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 001-38410

BioXcel Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**82-1386754**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
555 Long Wharf Drive	**06511**
New Haven CT	(Zip Code)
(Address of principal executive offices)	

Registrant's telephone number, including area code: **(475) 238-6837**

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

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.001 per share	**BTAI**	**Nasdaq Capital 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 Section 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 Act). Yes ☐ No ☒

As of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $41,276,960 (based upon the closing sale price of the registrant's common stock reported on the Nasdaq Capital Market on that date). This calculation excludes shares held by the registrant's current directors and executive officers and stockholders that the registrant has concluded are affiliates of the registrant.

There were 5,486,038 shares of our common stock outstanding at March 26, 2025.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The words "anticipate," "believe," "can," "continue," "could," "designed," "estimate," "expect," "forecast," "goal," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements use these words or expressions. All statements contained in this Annual Report on Form 10-K, other than statements of historical fact, are forward-looking statements, including, without limitation, statements regarding:

- our sales strategy for IGALMI®;
- our ability to raise additional capital and continue as a going concern;
- our ability to stay listed on the Nasdaq Capital market;
- compliance with covenants under our financing arrangements;
- developments relating to our SERENITY and TRANQUILITY programs;
- the size of our total addressable markets and related underlying estimates;
- our plans relating to clinical trials and marketing applications for our product candidates;
- our plans to research, develop and commercialize our current and future product candidates;
- our plans to seek to enter into collaborations for the development and commercialization of certain product candidates;
- the potential benefits of any future collaboration;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the timing of and results of discussions we have with regulators;
- the rate and degree of market acceptance, clinical utility, number of prescribers and formulary wins of IGALMI® and any product candidates for which we receive marketing approval;
- our commercialization, marketing and manufacturing capabilities and strategy, including the potential benefits from any advertising campaigns;
- our participation in, and any potential benefits from, events, conferences, presentations and conventions;
- our intellectual property position and strategy;
- our estimates regarding expenses, future revenue, capital requirements and need for additional financing;
- potential investments in, or other strategic options for, our subsidiary, OnkosXcel Therapeutics, LLC ("OnkosXcel");
- developments relating to our competitors and our industry;
- the impact of government laws and regulations;
- developments related to legal proceedings and investigations; and
- our relationship with BioXcel LLC.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, those listed under Part I, Item 1A. "Risk Factors," Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K. These and other important factors discussed under the caption "Risk Factors" in our other filings with the Securities and Exchange Commission ("SEC") could cause actual results to differ materially from those indicated by the forward-looking statements made in this filing. Given these uncertainties, you should not rely on these forward-looking statements as predictions of future events. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise

expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

As used in this Annual Report on Form 10-K, unless otherwise specified or the context otherwise requires, the terms "we," "our," "us," the "Company" or "BTI" refer to BioXcel Therapeutics, Inc., and "BioXcel, LLC" refers to the Company's former parent company and stockholder, BioXcel LLC, and its predecessor, BioXcel Corporation. All brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners, including IGALMI®, which is a trademark of BioXcel Therapeutics, Inc.

We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investors & Media section of its website at *www.bioxceltherapeutics.com*. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting the "Email Alerts" option under the News / Events menu of the Investors & Media section of our website at *www.bioxceltherapeutics.com*.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common stock. The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history and have not generated substantial product revenues to date, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts or otherwise seek strategic alternatives.
- Nasdaq may delist our common stock from trading on its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.
- We have significant indebtedness and other contractual obligations that could impair our liquidity, restrict our ability to do business and thereby harm our business, results of operations and financial condition. We may not have sufficient cash flow from operations to satisfy our obligations under our financing facilities.
- Our strategic reprioritization and other workforce reductions in force may not achieve our intended outcome.
- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.
- We have limited experience in drug discovery and drug development.
- Developments relating to our TRANQUILITY II Phase 3 trial may impact the timing of our development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease and may also subject us to additional risks and uncertainties, including regulatory, stockholder or other actions, loss of investor confidence and negative impacts on the trading price of our common stock.
- In the near term, we are dependent on the success of IGALMI®, and four of our product candidates, BXCL501, BXCL502, BXCL701 and BXCL702. If we are unable to complete the clinical development of or obtain marketing approval for our product candidates or successfully commercialize IGALMI® or our product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.
- Interim "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The regulatory approval processes of the United States ("U.S.") Food and Drug Administration ("FDA"), and comparable foreign authorities are lengthy, time consuming, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- Clinical trials are expensive, difficult to design, difficult to conduct and involve an uncertain outcome.

- We depend on enrollment of patients in our clinical trials to continue development of our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

- Our estimated number of episodes of agitation and our corresponding estimated total addressable market are subject to inherent challenges and uncertainties. If we have overestimated the number of episodes or the size of our total addressable market for our current and potential future products or product candidates, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be harmed.

- The discovery and development of product candidates based on EvolverAI, BioXcel LLC's proprietary pharmaceutical discovery and development engine, as well as our own AI platform is novel and unproven, and we do not know whether we will be able to develop any products of commercial value.

- Regulators may limit our ability to develop or implement our proprietary AI algorithms and/or may eliminate or restrict the confidentiality of our proprietary technology, which could have an adverse effect on our business, results of operations, and financial condition.

