other comparable foreign regulatory authorities. Participant enrollment is a significant factor in the timing of clinical trials. Our ability to enroll eligible participants 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 participants available to us, as some participants 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 participants who are available for our clinical trials at such clinical trial sites. In addition, there may be limited participant pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical trials will further limit the pool of available study participants as we will require that participants 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. Participant enrollment for our ongoing and planned clinical trials may be affected by other factors, including:

- size and nature of the participant population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs or other methods of treatment for the disease under investigation;
- participant eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and participants' 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 participants for biomarkers to indicate which participants may be eligible for enrollment in our clinical trials;
- delays in or temporary suspension of the enrollment of participants 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 participant consents;
- participant referral practices of physicians;
- the ability to monitor participants adequately during and after treatment;and
- proximity and availability of clinical trial sites for prospective participants.

These factors may make it difficult for us to enroll enough participants to complete our clinical trials in a timely and cost-effective manner. Our inability to enroll a sufficient number of participants 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 participants 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.

Type 2 diabetes 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 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 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 icovamenib, BMF-500, BMF-650, 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 icovamenib, BMF-500 and BMF-650 are based on estimates and third-party sources. If the market opportunities for icovamenib, BMF-500 and BMF-650 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 non-clinical or clinical trials.

The incidence and prevalence for target patient populations of icovamenib, BMF-500 and BMF-650 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 icovamenib, BMF-500, BMF-650 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 participant 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.

To our knowledge, there are no clinical-stage programs that aim to specifically regenerate insulin-producing beta cells in the islets by targeting menin for diabetes. There are over 60 approved agents and therapies being utilized to address diabetes. Such approved agents and therapies are intended to provide specific benefits to patients; however, we are not aware of any successfully addressing the root cause of diabetes, a depleted pool of functional beta cells. Several programs are targeting beta cell proliferation, including DYRK1A inhibitors. However, in addition to specific safety challenges, studies have shown that this approach may not only proliferate beta cells but also other pancreatic cells, which would not necessarily improve the ratio of alpha to beta cells in the pancreas.

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 diabetes and obesity. 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 icovamenib, BMF-500, BMF-650 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 participant registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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 this Annual Report on Form 10-K 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 participant recruitment or the ability of enrolled participants 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.

For example, in June 2024, we announced that the FDA placed our INDs for icovamenib in our Phase I/II clinical trials of icovamenib in type 2 and type 1 diabetes on clinical hold based on the level of possible drug-induced hepatotoxicity observed in the completed dose escalation phase of COVALENT-111. Even though the FDA lifted the clinical hold and has allowed clinical trials of icovamenib in type 1 and type 2 diabetes to resume, we cannot make assurances that participants treated with icovamenib will not develop hepatoxicity or other adverse events in the future. If such additional adverse events were to emerge, further advancement of our clinical trials could be halted or delayed and we may not receive regulatory approval for icovamenib in type 1 or type 2 diabetes. Even if we receive regulatory approval for icovamenib in type 1 or type 2 diabetes, our labeling may be restricted and/or marketing acceptance of our product may be diminished and the commercial potential of our icovamenib diabetes programs may be materially and negatively impacted.

Icovamenib, BMF-500, BMF-650 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 icovamenib leads to levels of menin inhibition that far exceed those achieved by well-studied non-covalent menin inhibitors, it is possible that participants' responses could be both unexpected and negative. In addition, we or our future collaborators may study icovamenib in combination with other therapies, which may exacerbate adverse events associated with the therapy. Further, our product candidates will be used in participants that have weakened immune systems, which may exacerbate any potential side effects associated with their use. Participants treated with icovamenib, BMF-500, BMF-650 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 participants in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such participants may be using or due to the gravity of such participants' illnesses. For example, it is expected that some of the participants enrolled in our clinical trials of icovamenib 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 participants to the clinical trials, participants 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 participants 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 REMS, which could include a medication guide outlining the risks of such side effects for distribution to participants;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- we could be sued and held liable for harm caused to participants; 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 participants 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 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 participant enrollment continues and more participant data become available or as participants 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.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, 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, 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 available 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, 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 this Annual Report on Form 10-K titled “Business—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 restrictions on product development plans, or clinical holds;
- costs to defend the related litigation;
- diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our share price.

Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance that we believe is appropriate for our stage of development, our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage and may need to obtain higher levels prior to marketing any of our product candidates if approved. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future

corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

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

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

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

Risks Related to Regulatory Process and Other Legal Compliance Matters

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

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA. Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including our lead product candidate icovamenib, 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 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 suspend or prohibit completion of our clinical trials, such as through the clinical hold placed on our INDs for our Phase I/II clinical trials of icovamenib in type 2 and type 1 diabetes, which was lifted in September 2024, or they 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 public health emergencies like 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 product candidate has an acceptable benefit-risk ratio for its proposed indication;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures, specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- our third-party contractors may fail to comply with regulatory requirements or otherwise fail or be unable to adequately perform their obligations to allow for the conduct of our planned or future clinical studies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

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 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 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.

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

Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

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

If a prolonged government shutdown occurs, or if global health concerns or shortages in resources 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, GLP requirements, and GCP 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 this Annual Report on Form 10-K titled "Business—Government Regulation —Healthcare Reform."

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 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 this Annual Report on Form 10-K 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, the 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 participant 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.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

The United States Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our former Chief Executive Officer, 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 the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

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

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

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

As of December 31, 2024, we had 106 full-time employees, including 79 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 icovamenib, 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 icovamenib, 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 icovamenib, 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 icovamenib, 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 icovamenib, 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 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, the United States government has imposed a 10% additional tariff on imports from China and may impose more restrictions on goods. As such, a trade war or other trade restrictions could lead to additional tariffs on the chemical intermediates we use that are manufactured in China. In addition, legislative proposals (for example, the BIOSECURE Act and related legislation in Congress) were previously considered but not passed by Congress and, if enacted, would have negatively impacted 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 were identified by these legislative proposals as "biotechnology companies of concern," and the potential downstream adverse impacts of this proposed legislation – had it passed – would have included 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 participants. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of participants may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our preclinical studies or clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our product candidates. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting preclinical studies, clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols or regulatory requirements or for other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be adversely affected, our costs could increase and our ability to generate revenue could be delayed.

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

We currently rely and 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 and tightening regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;

- our third-party manufacturers may experience change of control of their ownership including ownership by a competitor,
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available 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. Legislation was proposed that, if enacted, could have 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 components or processes used in or for our product candidates, if required, may not be accomplished quickly and would create increased cost, or adversely impact the quality of our product candidates. If we are able to find a replacement supplier, the replacement supplier would need to be qualified, would need to process our technology transfer and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single-source ingredients, components and materials used in our product candidates, any interruption or delay in the supply of ingredients, components or materials or our inability to obtain ingredients, components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers may use highly flammable reagents at high

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

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

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

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy and obtain marketing approval.

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

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

As a result, if we enter into future collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot

be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Furthermore, if conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Any delays in entering into future collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

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

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

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

Risks Related to Intellectual Property

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

We rely 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 icovamenib 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.

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 EU and certain other countries. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product candidate will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and

preclinical data and launch their product earlier than might otherwise be expected, and our competitive position, business, financial condition, results of operations and prospects could be materially adversely affected.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (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 ANDA 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.

Marketing exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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

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

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our technology or product candidates. Also, former employees may become employed by competitors who develop similar technology or product candidates, and could assist the competitor in designing around our patents or trade secrets. While it is our policy to require our employees and contractors who may be involved in the development of our intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or our

ownership of our patents, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our technology or product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain. Defending against such 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 to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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

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

Intellectual property rights do not necessarily address all potential threats.

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

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

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

Risks Related to Our Common Stock

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 such as the recent clinical hold on our INDs for the Phase I/II clinical trials of icovamenib in type 2 and type 1 diabetes, from June 2024 to September 2024;
- 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 supply for any of our product candidates or the components thereof, 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;
- our ability to develop our product candidates for the treatment of type 1 and type 2 diabetes 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 volatile. 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 price at which you purchased shares of our common stock, 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 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 (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 (Securities Act). 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 (the 2021 Plan). The number of shares available for future grant under the 2021 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 2021 Plan). We have also reserved

shares of common stock for issuance pursuant to our 2021 Employee Stock Purchase Plan (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 2021 Plan and the ESPP promptly following the effectiveness of any such increase. If our Board elects to increase the number of shares available for future grant under the 2021 Plan or the ESPP, our stockholders may experience additional dilution, and our stock price may fall.

Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our securities.

In March 2025, we notified the Listing Qualifications Department of The Nasdaq Stock Market LLC (Nasdaq) that we are not in compliance with the audit committee requirement under Nasdaq Listing Rule 5605(c)(2)(A) due to having only two members on the audit committee of our board of directors, due to a vacancy resulting from the resignation of Michael J.M. Hitchcock, Ph.D., from the audit committee effective as of March 25, 2025. We have the opportunity to regain compliance within the cure period provided in Nasdaq Listing Rule 5605(c)(4), as follows: until the earlier of (i) our next annual meeting of stockholders or (ii) one year from Dr. Hitchcock's resignation, or March 25, 2026. However, if our annual stockholder meeting occurs within 180 days of Dr. Hitchcock's resignation from the audit committee, we will instead have 180 days from Dr. Hitchcock's resignation, or September 21, 2025, to regain compliance with Nasdaq Listing Rule 5605(c)(2)(A). We are evaluating the membership of the audit committee and intend to regain compliance with Nasdaq Listing Rule 5605(c)(2)(A) by appointing a new or existing Board member who meets the independence requirements under Nasdaq rules and the Exchange Act prior to the expiration of the applicable cure period described above. However, there can be no assurance that we will be able to continue to satisfy Nasdaq's continued listing requirements with respect to audit committee composition or otherwise. If we fail to comply with Nasdaq's continued listing requirements, our common stock could cease to be listed for trading on Nasdaq and instead be available for trading only over-the-counter, which could further depress our stock price.

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 29% of our outstanding voting stock as of December 31, 2024. In particular, as of December 31, 2024, Thomas Butler, our former Chief Executive Officer, and Ramses Erdtmann were both 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 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 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 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 DGCL, 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 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 participants 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;
- tariffs (including tariffs that have been or may in the future be imposed by the United States or other countries), trade protection measures, import or export licensing requirements, trade embargoes, sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), other trade barriers (including further legislation or actions taken by the United States or other countries that restrict trade), and protectionist or retaliatory measures taken by the United States or other countries; 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 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, 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 our initial public offering (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 Jumpstart Our Business Startups Act (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 identified a significant deficiency in our internal controls over financial reporting pertaining to fiscal year ended December 31, 2024 and 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 this Annual Report on Form 10-K 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 and the financial statements;
- reduced disclosure obligations regarding executive compensation and our periodic reports and proxy statements; and
- exemptions from the requirements of holding non-binding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 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 material cybersecurity 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, including trade secrets, other intellectual property, and personal 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. Systems containing Sensitive Information are vulnerable to service interruptions, malfunction, natural disasters, terrorism, war, software and hardware failures, telecommunication and electrical failures, theft or loss from inadvertent or intentional actions by employees, contractors, consultants, business partners and/or other third parties, malware, malicious code (such as viruses and worms), software bugs, ransomware, denial-of-service attacks (including credential stuffing), social engineering and other means that affect service reliability and threaten the security, confidentiality, integrity and availability of information.

We may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. 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 cybersecurity incidents, data breaches or other 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 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 or misuse of our Sensitive Information. Like other companies in our industry, we, and third parties related to us, have experienced threats and cybersecurity incidents relating to our information technology systems and infrastructure.

While we implement commercially reasonable information security safeguards, consistent with companies of the same size and scope as ours, there is no guarantee 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, data breaches or other cybersecurity 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, data breaches, cybersecurity incidents, or other 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 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 participants 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 cybersecurity incident or data breach 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 cybersecurity incidents and data breaches, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach, incident, or compromise. We also rely on third parties to manufacture our product candidates, and similar material events relating to their computer systems could also have a material adverse impact. To the extent that any disruption or data breach, cybersecurity 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 contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations.