- Although the FDA has approved IGALMI® for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder, we will still face extensive and ongoing regulatory requirements and obligations for IGALMI® and for any product candidates for which we obtain approval.

- Although we obtained FDA approval for IGALMI®, our products and product candidates may not be accepted by physicians or the medical community in general, and there may be insufficient insurance coverage and reimbursement.

- If we are found in violation of federal, state or foreign health care "fraud and abuse" laws, we may be required to pay significant fines and penalties, which may adversely affect our business, financial condition and results of operations.

- We continue to depend on BioXcel LLC to provide us with certain services for our business.

- We are substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates, and our commercial supplies of IGALMI®, and we intend to rely on third parties to produce commercial supplies of any other approved product candidate.

- We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- Data breaches or cyber-attacks could disrupt our business, operations and information technology systems, and financial results, or result in the loss or exposure of confidential or sensitive Company information.

- We are and may in the future be subject to legal proceedings, claims and investigations in or outside the ordinary course of business. Such proceedings, claims and investigations could be costly and time-consuming to defend and could result in unfavorable outcomes, which may have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock.

- Unfavorable global political or economic events and conditions could adversely affect our business, financial condition or results of operations.

- We face risks associated with the increased scrutiny relating to environmental, social and governance matters.

- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Annual Report includes our trademarks, trade names and service marks, including, without limitation, "IGALMI®" and our logo, which are our property and are protected under applicable intellectual property laws. Solely for convenience, trademarks, trade names and service marks may appear in this Annual Report without the ®, TM and SM symbols, but such references are not intended to indicate, in any way, that we or the applicable owner forgo or will not assert, to the fullest extent permitted under applicable law, our rights or the rights of any applicable licensors to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this Annual Report concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. While we believe the information from these third-party publications, research, surveys and studies included in this Annual Report is reliable, we do not guarantee the accuracy or completeness of such information, and we have not independently verified this information. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in this Annual Report under "Forward Looking Statements," "Risk Factor Summary" and Part I, Item 1A "Risk Factors." These and other factors could cause our future performance and market expectations to differ materially from our assumptions and estimates.

PART I

Item 1. Business

Overview

BioXcel Therapeutics, Inc. ("BTI," the "Company," "we," "us" or "our") is a biopharmaceutical company utilizing artificial intelligence ("AI") to develop transformative medicines in neuroscience and, through the Company's wholly owned subsidiary, OnkosXcel Therapeutics LLC ("OnkosXcel"), immuno-oncology. We are focused on utilizing cutting-edge technology and innovative research to develop high-value therapeutics aimed at transforming patients' lives. We employ various AI platforms to reduce therapeutic development costs and potentially accelerate development timelines. Our approach leverages existing approved drugs and/or clinically evaluated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. We believe this differentiated approach has the potential to reduce the expense and time associated with drug development in diseases with substantial unmet medical needs.

Our most advanced neuroscience candidate is BXCL501. In indications other than those approved by the United States ("U.S.") Food and Drug Administration ("FDA") as IGALMI®, BXCL501 is an investigational, proprietary, orally dissolving film formulation of dexmedetomidine (or "Dex") in development for the treatment of agitation associated with psychiatric and neurological disorders.

On April 6, 2022, we announced that the FDA approved IGALMI® sublingual film for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. IGALMI® is approved to be self-administrated by patients under the supervision of a health care provider. On July 6, 2022, we announced that IGALMI® was commercially available in doses of 120 and 180 micrograms.

On September 5, 2024, we announced the initiation of our SERENITY At-Home trial, a double-blind, placebo-controlled study to evaluate the safety of a 120 mcg dose of BXCL501 in 200 patients for acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting. On November 12, 2024, we announced that the first patient had been randomized in the trial, and on March 27, 2025, that 24 clinical trial sites had been opened and 127 patients had been enrolled. Topline data results, which are expected in the second half of 2025, are intended to support a supplemental new drug application ("sNDA") submission to potentially expand the label of IGALMI® (dexmedetomidine) sublingual film in the at-home setting.

We are continuing to develop BXCL501 for the potential acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting and for the potential acute treatment of agitation (non-daily) associated with dementia due to probable Alzheimer's disease in the at-home setting and in care facilities.

As described further below, we have deprioritized the development of BXCL501 for certain other proposed indications, as a potential adjunctive treatment for major depressive disorder ("MDD"), as well as our BXCL701 program, except as noted under "Immuno-Oncology" below.

On September 5, 2024, we submitted to the FDA the proposed protocol for our TRANQUILITY In-Care Phase 3 trial designed to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 for agitation associated with Alzheimer's dementia. See further discussion in *"Our Neuroscience Clinical Programs"* below.

On October 15, 2024, we announced a U.S. Department of Defense grant to the University of North Carolina to fund a study of BXCL501 (sublingual dexmedetomidine) for treating Acute Stress Disorder (ASD). See further discussion in *"Additional Neuroscience Opportunities"* below.

Our most advanced immuno-oncology candidate, BXCL701, is an investigational oral innate immune activator being developed by OnkosXcel as a potential therapy for the treatment of aggressive forms of prostate cancer, pancreatic cancer, and other solid and liquid tumors.

Nasdaq Notice

On September 16, 2024, the Company received a letter from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") that it was not in compliance with Nasdaq Listing Rule 5550(a)(2) because its common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days.

On February 6, 2025, the Company announced that it would effect a 1-for-16 reverse stock split of its common stock. The reverse stock split became effective at 5:00 p.m. on February 7, 2025, and the company's common stock began trading on a split-adjusted basis (above $1 per share) at the opening of the market on Monday, February 10, 2025.

To regain compliance, the Company was required to maintain a minimum closing bid price of $1.00 per share for at least 12 consecutive trading days. This requirement was met on February 26, 2025.

As previously reported, on September 20, 2024, we received a letter from the Nasdaq Staff notifying us that for the 30 consecutive business days prior to the date of the letter, the Company's market value of listed securities ("MVLS") closed below the minimum $35 million requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2) (the "MVLS Requirement"). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company was granted a period of 180 calendar days, or until March 19, 2025, to regain compliance.

As anticipated, on March 20, 2025, the Company received another letter from the Staff stating that, as a result of the Company's continued non-compliance with the MVLS Requirement, its securities would be delisted from Nasdaq unless the Company appealed the Staff's delisting determination by requesting a hearing before the Nasdaq Hearings Panel (the "Panel"). The Company made timely request for a hearing before the Panel to appeal the Staff's determination. The Company's common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process; however, there can be no assurance that the Company will ultimately regain compliance and remain listed on Nasdaq.

2024 Clinical Prioritization

As discussed in Note 4, *Restructuring* in the notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, on May 8, 2024 the Company took additional actions as part of its continued efforts to preserve cash and prioritize investment in its core clinical programs. As part of these actions, the Company initiated a reduction of approximately 15% of the Company's workforce.

On September 17, 2024, the Company approved a plan for an additional reduction in its workforce by 15 employees (including all but one sales and marketing employee), or approximately 28% of the Company's headcount (the "Clinical Prioritization"), in order to extend its cash runway and prioritize investment on the clinical development of its lead neuroscience asset, BXCL501.

Neuroscience

Our Neuroscience Strategy

Our goal is to become the leading AI-enabled neuroscience therapeutics company. We continue to evaluate all strategic options for our neuroscience assets, which could include licensing, partnering, and co-commercialization.

Our Novel Drug Re-Innovation Approach

We aim to deploy and implement, throughout the drug development process, an AI ecosystem designed to rapidly identify medications related to our key focus areas of neuroscience and immuno-oncology. Our in-house, uniquely integrated AI-to-drug-development capability is complemented by the services and technology of BioXcel LLC, our former parent company. It includes a labeled properties graph (also referred to as a "knowledge graph") that visually relates collected big data in the form of entities and their properties that include neuropsychiatric symptoms, brain circuits, drug targets, and existing drugs. We believe that understanding the relation between entities relevant to drug development may lead to novel potential uses for existing drugs. Predictive algorithms or queries of the knowledge

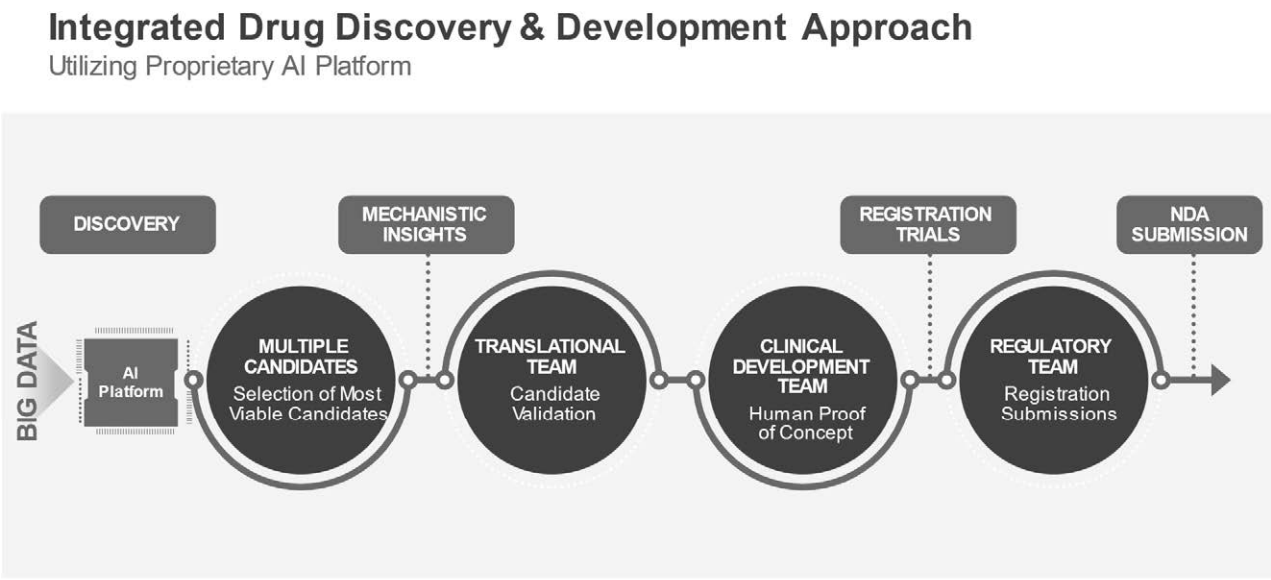
graph may uncover not only single drugs but potentially identify new combinations of drugs that we believe may be more effective in treating disorders than single agents. New combinations of drugs may lower tolerable doses of drugs and provide the basis for stronger intellectual property positions. Our AI team prioritizes the most valuable external opportunities in a data-driven manner. These opportunities may be found in new potential uses for launched drugs, in drugs that are part of pharmaceutical company pipelines no longer being pursued, or within academic efforts to develop new drug candidates.