Our insurance policies, if any, may not be adequate to compensate us for the potential losses arising from any such cybersecurity incident, data 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 events and conditions could adversely affect our business, financial condition and operating results.

Changes in U.S. government and other nations' administrations and their associated shifts in policy and priorities could also impact our operations and market conditions. Our business is sensitive to geopolitical issues, including foreign policy actions taken by governments such as tariffs, sanctions, embargoes, export and import controls, and other trade restrictions, which can affect the demand for, and our ability to sell, our products and services, cause disruptions to our supply chain, and, ultimately, could adversely affect our business. Global conflicts, including Russia's invasion of Ukraine, conflicts in the Middle East, and heightened tensions in the Pacific region, have significantly elevated global geopolitical tensions and security concerns. Economic sanctions, export controls, and other trade restrictions could directly and indirectly result in the disruption of our business and supply chain. Although we do not have any clinical trial sites or operations in the currently affected regions, if the current conflict expands further into the region or continues, resulting heightened economic sanctions from the United States and the international community, in addition to environmental regulations, could limit our ability to procure or use certain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. We continue to monitor any adverse impact that the outbreak of war and the subsequent institution of sanctions by the United States and other countries may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and third parties with whom we conduct business.

Significant political, trade, or regulatory developments in the jurisdictions in which we sell our products, if approved, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

The U.S. Congress, the Trump administration, or any new administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U. S. policy occurred and since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Environmental, social and governance matters may impact our business and reputation.

In addition to the changing rules and regulations related to environmental, social and governance (ESG) matters imposed by governmental and self-regulatory organizations, a variety of third-party organizations, institutional investors and customers evaluate the performance of companies on ESG topics, and the results of these assessments are widely publicized. These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. Reduced access to or increased cost of capital may occur as financial institutions and investors increase expectations related to ESG matters.

Developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG-related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, social investments and other ESG-related

matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Furthermore, statements about our ESG-related initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals, including our previously announced commitments to reduce greenhouse gas emissions, within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected. In addition, in recent years "anti-ESG" sentiment has gained momentum across the U.S., with several states and Congress having proposed or enacted "anti-ESG" policies, legislation, or initiatives or issued related legal opinions, and the President having recently issued an executive order opposing diversity equity and inclusion (DEI) initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, legal opinions, and scrutiny could result in us facing additional compliance obligations, becoming the subject of investigations and enforcement actions, or sustaining reputational harm.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We regularly assess risks from cybersecurity threats; monitor our information systems for potential vulnerabilities; and test those systems pursuant to our internal information technology policies which are inclusive of cybersecurity policies, processes, and practices. To protect our information systems from cybersecurity threats, we use various security tools that are designed to help identify, escalate, investigate, resolve, and recover from security incidents in a timely manner. Our Cybersecurity Committee, which is comprised of representatives from our business operations and support functions, assesses risks based on current risks we are aware of, probability and potential impact to key business systems and processes. Risks that are considered high are incorporated into our overall risk management program. A mitigation plan is developed for each identified high risk, with progress reported to the Cybersecurity Committee and tracked as part of our overall risk management program overseen by the Audit Committee of our board of directors.

We collaborate with third party vendors as deemed necessary to assess the effectiveness of our information technology environment, which is inclusive of our cybersecurity prevention and response systems and processes. These third party vendors include cybersecurity assessors, consultants, and other external cybersecurity experts to assist in the identification, verification, and validation of cybersecurity risks, as well as to support associated mitigation plans when necessary. We have implemented a third-party cybersecurity risk management process to conduct due diligence on external entities that are determined to be of higher risk due to the Sensitive Information that they have access to, including those that perform cybersecurity services.

Cybersecurity threats, including those resulting from any previous cybersecurity incidents, have not materially affected our Company, including our business strategy, results of operations, or financial condition. We do not believe that cybersecurity threats resulting from any previous cybersecurity incidents of which we are aware are reasonably likely to materially affect our Company. Refer to the risk factor captioned “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” in Part I, Item 1A. “Risk Factors” for additional description of cybersecurity risks and potential related impacts on our Company.

Governance

Our board of directors oversees our risk management process, including as it pertains to cybersecurity risks, directly and through its committees. The Audit Committee of the board oversees our risk management program, which focuses on the most significant risks we face in the short-, intermediate-, and long-term timeframe. Audit Committee meetings include discussions of specific risk areas throughout the year, including, among others, those relating to cybersecurity threats, when applicable, and reports from the Chief Financial Officer on our enterprise risk profile on an annual basis. The Audit Committee reviews our information technology environment risk, which is inclusive of our cybersecurity risk profile with management on a periodic basis using key performance and/or risk indicators. These key performance indicators are metrics and measurements designed to assess the prevention, detection, and mitigation efforts of our cybersecurity program, as well as our remediation of cybersecurity incidents, as applicable.

We take a risk-based approach to cybersecurity and have implemented cybersecurity policies throughout our operations that are designed to address cybersecurity threats and incidents. Our Head of Information Technology, and the Cybersecurity Committee, is responsible for the establishment and maintenance of our cybersecurity program, as well as the assessment and management of cybersecurity risks. The current Head of Information Technology has over 20 years of experience in information security and possesses the education, skills, experience, and industry certifications expected by our company of an individual assigned to these duties. The Head of Information Technology provides periodic updates on our information technology environment risk, which is inclusive of our cybersecurity risk profile, to the Board of Directors, which includes the Audit Committee members.

Item 2. Properties

We currently lease approximately 45,799 square feet of office, laboratory and manufacturing space in Redwood City and San Carlos, California under three leases which expire in July 2025 and January 2032. We believe these facilities are sufficient to meet our near-term needs and that any additional space we may require will be available on commercially reasonable terms.

Item 3. 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 4. Mine Safety Disclosures

Not Applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Our Common Stock

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "BMEA" since April 16, 2021. Prior to that date, there was no public trading market for our common stock.

Holders of Record

As of March 24, 2025, there were 40 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees.

Dividend Policy

We have never declared or paid cash dividends on our capital stock to investors. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by the terms of any future debt or preferred securities.

Unregistered Sales of Equity Securities

Since January 1, 2022, we have not issued any unregistered securities.

Purchases of Equity Securities by Issuers and Affiliated Purchasers

None.

Item 6. Selected Financial Data

Not Applicable.

Item 7. 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 financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 Annual Report on Form 10-K, our actual results could differ materially from the results described, in or implied, by these forward-looking statements.

Overview

We are a clinical-stage diabetes and obesity medicines company focused on the discovery and development of oral covalent small molecule drugs to treat patients with metabolic diseases. 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 small molecule product candidates.

Our lead clinical program's drug candidate, icovamenib, is an orally bioavailable, and selective covalent inhibitor of menin currently in two clinical and multiple preclinical studies, investigating icovamenib's potential in type 1 and type 2 diabetes, as well as its impact in obesity. Menin serves as a checkpoint to prevent beta cell proliferation. Thus, we believe inhibiting menin via icovamenib has the potential to enable the proliferation, preservation, and reactivation of healthy, function beta

cells capable of producing insulin, thereby leading to long-term glycemic control in patients with type 1 and type 2 diabetes. Menin is also an important transcriptional regulator known to play a direct role in oncogenic signaling in multiple cancers and in beta cell homeostasis.

In preclinical studies, the administration of icovamenib has produced a pronounced effect in preclinical models of diabetes, normalizing glucose levels during treatment and even after drug washout. As of December 31, 2024 icovamenib is being evaluated in type 1 and type 2 diabetes across two ongoing clinical trials. With its strategic focus to become a diabetes and obesity medicines company, we plan to conclude our studies exploring icovamenib's potential in oncology and explore partnerships to further advance our oncology assets (BMF-500, a covalent inhibitor of FLT3, currently in a Phase I study), while concentrating internal resources on metabolic disorders.

Beyond icovamenib, we are utilizing our novel FUSION™ System to pioneer covalent treatments against other high-value genetic drivers of disease. In October 2024, we announced the nomination of BMF-650 our investigational, next-generation, oral small molecule GLP-1 RA, which is currently advancing through IND-enabling studies. With its unique pharmacokinetic profile and enhanced bioavailability, we believe BMF-650 has the potential to provide a best-in-class therapeutic option for diabetes and obesity. Our goal is to utilize our capabilities and our FUSION™ System platform to become the leader in developing covalent small molecules to maximize the depth and durability of clinical benefit when treating various diseases.

Since commencing operations in 2017, we have devoted substantially all of our efforts and financial resources to conducting research and development activities, including drug discovery and preclinical studies, establishing and maintaining our intellectual property portfolio, the manufacturing of clinical and research material, organizing and staffing our company, business planning, raising capital and providing general and administrative support for these operations. We have not generated any revenue from product sales and, as a result, we have never been profitable and have incurred net losses since commencement of our operations.

As of December 31, 2024, we had an accumulated deficit of $387.3 million. We incurred net losses of $138.4 million and $117.3 million for the years ended December 31, 2024 and 2023, respectively. Based on our current operating plan, we believe that our existing cash and cash equivalents, and restricted cash as of December 31, 2024, without any future financing, will not be sufficient for us to continue as a going concern for at least one year from the issuance date of the financial statements appearing elsewhere in this Annual Report on Form 10-K. 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;
- conduct our ongoing preclinical studies and Phase I clinical trial of icovamenib in various types of liquid tumors, our planned Phase I/Ib clinical trial of icovamenib in solid tumors with kirsten rat sarcoma viral oncogene homolog gene mutations, our Phase I/II clinical trial of icovamenib in type 2 diabetes and our Phase II clinical trial of icovamenib in 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 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 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.

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. Subsequent to the close, 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. In addition, immediately prior to the closing of the IPO, all outstanding shares of our convertible preferred stock automatically converted into 7,064,925 shares of common stock. Proceeds from the IPO, net of underwriting discounts and commissions and offering costs were $152.8 million. On April 3, 2023, we issued and sold 5,750,000 shares of common stock, which included 750,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $30.00 per share in an underwritten public offering pursuant to a shelf registration on Form S-3. Our net proceeds from the offering were $161.8 million, after deducting underwriting discounts and commissions and offering costs of $10.7 million.

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 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 icovamenib 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 clinical trials, including our ongoing Phase I/II clinical trial of icovamenib in type 2 diabetes and Phase II clinical trial of icovamenib in type 1 diabetes, our preclinical development activities, as well as any future preclinical development and clinical trials of our product candidates, and other research and development activities we may conduct;
- 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 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 Years Ended December 31, 2024 and 2023

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

	Year Ended December 31,		
	2024	2023	$ Change
Operating expenses:			
Research and development	$ 118,085	$ 102,546	$ 15,539
General and administrative	25,985	23,589	2,396
Total operating expenses	144,070	126,135	17,935
Loss from operations	(144,070)	(126,135)	(17,935)
Interest and other income, net	5,644	8,880	(3,236)
Net loss	$ (138,426)	$ (117,255)	$ (21,171)

Research and Development Expenses

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

	Year Ended December 31,		
	2024	2023	$ Change
External costs			
Clinical activities related expenses	$ 48,100	$ 36,098	$ 12,002
Preclinical activities related expenses	11,815	10,165	1,650
Expenses related to manufacturing of clinical and research material	7,262	13,237	(5,975)
Other external costs	10,948	5,528	5,420
Internal costs:			
Personnel-related expenses (including stock-based compensation)	31,856	28,838	3,018
Facilities and other allocated expenses	8,104	8,680	(576)
Total research and development expenses	$ 118,085	$ 102,546	$ 15,539

Research and development expenses increased by $15.5 million during the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase of $13.1 million in external costs was primarily driven by an increase of $12.0 million related to clinical activities, an increase of $5.4 million related to consultants, advisors and other professional services to support our clinical studies, discovery research and overall research and development program, and increase of $1.7 million related to preclinical activities mainly driven by timing of our exploratory programs. Manufacturing related costs decreased by $6.0 million primarily driven by timing of services performed by our contract manufacturers. Personnel-related expenses, including stock-based compensation, increased by $3.0 million due to an increase in headcount.