Traditional drug development is marred by low success rates, long drug development cycles, and exorbitant development costs that are increasing year over year. In addition, many serious diseases remain unaddressed due to limitations of the current drug discovery paradigm. The pharmacological universe spans more than 27,000 active pharmaceutical agents, of which only approximately 4,000 are approved and marketed. Marketed drugs may not be exclusively effective in the indication for which they are approved but relevant to other indications, including rare diseases, and thus represent an untapped potential for addressing unmet medical needs and recouping research and development costs. Many of the remaining agents are active clinical candidates that are shelved or have failed for reasons other than toxicity, which offers the opportunity to re-innovate for other indications or patient segments. Such agents potentially represent an unrealized investment of billions of research and development dollars by the private and public sectors, while failing to remediate immeasurable patient suffering and sacrifice during clinical development. Also, these compounds may have known pharmaco-dynamic and pharmaco-kinetic properties, potentially allowing for a more data-driven selection of appropriate doses for development programs. Finally, with respect to neuropsychiatric indications, we prioritize those compounds with structural design features that we believe may contribute to high blood-brain barrier permeability, and therefore could increase the likelihood of compound penetration into the brain. Lack of brain penetration is a common cause for failure of many drugs developed for neuropsychiatric indications. In addition, we are prioritizing compounds with available human safety data, acceptable pharmacokinetic results, and data that support a high probability of achieving reasonable brain concentrations after dosing. The compounds in our pipeline have been identified using this proprietary platform.

This drug re-innovation model has been exemplified by the successful development and commercialization of drugs such as Tecfidera® (Biogen, Inc.), Thalomid® (Celgene Corporation), and Viagra® (Pfizer, Inc.). All of these drugs were identified by insights in biology and disease pathophysiology. The successful business models of biotech companies like Axsome Therapeutics, Inc. and Karuna Therapeutics, Inc. (acquired by Bristol Myers Squibb) are based on the re-innovation and combination of existing clinical candidates or marketed drugs to provide novel solutions for patients. Unfortunately, such discoveries have been severely limited in scope due to the lack of a genuinely integrated approach to mining big data and advanced analytics.

Our AI-based discovery and development process is the foundation of our drug re-innovation model for identifying the next wave of potential medicines. Our therapeutic area experts have substantial experience across the drug discovery and development value chain. We believe that our method of finding potential product candidates gives us a higher probability of success because it combines AI expertise and intuition of human experience in drug development. We believe the combination of AI and drug discovery and development expertise facilitates the generation of therapeutic candidates and gives us a significant competitive advantage.

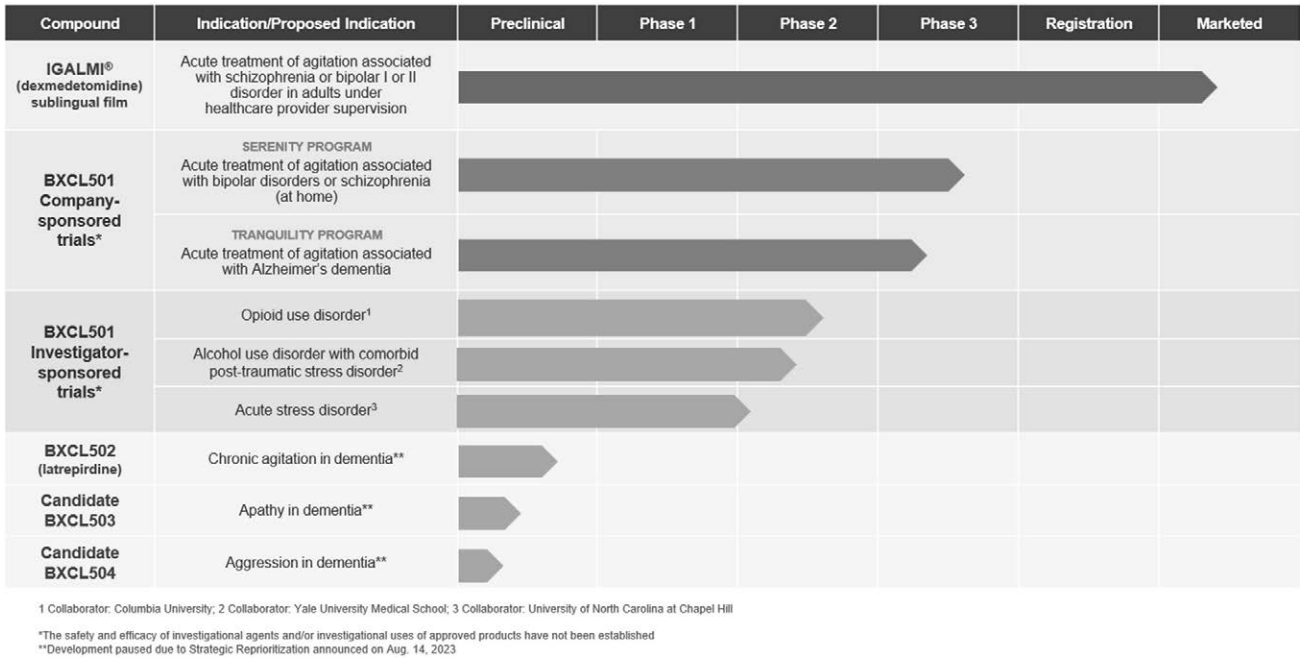
Our approach is illustrated below:



We continue to integrate and evolve our neuroscience and immuno-oncology AI machine learning and drug discovery and development platform. Our platform led to the identification of Dex, the rapid development of BXCL501, and its approval by the FDA as IGALMI®, as well as the advancement of BXCL501 for other potential indications. We are continuing to leverage our platform to identify and develop new neuroscience and immuno-oncology programs.

Our Neuroscience Clinical Programs

The following is a summary of the status of our neuroscience clinical development programs as of the date of this Annual Report on Form 10-K:



1 Collaborator: Columbia University; 2 Collaborator: Yale University Medical School; 3 Collaborator: University of North Carolina at Chapel Hill

*The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established
**Development paused due to Strategic Reprioritization announced on Aug. 14, 2023

As a selective adrenergic agent with a sublingual or buccal route of administration, BXCL501 is designed to be easy to administer and has shown a rapid onset of action in multiple clinical trials, including clinical trials studying patients with schizophrenia, bipolar disorders, and dementia. We believe the results from these studies suggest that BXCL501 has the potential to generate a calming effect without producing excessive sedation. We believe that BXCL501 is highly differentiated from antipsychotics currently used as a standard of care for the treatment of agitation that often produce unwanted side effects such as excessive sedation and extra-pyramidal motor effects. Managing patient agitation in neuropsychiatric and neurodegenerative disorders represents a significant challenge for physicians and caregivers. We believe that BXCL501 has the potential to address these challenges while providing an efficient treatment regimen for patients.

Agitation Overview and Market Opportunity

Agitation in patients with neuropsychiatric diseases is a serious medical condition. Agitation is characterized by feelings of unease, excessive talking, and/or unintentional and purposeless motions, such as wringing of the hands or pacing. People experiencing agitation may also express excitement, hostility, poor impulse control, tension, uncooperativeness, and occasional disruptive behavior, which may lead to aggression and violence. In many cases, people develop agitation when treatment for their underlying disorder is not working well. Stressful situations or traumatic events can also trigger agitation. Agitation can occur suddenly or slowly and vary in length, lasting for a few minutes or for an extended period.

With the agitation issues associated with schizophrenia and bipolar disease coupled with a fast-growing elderly population that is potentially likely to experience agitation associated with Alzheimer's disease, the difficulties and expenses of acute treatment of agitation are expected to grow significantly. We estimate that in the United States, there are approximately 1.9 million patients diagnosed with Alzheimer's disease-related dementia ("AAD") and that those patients experience agitation at a rate of about six episodes per month, on average. In addition, we estimate that there are approximately 1.6 million Americans diagnosed with schizophrenia or bipolar disorders and that those patients experience agitation at a rate of about three episodes per month, on average. We, therefore, believe there is significant

potential market opportunity for BXCL501 if approved for use in these patient populations in the at-home setting. The foregoing estimates of the incidence of each patient population and the number of agitation episodes experienced and potential market opportunity are based on management's estimates and third-party data, which may be materially different from actual agitation episodes and actual treatable patients. For additional information regarding risks associated with these estimates, see Part I, Item 1A, Risk Factors *"— Our estimated number of episodes of agitation and our corresponding estimated total addressable market are subject to inherent challenges and uncertainties. If we have overestimated the number of episodes or the size of our total addressable market for our current and potential future products or product candidates, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be harmed."*

Treatments for Agitation

Antipsychotics, the current standard of care for acute treatment of agitation associated with schizophrenia and bipolar disorder, are also used off-label to treat agitation in dementia and other conditions. Side effects of these medications include movement disorders, including akathisia and extrapyramidal symptoms. One of the serious limitations of these drugs is that they can sedate the patient and do not permit verbal interaction with the hospital staff to continue. Intramuscular ("IM")-delivered antipsychotics, such as haloperidol and olanzapine, are used extensively in this setting but are invasive and often require patient restraint. This type of treatment can dehumanize patients and cause trauma that could have long-term impact on them. Furthermore, these treatments include a black box warning for use in elderly patients.

While sublingual tablet formulations utilizing antipsychotics have been developed, these formulations have long half-lives (21-24 hours) and significant side effects when given acutely or chronically. Oral agents such as benzodiazepines are also used but have a slow onset of action and are consequently ineffective in the acute treatment of agitation. Side effects of these agents include sedation, amnesia, confusion, and paradoxical responses. They can intensify cognitive slowing and worsen memory and motor impairment, contributing to an increased risk of falls and fractures. In addition, long-term use of benzodiazepines has been found to be habit-forming and can cause addiction or relapse to abuse substances. Nonadherence with oral agents can also be problematic as patients may attempt to spit out these medications. We believe that, based on the current method of administration of oral medicine for agitation, an orally dissolving, mucoadhesive film could offer compliance advantages by making it less likely that patients will avoid treatment.

The sublingual or buccal route of administration is an accepted alternative to oral administration of drug delivery to the central nervous system when rapid onset or more controlled delivery is required. Currently, there are six products approved for film administration, including our product, IGALMI®. For example, BioDelivery Sciences International, Inc., a commercial-stage specialty pharmaceutical company, has developed a buccal film formulation of buprenorphine for chronic pain management and buprenorphine and naloxone for opioid dependence. We developed BXCL501 as a differentiated sublingual film dosage form of Dex, which we believe may offer benefits such as ease of use and quick absorption for rapid therapeutic effects.

Mechanism of Action: α2a Adrenergic Receptor and NE Role in Acute Agitation

BXCL501 is a sublingual formulation of Dex that is designed to be easily administered and have a rapid onset of action. Dex is approved in the U.S. for the sedation of initially intubated and mechanically ventilated patients during treatment in the intensive care unit ("ICU"). It is also used in the intensive care setting for sedation of non-intubated patients prior to and/or during surgical and other invasive procedures. Dex, launched in the U.S. as Precedex™ in 1999, is a selective α2a adrenergic receptor agonist that has a strong safety record and has been studied in over 130 clinical trials to date. It has also been sold in the European Union ("EU") and other countries under the trade name Dexdor® as a sedative for intensive care patients. Dex was approved by the European Commission for sedation of adult ICU patients requiring a sedation level no deeper than arousal in response to verbal stimulation (corresponding to Richmond Agitation-Sedation Scale 0 to -3). It has been used to prevent or treat hyperactive delirium resulting from anesthesia in

the ICU. Given these uses of the IV formulation of Dex, we believe Dex formulated in a sublingual film and at much lower doses allows for ease of administration in settings where rapid acute treatment of agitation is needed.

IGALMI® Commercial Strategy

We continue to support IGALMI® in the hospital setting through limited and focused commercial activity. In the third quarter of 2023, we revised our commercial strategy for IGALMI® in the institutional setting, reducing in-hospital commercialization expenses, suspending programs no longer deemed core to our business, and shifting focus to the development of BXCL501 for use in the at-home and care facilities in the treatment of acute agitation in schizophrenia and bipolar disorders, and in the treatment of acute agitation (non-daily) associated with dementia due to probable Alzheimer's disease (collectively, the "Reprioritization").

Following the Reprioritization, a small Corporate Account Director team supported existing customers and targeted Integrated Delivery Networks ("IDNs") with educational assistance and contracting opportunities, while our trade operation supported customers with drug supply. The goal of this approach was to help maintain current business and potentially broaden IGALMI® utilization through volume contracting.

As part of the Clinical Prioritization announced on September 19, 2024, we made further workforce reductions including sales and marketing employees, as the Company announced it would maintain IGALMI™ in the market with minimal commercial support. The Clinical Prioritization staff reductions may have future impacts on net revenue. Net revenues from IGALMI® product sales for the years ended December 31, 2024 and 2023 were $2.3 million and $1.4 million, respectively.

We are currently seeking potential commercial partners. Our continued commercialization efforts for IGALMI® are designed to build the foundation to launch additional potential follow-on indications. If IGALMI® would be approved outside the U.S., we would consider launching the product through collaborations with third parties.

BXCL501 Development

In indications other than those approved by the FDA as IGALMI®, BXCL501 remains an investigational, proprietary, orally dissolving film formulation of Dex, a selective alpha-2 receptor agonist, targeting symptoms from stress-related behaviors such as agitation. BXCL501 is our most advanced neuroscience clinical program, being evaluated for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting and for the acute treatment of agitation (non-daily) in patients with dementia due to probable Alzheimer's disease in care facilities and at-home settings.

As a selective adrenergic agent with a sublingual or buccal route of administration, BXCL501 is designed to be easily administered and, compared to medications that may take days or weeks, has shown a relatively rapid onset of action in multiple clinical trials, including those studying patients with bipolar disorders, schizophrenia, and Alzheimer's disease. We believe results from these studies suggest that BXCL501 has the potential to reduce agitation without producing excessive sedation. We also believe BXCL501 is highly differentiated from antipsychotics, which are currently used as first-line standard-of-care treatments despite often producing unwanted side effects such as excessive sedation or extra pyramidal motor effects. Managing patient agitation in neuropsychiatric and neurodegenerative disorders represents a significant challenge for physicians and caregivers. We believe BXCL501 has the potential to address these challenges while providing an efficient treatment regimen for patients.

We also believe that BXCL501, if approved for the respective indications, has the potential to become the standard of care for the acute treatment of agitation arising from diseases such as schizophrenia, bipolar disorder and Alzheimer's disease.

In addition, given the differentiated design of BXCL501 and its mechanism of action, we believe BXCL501 has the potential to address several diseases or conditions for which agitation is a symptom of the condition or underlying disease, including opioid withdrawal and post-traumatic stress disorder ("PTSD"), which are being evaluated in investigator-sponsored trials run by several leading academic research institutions.