General and Administrative Expenses

General and administrative expenses increased by $2.4 million during the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase was primarily due to increased personnel-related expenses, including stock-based compensation, of $1.4 million due to an increase in headcount. Consulting and professional expenses increased by $1.5 million due to legal, accounting, consulting and other services offset by a decrease in insurance expense by $0.3 million.

Interest and Other Income, Net

Interest and other income, net was $5.6 million for the year ended December 31, 2024 compared to $8.9 million for the year ended December 31, 2023. The decrease of $3.2 million was primarily due to the decrease in cash, cash equivalents, and restricted cash balance.

Comparison of the Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,		
	2023	2022	$ Change
Operating expenses:			
Research and development	$ 102,546	$ 62,713	$ 39,833
General and administrative	23,589	20,921	2,668
Total operating expenses	126,135	83,634	42,501
Loss from operations	(126,135)	(83,634)	(42,501)
Interest and other income, net	8,880	1,806	7,074
Net loss	$ (117,255)	$ (81,828)	$ (35,427)

Research and Development Expenses

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

	Year Ended December 31,		
	2023	2022	$ Change
External costs			
Clinical activities related expenses	$ 36,098	$ 9,439	$ 26,659
Preclinical activities related expenses	10,165	13,095	(2,930)
Expenses related to manufacturing of clinical and research material	13,237	12,619	618
Other external costs	5,528	2,693	2,835
Internal costs:			
Personnel-related expenses (including stock-based compensation)	28,838	19,361	9,477
Facilities and other allocated expenses	8,680	5,506	3,174
Total research and development expenses	$ 102,546	$ 62,713	$ 39,833

Research and development expenses increased by $39.8 million during the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase of $27.2 million in external costs was primarily driven by an increase of $26.7 million related to clinical activities due to increased enrollment of our diabetes and oncology trials. Preclinical activities related expenses decreased by $2.9 million primarily driven by timing of our exploratory programs. Other external costs increased by $2.8 million primarily driven by external consultants and professional services to support clinical and preclinical activities. Manufacturing related costs increased by $0.6 million primarily driven by timing of services performed by our contract manufacturers. Personnel-related expenses, including stock-based compensation, increased by $9.5 million due to an increase in headcount. Facilities and other allocated expenses increased by $3.2 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 $2.7 million during the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was primarily due to increased personnel-related expenses, including stock-based compensation, of $2.3 million due to an increase in headcount. Professional services and administrative expenses increased by $1.0 million due to legal, accounting, consulting and other services incurred as a public company offset by a decrease in insurance expense of $0.6 million.

Interest and Other Income, Net

Interest and other income, net was $8.9 million for the year ended December 31, 2023 compared to $1.8 million for the year ended December 31, 2022. The increase of $7.1 million was primarily due to interest earned from cash and investment balances.

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 close 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 from the IPO, net of underwriting discounts and commissions and offering costs, were $152.8 million.

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 $161.8 million after deducting underwriting discounts, commissions, and offering costs.

Additionally, we are party to an equity distribution agreement, dated November 25, 2022, with Piper Sandler & Co. (Piper Sandler) with respect to an at-the-market offering program, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $100.0 million (which is included in the $350.0 million originally registered under the Shelf Registration Statement) through Piper Sandler as the sales agent. In the year ended December 31, 2024, we did not sell any shares of common stock pursuant to the sales agreement with Piper Sandler.

As of December 31, 2024, we had cash, cash equivalents and restricted cash of $58.6 million. As of December 31, 2024, we had an accumulated deficit of $387.3 million. We have incurred substantial operating losses and have used cash in our operating activities since inception. Without any future financing, the current operating plan under the existing cash and cash equivalents, and restricted cash as of December 31, 2024, will not be sufficient for us to fund our operating expenses and capital expenditure requirements for at least twelve months following the issuance date of the financial 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 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 equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional funding may not be available to us on acceptable terms or at all. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

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

- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;
- the costs associated with being a public company;
- the cost associated with commercializing our product candidates, if they receive regulatory approval;
- 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 any global health emergency 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 others rights to our product candidates in certain territories or indications that we would prefer to develop and commercialize ourselves.

See the section of this Annual Report on Form 10-K 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):

	Year Ended December 31,		
	2024	**2023**	**2022**
Net cash (used in) provided by:			
Operating activities	$ (119,894)	$ (96,592)	$ (62,417)
Investing activities	(362)	(2,220)	27,341
Financing activities	1,668	163,798	1,239
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (118,588)	$ 64,986	$ (33,837)

Net Cash Used in Operating Activities

Net cash used in operating activities was $119.9 million for the year ended December 31, 2024 and consisted of a net loss of $138.4 million offset by increase in net assets of $5.1 million and non-cash adjustments of $23.7 million. The increase in net assets consisted primarily of an increase in prepaid expenses and other current assets of $7.7 million, a decrease in other assets of $4.9 million, an increase in accounts payable of $6.1 million, a decrease in accrued expenses and other current liabilities of $6.9 million and a decrease in operating lease liabilities of $1.5 million. Non-cash adjustments consisted primarily of stock-based compensation expense of $19.1 million, operating lease expense of $2.8 million and depreciation expense of $1.7 million.

Net cash used in operating activities was $96.6 million for the year ended December 31, 2023. Cash used in operating activities in 2023 was mainly the result of the net loss of $117.3 million and decrease in operating lease liabilities of $2.2 million. This was offset by an increase in accounts payable and accrued liabilities of $4.4 million and stock-based compensation expense of $14.1 million.

Net cash used in operating activities was $62.4 million for the year ended December 31, 2022. Cash used in operating activities in 2022 was mainly the result of the net loss of $81.8 million and increase in prepaid expenses and other assets of $3.6 million. This was offset by an increase in accounts payable and accrued liabilities of $11.9 million and stock-based compensation expense of $10.3 million.

Net Cash Provided by (Used in) Investing Activities

Net cash used in investing activities was $0.4 million for the year ended December 31, 2024. Cash used in investing activities was mainly related to purchases of property and equipment.

Net cash used in investing activities was $2.2 million for the year ended December 31, 2023. Cash used in investing activities was mainly related to purchases of property and equipment offset by maturities of investments.

Net cash provided by investing activities was $27.3 million for the year ended December 31, 2022. Cash provided by investing activities was mainly related to maturities of investments offset by purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $1.7 million for the year ended December 31, 2024. Cash provided by financing activities was mainly related to net proceeds received from stock option exercises and purchases under the ESPP.

Net cash provided by financing activities was $163.8 million for the year ended December 31, 2023. Cash provided by financing activities was mainly related to net proceeds received from the issuance of common stock from our public offering.

Net cash provided by financing activities was $1.2 million for the year ended December 31, 2022. Cash provided by financing activities was mainly related to proceeds received from stock option exercises and purchases under the ESPP.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist primarily of costs of research, preclinical studies, clinical trials, and manufacturing. Personnel costs of our research and product development employees is also a major component of research and development expenses which also includes non-personnel costs such as fees payable to third parties for clinical and preclinical studies and research services, laboratory supplies, equipment maintenance, and other consulting costs.

We record accruals for estimated costs of research, preclinical studies, clinical trials, and manufacturing, which are significant components of research and development expenses. A substantial portion of our ongoing research and development activities is conducted by third-party service providers, CROs and CMOs. Our contracts with the CMOs generally include fees such as initiation fees, reservation fees, costs related to animal studies and safety tests, verification run costs, materials and reagents expenses, taxes, etc. Our contracts with CROs generally include pass-through fees such as regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. 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 us under such contracts. We accrue the costs incurred under agreements with these third parties based on estimates of actual work completed in accordance with the respective agreements. We determine the estimated costs through discussions with internal personnel and external service providers as to the progress, or stage of completion or actual timeline (start-date and end-date) of the services and the agreed-upon fees to be paid for such services. In the event we make advance payments, the payments are recorded as a prepaid expense and recognized as the services are performed.

Item 7A. 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 year ended December 31, 2024. We held $58.6 million in cash, cash equivalents, and restricted cash as of December 31, 2024. Cash equivalents consisted of money market funds. Restricted cash consisted of two stand-by letter of credits issued to our landlord in connection with the laboratory leases. We held no interest-bearing liabilities as of December 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 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of Biomea Fusion, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Biomea Fusion, Inc. (the "Company") as of December 31, 2024 and 2023, the related statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred net operating losses and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

San Francisco, CA

March 31, 2025

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

Biomea Fusion, Inc.
Balance Sheets
(in thousands, except share and per share data)

	December 31,	
	2024	**2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 58,279	$ 176,866
Prepaid expenses and other current assets	10,053	2,315
Total current assets	68,332	179,181
Property and equipment, net	3,766	5,159
Restricted cash	369	370
Other assets	619	5,503
Operating lease right-of-use assets	6,852	9,714
Total assets	$ 79,938	$ 199,927
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,932	$ 6,851
Accrued expenses and other current liabilities	6,662	13,543
Operating lease liabilities, current	2,079	2,466
Total current liabilities	21,673	22,860
Operating lease liabilities, non-current	6,692	7,830
Total liabilities	28,365	30,690
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 0 shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 36,310,713 and 35,866,610 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	438,820	418,058
Accumulated deficit	(387,251)	(248,825)
Total stockholders' equity	51,573	169,237
Total liabilities and stockholders' equity	$ 79,938	$ 199,927

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

Biomea Fusion, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,		
	2024	**2023**	**2022**
Operating expenses:			
Research and development	$ 118,085	$ 102,546	$ 62,713
General and administrative	25,985	23,589	20,921
Total operating expenses	144,070	126,135	83,634
Loss from operations	(144,070)	(126,135)	(83,634)
Interest and other income, net	5,644	8,880	1,806
Net loss	$ (138,426)	$ (117,255)	$ (81,828)
Other comprehensive loss:			
Unrealized gain on investments, net	—	1	9
Comprehensive loss	$ (138,426)	$ (117,254)	$ (81,819)
Net loss per common share, basic and diluted	$ (3.83)	$ (3.44)	$ (2.80)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	36,105,671	34,106,923	29,271,777

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

Biomea Fusion, Inc.
Statements of Stockholders' Equity (Deficit)
(in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2021	**29,115,421**	**$ 3**	**$ 228,532**	**$ (10)**	**$ (49,742)**	**$ 178,783**
Issuance of restricted stock	186,727	—	—	—	—	—
Exercise of stock options	81,067	—	516	—	—	516
Purchases under employee stock purchase plan	178,339	—	723	—	—	723
Stock-based compensation expense	—	—	10,336	—	—	10,336
Unrealized gain (loss) on investments, net	—	—	—	9	—	9
Net loss	—	—	—	—	(81,828)	(81,828)
Balance at December 31, 2022	**29,561,554**	**3**	**240,107**	**(1)**	**(131,570)**	**108,539**
Issuance of restricted stock	180,316	—	—	—	—	—
Exercise of stock options	125,192	—	937	—	—	937
Issuance of common stock from public offering, net of issuance costs of $10,697	5,750,000	1	161,802	—	—	161,803
Purchases under employee stock purchase plan	249,548	—	1,081	—	—	1,081
Stock-based compensation expense	—	—	14,131	—	—	14,131
Unrealized gain (loss) on investments, net	—	—	—	1	—	1
Net loss	—	—	—	—	(117,255)	(117,255)
Balance at December 31, 2023	**35,866,610**	**4**	**418,058**	**—**	**(248,825)**	**169,237**
Issuance of restricted stock	109,356	—	—	—	—	—
Exercise of stock options	106,339	—	518	—	—	518
Purchases under employee stock purchase plan	228,408	—	1,150	—	—	1,150
Stock-based compensation expense	—	—	19,094	—	—	19,094
Net loss	—	—	—	—	(138,426)	(138,426)
Balance at December 31, 2024	**36,310,713**	**$ 4**	**$ 438,820**	**$ —**	**$ (387,251)**	**$ 51,573**

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

Biomea Fusion, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities			
Net loss	$ (138,426)	$ (117,255)	$ (81,828)
Adjustments to reconcile net loss to net cash used in operating activities			
Depreciation expense	1,748	1,515	691
Non-cash operating lease expense	2,838	2,686	571
Stock-based compensation expense	19,094	14,131	10,336
Net amortization of premiums and accretion of discounts on investments	—	1	144
Changes in operating assets and liabilities:	—		
Prepaid expenses and other current assets	(7,738)	2,478	(1,725)
Other assets	4,884	(2,358)	(1,915)
Accounts payable	6,088	2,562	2,960
Accrued expenses and other current liabilities	(6,881)	1,886	8,914
Operating lease liabilities	(1,501)	(2,238)	(565)
Net cash used in operating activities	(119,894)	(96,592)	(62,417)
Cash flows from investing activities			
Purchase of property and equipment	(362)	(3,370)	(1,030)
Maturities of investments	—	1,150	28,371
Net cash (used in) provided by investing activities	(362)	(2,220)	27,341
Cash flows from financing activities			
Proceeds from issuance of common stock, net of offering costs	—	161,803	—
Proceeds from stock options exercised and purchases under the employee stock purchase plan	1,668	1,995	1,239
Net cash provided by financing activities	1,668	163,798	1,239
Net (decrease) increase in cash, cash equivalents, and restricted cash	(118,588)	64,986	(33,837)
Cash, cash equivalents, and restricted cash at the beginning of the period	177,236	112,250	146,087
Cash, cash equivalents, and restricted cash at the end of the period	$ 58,648	$ 177,236	$ 112,250
Non-cash financing and investing activities:			
Acquisition of operating lease right-of-use assets	$ —	$ 5,971	$ —
Acquisition of property and equipment in accounts payable and accrued liabilities	$ 7	$ —	$ 2,537
Remeasurement of operating lease right-of-use assets and lease liability	$ —	$ 5,668	—
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 58,279	$ 176,866	$ 111,899
Restricted cash	369	370	351
Total cash, cash equivalents and restricted cash	$ 58,648	$ 177,236	$ 112,250

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

Biomea Fusion, Inc.
Notes to 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 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 diabetes and obesity. 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.

Follow-On Offering

On April 3, 2023, the Company issued and sold 5,750,000 shares of common stock, which included 750,000 shares sold pursuant to the exercise of the underwriters' over-allotment option, at a public offering price of $30.00 per share in an underwritten public offering pursuant to a shelf registration on Form S-3. The net proceeds to the Company from the offering were $161.8 million, after deducting underwriting discounts and commissions and offering costs of $10.7 million.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming the Company will continue as a going concern, which assumes the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company believes that based on its current operating plan, its cash, cash equivalents and restricted cash will not enable it to fund its operating expenses and capital expenditure requirements for at least twelve months following the issuance date of the 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 incurred net operating losses and negative cash flows from operations since its inception and had an accumulated deficit of $387.3 million at December 31, 2024. As of December 31, 2024, the Company had cash, cash equivalents, and restricted cash of $58.6 million.

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 above. 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

Basis of Presentation

These financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, the Company evaluates its estimates, including, but not limited to, those related to 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 on its historical experience and also on assumptions that it believes are reasonable; however, actual results could significantly differ from those estimates.

Segments

The Company operates and manages its business as one reportable and operating segment, which is the business of developing covalent small molecule drugs to treat patients with diabetes and obesity. The Company's chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for allocating resources and evaluating financial performance. All long-lived assets are maintained in, and all losses are attributable to, the United States of America.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk, consist primarily of cash, cash equivalents and restricted cash. 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 restricted cash.

Other Risks and Uncertainties

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 potential product candidates, uncertainty of market acceptance of the Company's product candidates, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals or sole source suppliers 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 Accounting Standards Update ("ASU") 2016-13, *Measurement of Credit Losses on Financial Instruments,* on January 1, 2023. The Company's investments have been classified as available-for-sale and carried at estimated fair values and reported in cash equivalents, short-term investments, or long-term investments. Management determines the appropriate classification of the investments at the time they are acquired and evaluates the appropriateness of such classifications at each balance sheet date. Investments with contractual maturities greater than 12 months are considered long-term investments.

For available-for-sale debt securities in an unrealized loss position, the Company first assesses whether it intends to sell, or whether it is more likely than not that it will be required to sell the security before the 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 and comprehensive loss. If neither criteria 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. 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.

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 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 operations and comprehensive loss.

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 in other current assets on the balance sheets.

Property and Equipment, Net

Property and equipment are recorded at cost net of accumulated depreciation. 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 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.

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 years ended December 31, 2024, 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 December 31, 2024, 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 uses the "simplified" method to estimate the expected term. The Company utilizes this method as our stock options qualify as "plain-vanilla" options. 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.

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.

Leases

The Company determines if an arrangement is a lease at inception in accordance with Accounting Standard Codification 842, "Leases" (ASC 842). As of December 31, 2024, the Company's lease population consisted of real estate leases and the Company did not have finance leases.

Operating leases are included in operating lease right-of-use (ROU) 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. As most of 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. Lease incentives are recognized prospectively, on reimbursement, as reduction to the right-of-use asset and lease liabilities 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. 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 12 months.

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.

Recent Accounting Pronouncements - Adopted

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 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 adopted the standard for the fiscal year ending December 31, 2024 and the adoption of the standard did not have an impact to the Company's financial statements. Refer to Note 10 - Segment Reporting for additional disclosures.

Recent Accounting Pronouncements - Not Yet Adopted

In December 2023, the FASB issued Accounting Standards Update 2023-09, *Income Taxes - Improvements to Income Tax Disclosures* (ASU 2023-09) requiring enhancements and further transparency to certain income tax disclosures, most notably the tax rate reconciliation and income taxes paid. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis and retrospective application is permitted. The Company is currently evaluating the impact of the adoption of this standard on the Company's financial statements and related disclosures.

In November 2024, the FASB issued Accounting Standards Update 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* (ASU 2024-03), which requires disaggregated information about certain income statement expense line items on an annual and interim basis. ASU 2024-03 is effective for annual periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted and can be applied prospectively or retrospectively. The Company is evaluating the impact of the adoption of this standard on the Company's financial statements and related disclosures.

Note 3. Fair Value Measurement

The Company applies fair value accounting for all financial assets and liabilities. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs which reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The carrying amount of cash and cash equivalents, prepaid expenses, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of the short-term nature of these instruments.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company classifies money market funds as Level 1 within the fair value hierarchy as the fair value is based on quoted price in active markets. The Company classifies its investments in corporate debt securities, commercial paper and asset backed securities as Level 2 within the fair value hierarchy as the fair value is based on other observable inputs, including broker or dealer quotations or alternative pricing sources. When quoted prices in active markets for identical assets or liabilities are not available, the Company relies on non-binding quotes from its investment managers, which are based on proprietary valuation models of independent pricing services. These models generally use inputs such as observable market data, quoted market prices for similar instruments, or historical pricing trends of a security relative to its peers. To validate the fair value determination provided by its investment managers, the Company reviews the pricing movement in the context of overall market trends and trading information from its investment managers. In addition, the Company assesses the inputs and methods used in determining the fair value in order to determine the classification of securities in the fair value hierarchy. As of December 31, 2024 and 2023, there were no financial instruments classified as Level 3. The Company evaluates transfers between levels at the end of each reporting period and there were no transfers of financial instruments between the fair value measurement levels during the year ended December 31, 2024.

As of December 31, 2024, investments measured and recognized at fair value are as follows (in thousands):

		December 31, 2024			
	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	$ 56,031	$ —	$ —	$ 56,031
Total		$ 56,031	$ —	$ —	$ 56,031

		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 1, 2 and 3 during the year ended December 31, 2024 and 2023. As of December 31, 2024 and 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. There were no investments as of December 31, 2024 and December 31, 2023, as such, no allowance for credit losses has been recognized as of December 31, 2024. During the year ended December 31, 2024 and 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):

	December 31,	
	2024	2023
Laboratory equipment	$ 3,928	$ 3,852
Computer equipment	146	130
Furniture and fixtures	432	409
Leasehold improvements	3,439	3,195
Construction in progress	—	4
Total property and equipment, gross	7,945	7,590
Less: accumulated depreciation	(4,179)	(2,431)
Total property and equipment, net	$ 3,766	$ 5,159

Depreciation expense was approximately $1.7 million, $1.5 million, $0.7 million for the years ended December 31, 2024, 2023 and 2022, respectively.

Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2024	2023
Accrued research and development materials and services	$ 5,947	$ 6,952
Accrued personnel expenses	452	5,956
Accrued professional services	60	443
Other	203	192
Total accrued expenses and other current liabilities	$ 6,662	$ 13,543

Note 5. Capital Structure

Common Stock

As of December 31, 2024 and 2023, the Company was authorized to issue 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 December 31, 2024 and 2023, no dividends have been declared.

The Company had reserved common stock for future issuance as follows:

	December 31,	
	2024	2023
Stock options, issued and outstanding	9,168,745	7,357,607
Stock options, authorized for future issuance	2,680,934	799,485
Employee stock purchase plan, available for future issuance	583,263	451,886
Restricted stock, issued and outstanding	—	111,920
Total	12,432,942	8,720,898

The stock options authorized for future issuance as of December 31, 2023, exclude the 2,000,000 stock options authorized under the 2023 inducement plan shares on November 17, 2023.

Note 6. Stock-Based Compensation

2020 Equity Incentive Plan

The Company adopted the 2020 Equity Incentive Plan (the "2020 Plan") on December 18, 2020. The 2020 Plan reserved 4,327,799 shares of common stock to grant stock-based compensation awards, including stock options and restricted stock awards, to employees and non-employees. As of April 9, 2021, the Company ceased granting awards under the 2020 Plan. However, 2020 Plan awards will remain subject to the terms of the 2020 Plan.

2021 Equity Incentive Plan

In April 2021, the Company adopted the 2021 Equity Incentive Plan (the "2021 Plan"). Options granted under the 2021 Plan expire no later than 10 years from the date of grant. The exercise price of options granted under the 2021 Plan must at least be equal to the fair market value of the Company's common stock on the date of grant. With respect to any participant who owns more than 10% of the voting power of all classes of the Company's outstanding stock, the term of an incentive stock option granted to such participant must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. Employee stock options generally vest $1/16^{th}$ quarterly over four years subject to continued service to the Company.

Subject to adjustment in the case of certain capitalization events as provided in the 2021 Plan, the Company initially reserved 3,370,000 shares of the Company's common stock for issuance pursuant to awards under the 2021 Plan. The 2021 Plan is administered by the Compensation Committee of the Company's Board of Directors. The number of shares of the Company's common stock available for issuance under the 2021 Plan will also include an annual increase 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. As of December 31, 2024, 843,684 shares of common stock remained available for issuance under the 2021 Plan. Effective January 1, 2025, the number of shares of common stock available under the 2021 Plan increased by 1,815,535 shares pursuant to the evergreen provision of the 2021 Plan.

2023 Inducement Plan

On November 17, 2023, the Company's board of directors adopted the 2023 Inducement Equity Plan (Inducement Plan) pursuant to which the Company reserved 2,000,000 shares of common stock, to be used exclusively for grants of equity-based awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan provides for the grant of equity-based awards in the form of non-qualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock unit awards, unrestricted stock awards, dividend equivalent rights or Other Stock Based Awards (as defined in the Inducement Plan). The Inducement Plan was adopted by the board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. As of December 31, 2024, 1,837,250 shares of common stock remained available for issuance under the Inducement Plan.

2021 Employee Stock Purchase Plan

The Company adopted a 2021 Employee Stock Purchase Plan (ESPP) in April 2021. The ESPP enables eligible employees of the Company and designated affiliates to purchase shares of common stock at a discount of 15%. Subject to adjustment in the case of certain capitalization events, a total of 306,000 common shares of the Company were available for purchase at adoption of the ESPP. Pursuant to the ESPP, the annual share increase pursuant to the evergreen provision is determined based on the lesser of (i) 1% 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. As of December 31, 2024, 583,263 shares of common stock remained available for issuance under the ESPP. Effective January 1, 2025, the number of shares of common stock available under the ESPP increased by 363,107 shares pursuant to the evergreen provision of the ESPP.