BXCL501 Clinical Trials

SERENITY Program: Agitation Associated with Bipolar Disorders I and II or Schizophrenia (at-home setting)

We initiated the clinical study of BXCL501 in patients with agitation associated with bipolar disorders or schizophrenia in SERENITY III, which consisted of two parts. The first part was comparable to our pivotal SERENITY I and II studies. Using similar inclusion and exclusion criterion under a well-controlled in-patient setting, acutely agitated patients with bipolar disorders or schizophrenia were randomized to self-administer either 60 mcg of BXCL501 or placebo in a double-blind placebo-controlled trial. The primary endpoint of Part I was efficacy, as measured by the change in PEC score change from baseline at two hours post-dose. The secondary objectives of Part I were safety and tolerability.

On May 25, 2023, we reported topline results from Part I of the study. Although the trial did not meet its primary efficacy endpoint, we believe the efficacy results, observed with the 60 mcg dose, representing half of the lowest approved dose of IGALMI® for in-patient use (120 mcg), were promising. Specifically, greater than 50% of individuals were responders, defined as those patients who achieved a 40% or greater reduction in PEC score. Furthermore, this population responder rate was consistent and dose-proportionate to the same response rates observed in the larger SERENITY I and II trials. Although the primary efficacy endpoint as a group mean change in PEC score from baseline at 2 hours was not statistically significant at the primary endpoint at 2 hours (p=0.077), BXCL501 statistically separated from placebo at 4 hours (p=0.049).

Part II of the SERENITY III study was designed to evaluate the same dose tested in Part I, 60 mcg (with an optional additional 60 mcg dose), but in the at-home setting and focusing on safety only. However, because the trial did not meet its primary efficacy endpoint using this 60 mcg dose in Part I, we paused continuation of Part II of the study pending feedback from the FDA. We held a Type C meeting with the FDA on November 8, 2023 to discuss changes to Part II of our SERENITY III study. We proposed the evaluation of an 80 mcg dose based on previous clinical experience with this dose during our Phase 1b trial in schizophrenia patients with agitation, and pharmacokinetic and pharmacodynamic modeling suggesting that use of an 80 mcg dose of BXCL501 could provide an optimal balance between safety and efficacy for at-home use. Based on feedback from the FDA during the meeting, we made the decision to evaluate a 120 mcg dose in the at-home setting. The 120 mcg dose has already demonstrated efficacy based on the approval of IGALMI® (when administered under the supervision of a healthcare provider, for a single agitation episode), so we sought further feedback from the FDA regarding the proposed design of this study amendment in a request for a follow-up meeting with the FDA, which was held on March 6, 2024.

Based on the FDA's feedback in advance of and during the March 6, 2024 meeting, we moved forward evaluating the use of the 120 mcg dose of BXCL501 in the at-home setting, and amended Part 2 of the SERENITY III study. We now refer to this study as the SERENITY At-Home trial, with safety as the primary objective and efficacy measures as exploratory endpoints to support use in the at-home setting. This was the FDA's recommendation in the November 8, 2023 FDA meeting, for the acute treatment of agitation in bipolar disorders or schizophrenia. We also plan to initiate a clinical study designed to enroll approximately 30 patient-informant dyads to evaluate the correlation between patient-and informant-reported efficacy measurement and the PEC scale, conducted by trained clinician raters as previously recommended by the FDA.

IGALMI® is already approved at the 120 mcg dose based on efficacy data that we previously generated in treating a single episode of agitation. Consistent with the data generated to date, the label for IGALMI® currently includes a limitation on use ("LOU"), noting the lack of efficacy or safety data beyond 24 hours following the first dose. During our March 6, 2024 Type C meeting with the FDA, we discussed, among other things, whether evaluating the at-home use of BXCL501 120 mcg, with safety as the primary objective and efficacy measures as exploratory endpoints, if successful, could support the submission of an sNDA seeking expansion of the current label for IGALMI® 120 mcg to allow at-home use and labeling without the current LOU. Based on FDA feedback, we believe that our ability to seek labeling without the current LOU will depend, in part, on the number of agitation episodes we observe during our planned study period. On April 22, 2024, we announced our plans, subject to funding, to advance the SERENITY At-Home trial. On September 5, 2024, we announced the initiation of our SERENITY At-Home trial. The pivotal Phase 3 trial is designed to evaluate the safety of BXCL501 in the at home setting. On November 12, 2024, we announced that

the first patient had been randomized in the trial. On March 27, 2025, 24 clinical trial sites had been opened and 127 patients have been enrolled, representing 63% of the total required enrollment in the trial. Topline data results, which are expected in the second half of 2025, are intended to support a supplemental new drug application ("sNDA") submission to potentially expand the label of IGALMI® (dexmedetomidine) sublingual film.