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 9,816	$ 6,933	$ 4,678
General and administrative	9,278	7,198	5,658
Total stock-based compensation expense	$ 19,094	$ 14,131	$ 10,336

As of December 31, 2024, there was $30.4 million of total unrecognized compensation cost related to stock options, restricted stock awards, and ESPP under the Plans. The unrecognized stock-based compensation cost is expected to be recognized over a weighted-average period of 2.0 years.

Stock Options

The following table summarizes stock option activity:

	Number of Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of December 31, 2023	7,357,607	$ 9.34	8.1	$ 42,071
Granted	2,274,385	13.15		
Exercised	(106,339)	4.86		
Cancelled	(356,908)	13.17		
Balance as of December 31, 2024	9,168,745	$ 10.19	7.6	$ 119
Options exercisable as of December 31, 2024	5,483,731	$ 9.59	7.0	$ 71

The fair value of stock options was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected term in years	6.0	6.0	6.0
Expected volatility	91.0%	79.9%	93.1%
Risk-free interest rate	4.1%	3.8%	3.1%
Dividend yield	—	—	—
Weighted average fair value of options granted	$ 10.04	$ 7.57	$ 5.25

The aggregate intrinsic value of options exercised for the years ended December 31, 2024, 2023, 2022 was $0.8 million, $1.7 million, and $0.4 million, respectively. Intrinsic values are calculated as the difference between the exercise price of the underlying options and the fair value of the common stock on the date of exercise.

Employee Stock Purchase Plan

The fair value of ESPP was estimated using the following weighted-average assumptions:

	Year Ended December 31,		
	2024	2023	2022
Expected term in years	1.3	1.3	1.3
Expected volatility	136.5%	80.9%	95.2%
Risk-free interest rate	4.6%	4.9%	2.5%
Dividend yield	—	—	—

Restricted Stock

The Company granted 824,429 restricted stock awards to employees and non-employees during the fourth quarter of 2020 that vest quarterly over four years. Restricted stock awards are share awards that entitle the holder to receive freely tradeable shares of the Company's common stock. The underlying shares are outstanding as of the issuance date. Any unvested shares are subject to forfeiture in the case that the grantee's service terminates prior to vesting of the restricted stock.

The following table summarizes the restricted stock activity:

	Number of Restricted Stock Awards	Weighted-Average Grant Date Fair Value
Balance, December 31, 2023	111,920	$ 4.06
Granted	—	—
Released	(109,356)	4.06
Forfeited	(2,564)	3.96
Balance, December 31, 2024	—	$ —

Note 7. Taxes

Biomea Fusion is subject to U.S. federal and state income taxes as a corporation. There was zero income tax expense for the years ended December 31, 2024, 2023 and 2022. The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate:

	Year Ended December 31,		
	2024	2023	2022
Federal statutory income tax rate	21.0%	21.0%	21.0%
State income tax rate	6.0%	11.1%	0.5%
Tax credits	2.9%	4.1%	1.1%
Stock-based compensation	(1.0)%	(1.0)%	(1.1)%
Change in valuation allowance	(28.8)%	(34.6)%	(21.5)%
Other	(0.1)%	(0.6)%	—
Effective income tax rate	0.0%	0.0%	0.0%

Deferred tax assets and liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 48,853	$ 31,469
Capitalized research and development	41,642	25,055
Accrued liabilities and reserves	—	1,562
Stock-based compensation	7,830	4,602
Intangible assets	1,927	1,607
Operating lease liabilities	2,431	2,857
Research and development credits	13,222	7,400
Gross deferred tax assets	115,905	74,552
Valuation allowance	(113,866)	(71,512)
Total deferred tax assets	2,039	3,040
Deferred tax liabilities:		
Property and equipment	(139)	(344)
Operating lease right-of-use assets	(1,900)	(2,696)
Total deferred tax liabilities	(2,039)	(3,040)
Net deferred tax assets	$ —	$ —

The provisions of ASC Topic 740, *Accounting for Income Taxes* (ASC 740), require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. For the years

ended December 31, 2024 and 2023, based on all available objective evidence, including the existence of cumulative losses, the Company determined that it was not more likely than not that the net deferred tax assets were fully realizable. Accordingly, the Company established a full valuation allowance against its deferred tax assets. The Company intends to maintain a full valuation allowance on net deferred tax assets until sufficient positive evidence exists to support reversal of the valuation allowance. The Company's valuation allowance increased by $42.4 million during the year ended December 31, 2024, primarily because of an increase to the Company's credits, stock compensation and capitalization of research and experimental expenses. In addition the Company was granted approval from the California Franchise Tax Board to utilize an alternative apportionment method to calculate the Company's California net operating losses which increased the Company's state net operating loss carryforward. The Company's valuation allowance increased by $44.2 million during the year ended December 31, 2023, primarily because of an increase to the Company's net operating losses, credits, stock compensation and the capitalization of research and development expenses.

At December 31, 2024, the Company had net operating loss carryforwards available to reduce future taxable income, if any, for federal and state income tax purposes of approximately $128.7 million and $313.4 million, respectively. The federal net operating loss carryforwards at December 31, 2024 can be carried forward indefinitely, subject to an annual limitation of 80% of taxable income. The state net operating loss carryforward are subject to expiration in various tax years.

At December 31, 2024, the Company also had federal and California research and development tax credit carryforwards of $12.4 million and $5.6 million, respectively, available to offset future income tax, if any. The federal credit carryforwards begins expiring in 2040, and the California credits can be carried forward indefinitely.

Under Section 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change attributes, such as research tax credits, to offset its post-change income may be limited. In general, an "ownership change" will occur if there is a cumulative change in the Company's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Therefore, certain of the Company's carryforward tax attributes may be subject to an annual limitation regarding their utilization against taxable income in future periods. The Company has performed a Section 382 study and has concluded that ownership changes have occurred. As a result, the federal and state NOL carryforwards and tax credit carryforwards may be subject to annual limitations before being applied to reduce future income tax liabilities.

Uncertain Tax Positions

The Company adopted the provisions of ASC 740, which requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. It also provides guidance on the recognition, measurement, classification and interest and penalties related to uncertain tax positions.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Beginning balance	$ 2,216	$ 624	$ 112
Increases for tax provisions related to prior year	84	227	133
Decreases for tax provision related to prior year	(104)	—	—
Increases for tax provisions related to current year	1,718	1,365	379
Ending balance	$ 3,914	$ 2,216	$ 624

The unrecognized tax benefits, if recognized, would not affect the effective income tax rate due to the valuation allowance that currently offsets deferred tax assets. Interest and penalties were zero. The Company does not expect the unrecognized tax benefits to change significantly over the next twelve months.

The Company files federal and state income tax returns. All periods since inception are subject to examination by federal and state authorities, where applicable. There are currently no pending income tax examinations.

Note 8. Commitments and Contingencies

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 sub-lease agreement for office space located at 900 Middlefield Road, 4th Floor, Redwood City, California, which commenced in January 2023 and expires in July 2025. In connection with the sub-lease, the Company made a security deposit of $2.1 million which is included in prepaid expenses and other current assets on the balance sheet at December 31, 2024. 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 lease for additional lab space located at 1585 Industrial Road, 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 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 December 31, 2024. As the term of the 1599 lease was extended, this did not result in a separate contract, accordingly, 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 lease included a lease incentive in the form of a tenant improvement allowance of up to $1.5 million.

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%. The Company has determined that impact of the remeasurement to be immaterial.

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

	December 31,		
	2024	2023	2022
Cash paid for operating lease liabilities	$ 3,794	$ 2,469	$ 700
Operating lease costs	3,993	4,099	711
Short-term lease costs	—	—	2,921
Variable lease costs	995	1,326	357

Supplemental balance sheet information related to operating leases is as follows:

	December 31,		
	2024	2023	2022
Weighted average remaining lease term	6.0	5.6	3.3
Weighted average discount rate	11.4%	10.9%	5.4%

Maturities of lease liabilities as of December 31, 2024 were as follows (in thousands):

Year Ending December 31,	Operating Lease Commitments
2025	2,903
2026	1,526
2027	1,443
2028	1,474
2029	1,518
Thereafter	3,308
Total undiscounted lease payments	12,172
Less: Present value adjustments	(3,401)
Total operating lease liabilities	$ 8,771
Operating lease liabilities, current	2,079
Operating lease liabilities, non-current	6,692
Total operating lease liabilities	$ 8,771

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the years ended December 31, 2024, 2023, and 2022, and to the best of its knowledge, no material legal proceedings are currently pending or threatened.

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

The following table sets forth the computation of the basic and diluted net loss per share (in thousands except share and per share data):

	Year Ended December 31,		
	2024	2023	2022
Numerator:			
Net loss	$ (138,426)	$ (117,255)	$ (81,828)
Denominator:			
Weighted-average common shares outstanding, basic and diluted	36,105,671	34,106,923	29,271,777
Net loss per share, basic and diluted	$ (3.83)	$ (3.44)	$ (2.80)

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share for all periods as the inclusion of all common stock equivalents outstanding would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	December 31,		
	2024	2023	2022
Stock options, issued and outstanding	9,168,745	7,357,607	5,341,975
Estimated shares issuable under the ESPP	16,717	31,645	17,655
Restricted stock, issued and outstanding	—	111,920	292,236
Total	9,185,462	7,501,172	5,651,866

Note 10. Segment Reporting

The Company operates and manages its business as one reportable and operating segment, which is the business of developing covalent small molecule drugs to treat patients with 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 to, the United States of America.

Below is the breakdown of the Company's research and development and general and administrative expenses for the years ended December 31, 2024, 2023 and 2022 (in thousands):

	Year Ended December 31,		
	2024	2023	2022
External costs			
Clinical research organization expenses			
COVALENT - 101	$ 2,386	$ 7,380	$ 1,793
COVALENT - 102	205	3,415	834
COVALENT - 103	3,710	2,007	—
COVALENT - 111	22,489	14,670	3,343
COVALENT - 112	5,048	1,306	—
Other clinical related expenses	14,262	7,320	3,469
Preclinical activities related expenses	11,815	10,165	13,095
Expenses related to manufacturing of clinical and research material	7,262	13,237	12,619
Other external costs	10,948	5,528	2,693
Internal costs:			
Personnel-related expenses (including stock-based compensation)	31,856	28,838	19,361
Facilities and other allocated expenses	8,104	8,680	5,506
Total research and development expenses	$ 118,085	$ 102,546	$ 62,713

	Year Ended December 31,		
	2024	2023	2022
External costs	$ 6,488	$ 5,007	$ 3,991
Internal costs:			
Personnel-related expenses (including stock-based compensation)	17,768	16,466	14,110
Facilities and other allocated expenses	1,729	2,116	2,820
Total general and administrative expenses	$ 25,985	$ 23,589	$ 20,921

Reconciliation of segment loss from operations to net loss:

	Year Ended December 31,		
	2024	2023	2022
Loss from operations of reportable segments	$ (144,070)	$ (126,135)	$ (83,634)
Interest and other income, net	5,644	8,880	1,806
Net loss	$ (138,426)	$ (117,255)	$ (81,828)

Note 11. Selected Quarterly Financial Data (Unaudited)

The following tables provide the selected quarterly financial data for the years ended December 31, 2024 and 2023 (in thousands, except share and per share data):

	2024			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 33,776	$ 31,825	$ 27,244	$ 25,240
General and administrative	7,283	7,073	6,795	$ 4,834
Total operating expenses	41,059	38,898	34,039	30,074
Loss from operations	(41,059)	(38,898)	(34,039)	(30,074)
Interest and other income, net	1,998	1,622	1,252	$ 772
Net loss	$ (39,061)	$ (37,276)	$ (32,787)	$ (29,302)
Net loss per share, basic and diluted	$ (1.09)	$ (1.03)	$ (0.91)	$ (0.81)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	35,890,370	36,043,561	36,220,736	36,265,001

	2023			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 24,395	$ 21,938	$ 25,347	$ 30,866
General and administrative	5,636	5,719	5,772	6,462
Total operating expenses	30,031	27,657	31,119	37,328
Loss from operations	(30,031)	(27,657)	(31,119)	(37,328)
Interest and other income, net	980	2,766	2,690	2,444
Net loss	$ (29,051)	$ (24,891)	$ (28,429)	$ (34,884)
Net loss per share, basic and diluted	$ (0.98)	$ (0.70)	$ (0.80)	$ (0.98)
Weighted-average number of common shares used to compute basic and diluted net loss per common share	29,586,468	35,348,293	35,653,988	35,754,165

Note 12. Subsequent Events

None.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our 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 Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our 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 disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, 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 and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no other changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act during the quarter ended December 31, 2024, that materially affected, or are 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.

Item 9B. Other Information

(a) None.

(b) During the quarter ended December 31, 2024, none of the Company's directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a plan or other arrangement intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any non-Rule 10b5-1 trading arrangements under the Exchange Act.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer and principal financial and accounting officer, or persons performing similar functions. A current copy of the code is posted on the Governance section of our website, which is located at investors.biomeafusion.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for our principal executive officer, principal financial and accounting officer, principal accounting officer, or persons performing similar functions, or any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

We have adopted an insider trading policy that applies to our director, officers, employees and selected consultants. We believe that our insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our insider trading policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accountant Fees and Services

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) List the following documents filed as a part of the report:

1. Financial Statements

   The financial statements filed as part of this Annual Report on Form 10-K are listed in the "Index to Financial Statements" under Part II, Item 8 of this Annual Report on Form 10-K.

2. Financial Statement Schedules

   Financial statement schedules have been omitted in this Annual Report on Form 10-K because they are not applicable, not required under the instructions, or the information requested is set forth in the financial statements or related notes thereto.

3. Exhibits

   The list of exhibits filed with this Annual Report on Form 10-K is set forth in the Exhibit Index preceding the signature page and is incorporated herein by reference or filed with this Annual Report on Form 10-K, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Item 16. Form 10-K Summary

Not applicable.

Exhibit Index

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
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	
10.1	Secondary Sublease, dated August 18, 2020, by and between the Registrant and Interactive Memories, Inc. d/b/a Mixbook	S-1/A	4/12/2021	10.2	
10.2	Form of Indemnification and Advancement Agreement for Directors and Officers	10-Q	5/16/2022	10.1	
10.3	Sublease Agreement between the Registrant and Box, Inc., dated September 7, 2022	8-K	9/9/2022	10.1	

10.4	Equity Distribution Agreement, dated November 25, 2022, by and between the Company and Piper Sandler & Co.	8-K	11/25/2022	1.1
10.5(a)#	Form Executive Change in Control and Severance Agreement	S-1/A	4/12/2021	10.11
10.5(b)#	Form of First Amendment to Change in Control and Severance Agreement	8-K	4/22/2022	99.1
10.5(c)#	Updated Form Executive Change in Control and Severance Agreement adopted November 13, 2023	10-K	3/24/2024	10.5(C)
10.6(a)#	2020 Equity Incentive Plan	S-1	3/26/2021	10.3(a)
10.6(b)#	Form of Stock Option Agreement under 2020 Equity Incentive Plan	S-1	3/26/2021	10.3(b)
10.7(a)#	2021 Incentive Award Plan	S-1/A	4/12/2021	10.4(a)
10.7(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Incentive Award Plan	S-1/A	4/12/2021	10.4(b)
10.7(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2021 Incentive Award Plan	S-1/A	4/12/2021	10.4(c)
10.7(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Incentive Award Plan	S-1/A	4/12/2021	10.4(d)
10.8#	Employee Stock Purchase Plan	S-1/A	4/12/2021	10.5
10.9#	Employment Offer Letter Agreement by and between the Registrant and Thomas Butler	S-1	3/26/2021	10.6
10.10#	Employment Offer Letter Agreement by and between the Registrant and Ramses Erdtmann	S-1	3/26/2021	10.7
10.11#	Employment Offer Letter Agreement by and between the Registrant and Franco Valle	10-Q	8/11/2021	10.2
10.12#	Employment Offer Letter Agreement by and between the Registrant and Juan Pablo Frias	10-Q	5/2/2024	10.1
10.13#	Non-Employee Director Compensation Program	S-1/A	4/12/2021	10.9
10.14(a)#	2023 Inducement Plan	S-8	1/5/2024	99.3(a)
10.14(b)#	Form of Non-Qualified Stock Option Agreement under the 2023 Inducement Plan	S-8	1/5/2024	99.3(b)

10.14(c)#	Form of Restricted Stock Award Agreement under the 2023 Inducement Plan	S-8	1/5/2024	99.3(c)	
10.14(d)#	Form of Restricted Stock Unit Agreement under the 2023 Inducement Plan	S-8	1/5/2024	99.3(d)	
19.1	Insider Trading Policy				X
21.1	Subsidiaries of the Registrant				X
23.1	Consent of Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (included on signature page to this Annual Report on Form 10-K)				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
97.1	Biomea Fusion, Inc.'s Compensation Recovery Policy				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

# Indicates a management compensation plan, contract or arrangement

* The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the SEC and are not to be incorporated by reference into any filing of the Registrant under the Securities Act or the Exchange Act, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Biomea Fusion, Inc.

Date: March 31, 2025 By: /s/ Michael J.M. Hitchcock
Interim Chief Executive Officer, Director
(Principal Executive Officer)

Date: March 31, 2025 By: /s/ Rainer Erdtmann
Chief Operating Officer, Director
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael J.M. Hitchcock as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Michael J.M. Hitchcock Michael J.M. Hitchcock	Interim Chief Executive Officer, Director (Principal Executive Officer)	March 31, 2025
/s/ Rainer Erdtmann Rainer Erdtmann	Chief Operating Officer, Director (Principal Financial and Accounting Officer)	March 31, 2025
/s/ Eric Aguiar, M.D. Eric Aguiar, M.D.	Director	March 31, 2025
/s/ Bihua Chen Bihua Chen	Director	March 31, 2025
/s/ Sumita Ray, J.D. Sumita Ray, J.D.	Director	March 31, 2025
/s/ Elizabeth Faust, Ph.D. Elizabeth Faust, Ph.D.	Director	March 31, 2025

Exhibit 19.1

BIOMEA FUSION, INC.

INSIDER TRADING POLICY

This memorandum sets forth the policy of Biomea Fusion, Inc. and its subsidiaries, if any (collectively, the "Company"), regarding trading in the Company's securities as described below and the disclosure of information concerning the Company. This Insider Trading Policy (the "Insider Trading Policy") is designed to prevent the misuse of material nonpublic information, insider trading in securities or the appearance of impropriety, to satisfy the Company's obligation to reasonably supervise the activities of Company personnel, and to help Company personnel avoid the severe consequences associated with violations of insider trading laws. It is your obligation to understand and comply with this Insider Trading Policy. Our board of directors has approved this policy and appointed the principal executive officer (with their designees, the "Compliance Officer") to administer the policy and to be available to answer your questions.

PART I. OVERVIEW

A. To Whom Does this Insider Trading Policy Apply?

This Insider Trading Policy is applicable to the Company's directors, officers, employees and selected consultants and applies to any and all transactions by such persons and their Affiliated Persons (as defined below) in the Company's securities, including its common stock, options to purchase common stock, any other type of securities that the Company may issue (such as restricted stock units, preferred stock, convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities.

This Insider Trading Policy, including, if applicable, the Trading Procedures contained herein, also applies to the following persons (collectively, these persons and entities are referred to as "Affiliated Persons"):

- your "Family Members" ("Family Members" are (a) your spouse, or domestic partner, children, stepchildren, parents, grandparents, siblings and in-laws who reside in the same household as you, (b) your children or your spouse's children who do not reside in the same household as you but are financially dependent on you, (c) any of your other family members who do not reside in your household but whose transactions are directed by you, and (d) any other individual over whose account you have control and to whose financial support you materially contribute. (Materially contributing to financial support would include, for example, paying an individual's rent but not just a phone bill.));
- all trusts, family partnerships and other types of entities formed for your benefit or for the benefit of a member of your family and over which you have the ability to influence or direct investment decisions concerning securities;
- all persons who execute trades on your behalf; and
- all investment funds, trusts, retirement plans, partnerships, corporations and other types of entities over which you have the ability to influence or direct investment decisions concerning securities; provided, however, that the Trading Procedures do not apply to any such entity that engages in the investment of securities in the ordinary course of its business (e.g., an investment fund or partnership) if such entity has established its own insider trading controls and procedures in compliance with applicable securities laws and an Insider (or an affiliated entity) has represented to the Company that such Insider's affiliated entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with applicable securities laws; and (c) are aware such securities laws prohibit any person or entity who has material, nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

You are responsible for ensuring compliance with this Insider Trading Policy, including the Trading Procedures contained herein, if applicable, by all of your Affiliated Persons.

Special Procedures for Persons with Regular Access to Inside Information:

Members of our Board and our executive officers are deemed to have access to all "inside information" under the insider trading laws. Other officers, employees and consultants may also require regular access to "inside information" in performing their work. For this reason and for their protection, additional trading procedures apply to these directors, officers, employees and consultants. We will notify all members of the Board, officers and designated employees and consultants (collectively, and solely for

the purpose of this Insider Trading Policy, "Insiders") that they are subject to these additional trading procedures (the "Trading Procedures"), which are set forth in Part II of this memorandum. All Insiders must comply with these Trading Procedures.

These Trading Procedures may from time to time establish trading blackout period restrictions, trading window periods, and pre-clearance requirements. Insiders covered by the Trading Procedures will be restricted from trading in the Company's securities during blackout periods. Additionally, Insiders will be required to pre-clear all transactions by such Insiders and their Affiliated Persons in the Company's securities. You will be notified if you are an Insider and required to comply with the Trading Procedures.

Post-Termination Responsibilities:

In the event that you leave the Company for any reason, this Insider Trading Policy, including, if applicable, the Trading Procedures contained herein, will continue to apply to you and your Affiliated Persons until the close of trading on the first trading day after any material nonpublic information known to you has become public or is no longer material.

B. What is Prohibited by this Insider Trading Policy?

It is generally illegal for you to trade in the securities of the Company, whether for your account or for the account of another, while in the possession of material, nonpublic information about the Company. It is also generally illegal for you to disclose material, nonpublic information about the Company to others who may trade on the basis of that information. These illegal activities are commonly referred to as "*insider trading*."

Prohibition on Trading in Company Securities

When you know or are in possession of material, nonpublic information about the Company, whether positive or negative, you are prohibited from the following activities:

- trading (whether for your account of for the account of another) in the Company's securities, which includes common stock, options to purchase common stock, any other type of securities that the Company may issue (such as preferred stock, convertible debentures, warrants, exchange-traded options or other derivative securities), and any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities, except for trades made pursuant to plans approved by the Compliance Officer in accordance with this policy that are intended to comply with Rule 10b5-1 under the Exchange Act;
- giving trading advice of any kind about the Company; and
- disclosing such material, nonpublic information about the Company, whether positive or negative, to anyone else (commonly known as "*tipping*").

The prohibitions on trading under this Insider Trading Policy do *not* apply to:

(1) an *exercise* of an employee stock option when payment of the exercise price is made solely in cash to the Company; or

(2) the *withholding* by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

The prohibitions on trading under this Insider Trading Policy *do* apply, however, to:

(1) the *sale* of Company securities upon or after the exercise of an employee stock option;

(2) the *use* of outstanding Company securities to pay part or all of the exercise price of an option; and

(3) any *sale* of stock as part of a broker-assisted cashless exercise of an option or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

These prohibitions continue whenever and for as long as you know or are in possession of material, nonpublic information. Remember, anyone scrutinizing your transactions will be doing so after the fact, with the benefit of hindsight. As a practical matter, before engaging in any transaction, you should carefully consider even the appearance of improper insider trading and how enforcement authorities and others might view the transaction in hindsight.

Prohibition on Trading in Securities of Other Companies

Whenever, during the course of your service to or employment by the Company, you become aware of material nonpublic information about another company (1) with which the Company has an existing business relationship, including but not limited to, the Company's distributors, vendors, customers or suppliers or collaboration, marketing, research, development or licensing partners, or (2) with which the Company is in active discussions concerning a potential transaction or business relationship, neither you nor your Affiliated Persons may trade in any securities of that company, give trading advice about that company, tip or disclose that information, pass it on to others or engage in any other action to take advantage of that information. If your work regularly involves handling or discussing confidential information of companies in either of the foregoing categories, you should consult with the Compliance Officer before trading in any of those company's securities.

Additionally, if you believe you may be in possession of nonpublic information about the Company that could potentially have a material effect on the stock price of a company with which the Company does not have an existing business relationship or with which the Company is not discussing a potential transaction or business relationship, you should exercise caution when trading in the securities of that company because the U.S. Securities and Exchange Commission (the "SEC") has successfully brought an insider trading claim against an insider in those circumstances.

C. What is Material, Nonpublic Information?

This Insider Trading Policy prohibits you from trading in the Company's securities if you are in possession of information about the Company that is both "*material*" and "*nonpublic*." If you have a question whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer.

"Material" Information

Information about the Company or any other company is "material" if it could reasonably be expected to affect the investment or voting decisions of a stockholder or potential investor, or if the disclosure of the information could reasonably be expected to significantly alter the total mix of information in the marketplace about the Company or any other company. In simple terms, material information is any type of information that would influence a reasonable investor to *buy or sell* a stock, bond, future or other security, or could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following items are examples of the types of information that should be considered carefully to determine whether they are material:

- program developments, regulatory or clinical status or updates, including communications with regulatory authorities, prior to issuance of a press release or public update;
- significant developments regarding collaborations, licenses, products, customers, suppliers, orders, contracts or financing sources (e.g., the acquisition or loss of a contract);
- potential collaboration discussions or information about an unannounced new collaboration, financing or other similar deals;
- projections of future earnings or losses, or other earnings guidance;
- earnings or revenue that are inconsistent with the consensus expectations of the investment community;
- potential restatements of the Company's financial statements, changes in auditors or auditor notification that the Company may no longer rely on an auditor's audit report;
- pending or proposed corporate mergers, acquisitions, tender offers, joint ventures or dispositions of significant assets;
- changes in senior management or the Board of Directors;
- significant actual or threatened litigation or governmental investigations or major developments in such matters;
- cybersecurity risks and incidents, including the discovery of significant vulnerabilities or breaches;
- changes in dividend policy, declarations of stock splits, or public or private sales of additional securities;
- potential defaults under the Company's credit agreements or indentures, or the existence of material liquidity deficiencies; and
- bankruptcies or receiverships.

By including the list of examples above, the Company does not mean to imply that each of these items above is per se material or that there are no other items that could be deemed material. The information and events on this list still require determinations as to their materiality (although some determinations will be reached more easily than others). For example, certain developments regarding a company's programs or contracts may clearly be material; yet that does not mean that all product developments or contracts will be material. This demonstrates why no "bright-line" standard or list of items can adequately address the range of situations that may arise. Furthermore, the Company cannot create an exhaustive list of events and information that have a higher probability of being considered material.

The SEC has stated that there is no fixed quantitative threshold amount for determining materiality, and that even very small quantitative changes can be qualitatively material if they would result in a movement in the price of the Company's securities.

"Nonpublic" Information

Material information is "nonpublic" if it has not been disseminated in a manner making it available to investors generally. To show that information is public, it is necessary to point to some fact that establishes that the information has become publicly available, such as the filing of a report with the SEC, the distribution of a press release, publishing the information on our website or posting on social media if those are regular ways we communicate with investors, disclosure in a scientific meeting or congress, or by other means that are reasonably designed to provide broad public access. Before a person who possesses material, nonpublic information can trade, there also must be adequate time for the market as a whole to absorb the information that has been disclosed. For the purposes of this Insider Trading Policy, information will be considered public after the close of trading on the first full trading day following the Company's public release of the information.

For example, if the Company announces material nonpublic information of which you are aware before trading begins on a Tuesday, the first time you can buy or sell Company securities is the opening of the market on Wednesday. However, if the Company announces this material information after trading begins on that Tuesday, the first time that you can buy or sell Company securities is the opening of the market on Thursday.

D. What are the Penalties for Insider Trading and Noncompliance with this Insider Trading Policy?

Both the SEC and the national securities exchanges, through the Financial Industry Regulatory Authority ("FINRA"), investigate and are very effective at detecting insider trading. The SEC, together with the U.S. Attorneys, pursue insider trading violations vigorously. For instance, cases have been successfully prosecuted against trading by employees in foreign accounts, trading by family members and friends, and trading involving only a small number of shares.

The penalties for violating rules against insider trading or tipping rules can be severe and include:

- forfeiting any profit gained or loss avoided by the trading;
- payment of the loss suffered by the persons who, contemporaneously with the purchase or sale of securities that are subject of such violation, have purchased or sold, as applicable, securities of the same class;
- payment of criminal penalties of up to $5,000,000;
- payment of civil penalties of up to three times the profit made or loss avoided; and
- imprisonment for up to 20 years.

The Company and/or the supervisors of the person engaged in insider trading may also be required to pay civil penalties or fines of $2.5 million or more, up to three times the profit made or loss avoided, as well as criminal penalties of up to $25,000,000, and could under certain circumstances be subject to private lawsuits.

Violation of this Insider Trading Policy or any federal or state insider trading laws may subject the person violating such policy or laws to disciplinary action by the Company up to and including termination of your employment or other relationship with the Company. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether this Insider Trading Policy has been violated. The Company may determine that specific conduct violates this Insider Trading Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

E. How Do You Report a Violation of this Insider Trading Policy?

If you have a question about this Insider Trading Policy, including whether certain information you are aware of is material or has been made public, you should consult with the Compliance Officer. In addition, if you violate this Insider Trading Policy or

any federal or state laws governing insider trading, or know of any such violation by any director, officer or employee of the Company, you should report the violation immediately to the Compliance Officer.

PART II. TRADING PROCEDURES

A. Special Trading Restrictions Applicable to Insiders

In addition to needing to comply with the restrictions on trading in Company securities set forth above, Insiders and their Affiliated Persons are subject to the following special trading restrictions:

1. *Prohibited Transactions*

- **No Short Sales**. No Insider may at any time sell any securities of the Company that are not owned by such Insider at the time of the sale (a "short sale").
- **No Purchases or Sales of Derivative Securities or Hedging Transactions**. No Insider may buy or sell puts, calls, other derivative securities of the Company or any derivative securities that provide the economic equivalent of ownership of any of the Company's securities or an opportunity, direct or indirect, to profit from any change in the value of the Company's securities or engage in any other hedging transaction with respect to the Company's securities, at any time.
- **No Company Securities Subject to Margin Calls**. No Insider may use the Company's securities as collateral in a margin account.
- **No Pledges**. No Insider may pledge Company securities as collateral for a loan (or modify an existing pledge).

2. Gifts.

No Insider may give, donate or make any other transfer of Company securities without consideration (e.g., a gift or a limited partner distribution, in the case of a fund) during a period when the Insider is not permitted to trade unless the donee agrees not to sell the shares until such time as the Insider can sell. In addition to charitable donations or gifts to family members, friends, trusts or others, this prohibition applies to distributions to limited partners by limited partnerships that are subject to this Insider Trading Policy. Making a gift shall be considered trading in securities for purposes of the pre-clearance procedures and post-trade reporting procedures set forth below.

3. No Trading During Retirement Plan Blackout Periods.

If the Company adopts a policy to allow ownership of Company stock in the Company's 401(k) or other retirement plan, then no Insider may trade in any Company securities, which were acquired in connection with such Insider's service or employment with the Company, during a retirement plan "blackout period" except as specifically permitted below. A blackout period includes any period of more than three (3) consecutive business days during which at least fifty percent (50%) of all participants and beneficiaries under all of the individual account plans maintained by the Company and members of its controlled group are prohibited from trading in Company securities through their plan accounts. Insiders will receive advance notice of any such blackout period from the Compliance Officer or his or her designee.

4. Special Blackout Periods.

There are times when the Company or certain of its directors, senior management or other team members may be aware of a material, nonpublic development. Although an Insider may not know the specifics of such development, if an Insider engages in a trade before such development is disclosed to the public or resolved, such Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute. In addition, a trade by an Insider during such period could result in adverse publicity for the Company.

Therefore, Insiders may not trade in the Company's securities if they are notified that the trading window is closed because of the existence of a material, nonpublic development. The Compliance Officer or his or her designee will subsequently notify the Insiders once the material nonpublic development is disclosed to the public or resolved and that, as a result, the trading window is again open. While the Compliance Officer will undertake reasonable efforts to notify the Insiders that material, nonpublic events have developed, or are soon likely to develop, it is each Insider's individual duty to ensure that they do not make any trade in Company securities when material, nonpublic information exists, regardless of whether such Insider is aware of such development.

B. Pre-Clearance Procedures

No Insider may trade in Company securities, even during an open trading window, unless the trade has been approved by the Compliance Officer in accordance with the procedures set forth below. The Compliance Officer will review and either approve or prohibit all proposed trades by Insiders in accordance with the procedures set forth below. In reviewing trading requests, the Compliance Officer may consult with the Company's other officers and/or outside legal counsel and will receive approval for his or her own trades from such other officers.

1. Procedures. No Insider may trade in Company securities until:

- The Insider has notified the Compliance Officer of the amount and nature of the proposed trade(s) using the Stock Transaction Request form attached to this Insider Trading Policy. In order to provide adequate time for the preparation of any required reports under Section 16 of the Exchange Act, a Stock Transaction Request form should, if practicable, be received by the Compliance Officer at least two (2) business days prior to the intended trade date;
- The Insider has certified to the Compliance Officer in writing prior to the proposed trade(s) that the Insider is not in possession of material, nonpublic information concerning the Company;
- If the Insider is an executive officer or director, the Insider has informed the Compliance Officer, using the Stock Transaction Request form attached hereto, whether, to the Insider's best knowledge, (a) the Insider has (or is deemed to have) engaged in any opposite way transactions within the previous six months that were not exempt from Section 16(b) of the Exchange Act and (b) if the transaction involves a sale by an "affiliate" of the Company or of "restricted securities" (as such terms are defined under Rule 144 under the Securities Act of 1933, as amended ("Rule 144")), whether the transaction meets all of the applicable conditions of Rule 144; and
- The Compliance Officer or his or her designee has approved the trade(s) and has certified such approval in writing. Such certification may be made via digitally-signed electronic mail.

The Compliance Officer does not assume the responsibility for, and approval from the Compliance Officer does not protect the Insider from, the consequences of prohibited insider trading.

2. Additional Information.

Insiders shall provide to the Compliance Officer any documentation reasonably requested by him or her in furtherance of the foregoing procedures. Any failure to provide such requested information will be grounds for denial of approval by the Compliance Officer.

3. Notification of Brokers of Insider Status

Insiders who are required to file reports under Section 16 of the Exchange Act shall inform their broker-dealers that (a) the Insider is subject to Section 16; (b) the broker shall confirm that any trade by the Insider or any of their affiliates has been precleared by the Company; and (c) the broker is expected to provide transaction information to the Insider and/or Compliance Officer on the date of a trade.

4. No Obligation to Approve Trades.

The existence of the foregoing approval procedures does not in any way obligate the Compliance Officer to approve any trade requested by an Insider. The Compliance Officer may reject any trading request at his or her sole discretion.

From time to time, an event may occur that is material to the Company and is known by only a few directors or executives. Insiders may not trade in Company securities if they are notified by the Compliance Officer that a proposed trade has not been cleared because of the existence of a material, nonpublic development. Even if that particular Insider is not aware of the material, nonpublic development involving the Company, if any Insider engages in a trade before a material, nonpublic development is disclosed to the public or resolved, the Insider and the Company might be exposed to a charge of insider trading that could be costly and difficult to refute even if the Insider was unaware of the development. So long as the event remains material and nonpublic, the Compliance Officer may determine not to approve any transactions in the Company's securities. The Compliance Officer will subsequently notify the Insider once the material, nonpublic development is disclosed to the public or resolved. If an Insider requests clearance to trade in the Company's securities during the pendency of such an event, the Compliance Officer may reject the trading request without disclosing the reason.

5. Completion of Trades.

After receiving written clearance to engage in a trade signed by the Compliance Officer, an Insider must complete the proposed trade within two (2) business days or make a new trading request. Even if an Insider has received clearance, the Insider may not engage in a trade if (i) such clearance has been rescinded by the Compliance Officer, (ii) the Insider has otherwise received notice that the trading window has closed or (iii) the Insider has or acquires material nonpublic information.

6. Post-Trade Reporting.

Any transactions in the Company's securities by an Insider (including transactions effected pursuant to a Rule 10b5-1 Plan (as defined below)) must be reported to the Compliance Officer by completing the "Confirmation of Transaction" section of the Stock Transaction Request form attached to this Insider Trading Policy on the same day in which such a transaction occurs. Each report an Insider makes to the Compliance Officer should include the date of the transaction, quantity of shares, price, the name of the broker-dealer through which the transaction was effected and whether the trade was made pursuant to a Rule 10b5-1 Plan. This reporting requirement may be satisfied by sending (or having such Insider's broker send) duplicate confirmations of trades to the Compliance Officer if such information is received by the Compliance Officer on or before the required date. Compliance by directors and executive officers with this provision is imperative given the requirement of Section 16 of the Exchange Act that these persons generally must report changes in ownership of Company securities within two (2) business days. The sanctions for noncompliance with this reporting deadline include mandatory disclosure in the Company's proxy statement for the next annual meeting of stockholders, as well as possible civil or criminal sanctions for chronic or egregious violators.

C. Exemptions

1. Pre-Approved Rule 10b5-1 Plan.

Transactions effected pursuant to an approved Rule 10b5-1 Plan (as defined below) will not be subject to the Company's trading windows (if any), retirement plan blackout periods (if any) or pre-clearance procedures, and Insiders are not required to complete a Stock Transaction Request form for such transactions. Rule 10b5-1 of the Exchange Act provides an affirmative defense from insider trading liability under the federal securities laws for trading plans, arrangements or instructions that meet certain requirements. A trading plan, arrangement or instruction that meets the requirements of Rule 10b5-1 (a "Rule 10b5-1 Plan") enables Insiders to establish arrangements to trade in Company securities outside of the Company's trading windows, even when in possession of material, nonpublic information.

The Company has adopted a separate Rule 10b5-1 Trading Plan Policy that sets forth the requirements for putting in place a Rule 10b5-1 Plan with respect to the Company's securities.

2. Employee Benefit Plans.

Exercise of Stock Options. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the exercise of an option to purchase securities of the Company when payment of the exercise price is made to the Company solely in cash, and the purchased securities are held, not sold. In addition, the securities acquired upon the exercise of an option to purchase Company securities are subject to all of the requirements of this Insider Trading Policy, including the Trading Procedures contained herein. Moreover, the Trading Procedures apply to the use of outstanding Company securities to pay part or all of the exercise price of an option, any net option exercise, any exercise of a stock appreciation right, share withholding, any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option. For directors and executive officers subject to the requirements of Section 16 of the Exchange Act, the exercise of an option to purchase securities of the Company (and any subsequent sale) each triggers the obligation to file a Form 4 within two days. For this reason, Insiders must comply with the post-trade reporting requirement described in Section C above for any such transaction.

Tax Withholding on Restricted Stock/Units. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to the withholding by the Company of shares of stock upon vesting of restricted stock or upon settlement of restricted stock units to satisfy applicable tax withholding requirements if (a) such withholding is required by the applicable plan or award agreement or (b) the election to exercise such tax withholding right was made by the Insider in compliance with the Trading Procedures.

Employee Stock Purchase Plan. The trading prohibitions and restrictions set forth in the Trading Procedures do not apply to periodic wage withholding contributions by the Company or employees of the Company which are used to purchase the Company's securities pursuant to the employees' advance instructions under the Company's 2021 Employee Stock Purchase Plan. However, no Insider may: (a) elect to participate in the plan or alter his or her instructions regarding the level of withholding or purchase by the Insider of Company securities under such plan; or (b) make cash contributions to such plan (other than through periodic wage withholding) without complying with the Trading Procedures. Any sale of securities acquired under such plan is subject to the prohibitions and restrictions of the Trading Procedures.

D. Waivers

An Insider seeking the waiver of any provision of these Trading Procedures must submit such request in writing to the Compliance Officer, who shall then transmit the waiver request to the Audit Committee of the Board of Directors. Any waiver of any provision of these Trading Procedures in a specific instance may be authorized in writing by the Audit Committee of the Board of Directors, and any such waiver shall be reported to the Company's Board of Directors.

PART III. COMMUNICATION AND ACKNOWLEDGEMENT

All directors, officers and employees of the Company, as well as selected consultants, will be provided with a copy of this Insider Trading Policy upon its adoption (or the adoption of any amendment thereto), or upon beginning service at the Company. A copy of the Insider Trading Policy is also available to all directors, officers and employees of the Company, and to selected consultants to which this Insider Trading Policy may apply from time to time, by requesting a copy from the Compliance Officer.

Receipt of the Insider Trading Policy will constitute consent for the Company to impose sanctions for violation of the Insider Trading Policy or Trading Procedures, and to issue any necessary stop-transfer orders to the Company's transfer agent to ensure compliance.

All directors, officers and employees of the Company, as well as selected consultants, will be required upon the Company's request to re-acknowledge and agree to comply with the Insider Trading Policy (including any amendments or modifications). For such purpose, an individual will be deemed to have acknowledged and agreed to comply with the Insider Trading Policy, as amended from time to time, when copies of such items have been delivered by regular or electronic mail (or other delivery option used by the Company) by the Compliance Officer or his or her designee.

* * *

Questions regarding this Insider Trading Policy are encouraged and may be directed to the Compliance Officer.

ADOPTED: February 17, 2022
EFFECTIVE: February 17, 2022
AMENDED: November 22, 2024

Exhibit 19.1

EXHIBIT A

STOCK TRANSACTION REQUEST*

Pursuant to the Insider Trading Policy of Biomea Fusion, Inc. (the "Company"), I hereby notify the Company of my intent to transact in the securities of the Company as indicated below:

REQUESTER INFORMATION

Insider's Name: _____

INTENT TO PURCHASE

Number of shares: _____

Intended trade date: _____

Means of acquiri ☐ Acquisition through employee benefit plan (please specify):

_____

☐ Purchase through a broker on the open market

☐ Other (please specify):

_____

INTENT TO SELL

Number of shares: _____

Intended trade date: _____

Means of Selling ☐ Sale through employee benefit plan (please specify):

_____

☐ Sell through a broker on the open market

☐ Other (please specify):

_____

INTENT TO GIFT

Number of shares: _____

Intended transfer date _____

Intended recipient: _____

Exhibit 19.1

SECTION 16

☐ I am not subject to Section 16.

☐ To the best of my knowledge, I have not (and am not deemed to have) engaged in an opposite way transaction within the previous 6 months that was not exempt from Section 16(b) of the Exchange Act.

☐ None of the above.

RULE 144 ((Not applicable if transaction requested involves a purchase)

☐ I am not an "affiliate" of the Company and the transaction requested above does not involve the sale of "restricted securities" (as those terms are defined in Rule 144 under the Securities Act of 1933, as amended).

☐ To the best of my knowledge, the transaction requested above will meet all of the applicable conditions of Rule 144.

☐ The transaction requested will be made pursuant to an effective registration statement covering such transaction.

☐ None of the above.

CERTIFICATION

I hereby certify that I am (1) not in possession of any material, nonpublic information concerning the Company, as defined in the Company's Insider Trading Policy (the "Policy") and (2) not purchasing any securities of the Company on margin in contravention of the Policy and the procedures stated therein. I understand that, if I trade while possessing such material, nonpublic information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties, and may be subject to discipline by the Company including termination. I also certify that the information provided on this form is accurate and complete to the best of my knowledge.

Insider's Signature _____ Date _____

AUTHORIZED APPROVAL

Signature of Compliance Officer (or designee) _____ Date _____

**NOTE: Multiple lots must be listed on separate forms or broken out herein.*

Exhibit 19.1

EXHIBIT B

ACKNOWLEDGMENT

I hereby acknowledge that I have read, that I understand, and that I agree to comply with, the Insider Trading Policy of Biomea Fusion, Inc. (the "Company"). I further acknowledge and agree that I am responsible for ensuring compliance with the Insider Trading Policy and the Trading Procedures included therein by all of my "Affiliated Persons" (including such persons listed below). I also understand and agree that I will be subject to sanctions, including termination of employment, that may be imposed by the Company, in its sole discretion, for violation of the Insider Trading Policy, and that the Company may give stop-transfer and other instructions to the Company's transfer agent or any brokerage firm managing the Company's equity incentive plan(s) against the transfer of any Company securities in a transaction that the Company considers to be in contravention of the Insider Trading Policy.

I hereby designate the following investment funds and partnerships as entities for which the Trading Procedures contained in the Insider Trading Policy shall not apply:

_____

I hereby represent to the Company that such entities: (a) engage in the investment of securities in the ordinary course of their respective businesses; (b) have established insider trading controls and procedures in compliance with applicable securities laws; and (c) are aware such securities laws prohibit any person or entity who has material, nonpublic information concerning the Company from purchasing or selling securities of the Company or from communicating such information to any other person under circumstances in which it is reasonably foreseeable that such person is likely to purchase or sell securities.

Date: _____

Signature: _____
Name: _____
Title _____

Exhibit 21.1

Subsidiaries of Biomea Fusion, Inc.

None.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-284148, 333-276391, 333-269112, 333-262477 and 333-255377 on Form S-8 and Registration Statement No. 333-267884 on Form S-3 of our report dated March 31, 2025, relating to the financial statements of Biomea Fusion, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2024.

/s/ Deloitte & Touche LLP

San Francisco, California

March 31, 2025

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, Michael J.M. Hitchcock, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 misleading with respect to the period covered by this report;

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

4. The registrant's other certifying officer(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 defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(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 performing the equivalent functions):

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

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

Date: March 31, 2025

By: /s/ Michael J.M. Hitchcock

Michael J.M. Hitchcock
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, Rainer Erdtmann, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 misleading with respect to the period covered by this report;

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

4. The registrant's other certifying officer(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 defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(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 performing the equivalent functions):

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

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

Date: March 31, 2025

By: /s/ Rainer Erdtmann
Rainer Erdtmann
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 Annual Report of Biomea Fusion, Inc. (the "Company") on Form 10-K for the year ended December 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: March 31, 2025

By: /s/ Michael J.M. Hitchcock

Michael J.M. Hitchcock
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 Annual Report of Biomea Fusion, Inc. (the "Company") on Form 10-K for the year ended December 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: March 31, 2025

By: /s/ Rainer Erdtmann

Rainer Erdtmann
Principal Financial and Accounting Officer

Exhibit 97.1

BIOMEA FUSION, INC.
COMPENSATION RECOVERY POLICY
Adopted as of November 17, 2023

Biomea Fusion, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview
The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement
In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 2, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned or vested when the Financial Reporting Measure is attained, not when the actual payment, grant or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation and received Incentive-Based Compensation after beginning service in any such role (regardless of whether such Incentive-Based Compensation was received during or after such person's service in such role): the president, principal financial officer, principal accounting

officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division or function (such as sales, administration or finance), any other officer who performs a policy making function or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure.

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy

shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee; provided, however, that the Board shall have exclusive authority to authorize the Company to prepare a Financial Restatement. In doing so, the Board may rely on a recommendation of the Audit Committee of the Board. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.