TRANQUILITY Program: Acute Agitation Associated with Dementia due to Probable Alzheimer's Disease (AAD)

On June 29, 2023, we announced positive topline results from TRANQUILITY II, a randomized, double-blind, placebo-controlled, parallel group trial that evaluated the safety and efficacy of BXCL501 for the acute treatment of Alzheimer's-related agitation in adults 65 years and older with mild to moderate dementia in assisted living facilities ("ALFs") and residential care settings who required minimal assistance with activities of daily living. The trial dosed 149 patients. Randomized patients self-administered 40 mcg or 60 mcg of BXCL501 or placebo for agitation episodes that occurred over a 12-week period. The primary endpoint was the change from pre-dose in Positive and Negative Syndrome Scale-Excitatory Component ("PEC") total score at 2 hours post-dose for the first treated episode of agitation. The key secondary efficacy endpoints were PEC change from pre-dose at 1 hour post-dose of study treatment for the first treated episode of agitation, and PEC change from pre-dose at 30 minutes post-dose of study treatment for the first treated episode of agitation.

The Phase 3 trial met its primary efficacy endpoint with the 60 mcg dose; a statistically significant and clinically meaningful 7.5 point reduction from baseline in PEC total score was observed at 2 hours versus 5.4 with placebo ($p=0.0112$). The 60 mcg dose also met the first key secondary endpoint of reducing agitation symptoms at 1 hour during the first episode of agitation ($p=0.0185$) but did not meet the other key secondary endpoint of change from baseline in PEC score at 30 minutes.

Efficacy for this dose was supported by several secondary measures, including the Clinical Global Impressions – Improvement Scale ("CGI-I") and Agitation-Calmness Evaluation Scale ("ACES"). Most patients (76%) responded to the first 60 mcg dose and were determined to be "Very Much" or "Much Improved" (CGI-I of 1 or 2, respectively) compared to 50% with placebo. The primary endpoint was not met for the 40 mcg dose, with a 5.7 point reduction from baseline in PEC score.

On June 29, 2023, we also announced that we had learned that an investigator in this study, who enrolled approximately 40% of the patients, engaged in misconduct. Since that time, we have taken steps to further investigate and evaluate the conduct of the TRANQUILITY II trial at this clinical site. Based on these steps to date, we believe that there have been no further instances of misconduct or fraud or other findings that adversely impact the data integrity or reliability of the eligibility, safety, and efficacy data obtained at the clinical trial site in question.

On March 3, 2025 we announced that the U.S. Food and Drug Administration (FDA) concluded that the inspection of a single site in its TRANQUILITY II Phase 3 trial was closed under 21 C.F.R.20.64(d)(3) and released the Establishment Inspection Report. The FDA designated "Voluntary Action Indicated" for the site. We believe this further supports the reliability of data from the TRANQUILITY II trial of BXCL501.

In a Type B/Breakthrough Therapy designation meeting with the FDA on October 11, 2023, we reviewed our TRANQUILITY clinical trial program and discussed the data package required to support submission of an sNDA for the potential approval of BXCL501 for the acute treatment of agitation in patients with mild to moderate dementia due to probable Alzheimer's disease in the ALF and at-home settings. Specifically, we sought feedback from the FDA as to whether our data package consisting of TRANQUILITY I and II, along with the clinical pharmacology and toxicology programs previously discussed with the FDA, would be sufficient to support an sNDA submission for the potential use of BXCL501 to treat agitation in patients with mild to moderate dementia due to probable Alzheimer's disease in either the at-home or ALF setting, or, if not, what additional data would be required. Based on the FDA's feedback in this meeting, we understand that the FDA will require additional efficacy data, including repeat efficacy data, and long-term safety data. We therefore requested another meeting with the FDA to further discuss the additional data that would be required to support an sNDA submission.

On February 20, 2024, we held a Type B/Breakthrough Therapy designation meeting with the FDA. The original purpose of this meeting was to obtain feedback on the design of a proposed at-home study that did not include caregiver-collected efficacy endpoints, based on our belief that obtaining caregiver assessments of efficacy would be challenging. We believe there are no validated caregiver endpoints for assessing efficacy in Alzheimer's disease patients in the at-home setting. As a result, we focused on requesting feedback from the FDA regarding our proposal for an at-home clinical study with safety as the primary objective, and to better understand what additional data would be required to submit an sNDA to support labeling for BXCL501 to include the acute treatment of agitation associated with dementia in probable Alzheimer's disease or, in the alternative, in this population in the care setting only. In its preliminary responses, the FDA reiterated its prior comments that we need to generate additional efficacy data, including repeat-dose efficacy data, to support an sNDA submission, as the FDA indicated that our proposed efficacy database, which currently includes the 70 patients who have been treated with 60 mcg of BXCL501 in TRANQUILITY I and TRANQUILITY II, would not contain substantial evidence of effectiveness absent additional data. The FDA advised that we generate the necessary efficacy data in care facilities prior to conducting any trials in the at-home setting. In addition, the FDA indicated the need to generate long-term safety data to support an sNDA submission, including from probable Alzheimer's disease patients exposed to BXCL501, for up to one year. Based on the FDA's feedback, we are currently planning to generate additional Phase 3 efficacy and safety data, in a variety of relevant care-facility settings and across severity of dementia, in our planned TRANQUILITY In-Care Phase 3 trial. In addition, we plan to discuss the details of the requirement for long-term safety data at a future meeting with the FDA. Also, although we announced in November 2023 that we were planning to conduct a Phase 3 trial in the at-home setting, with safety as the primary objective (TRANQUILITY At Home), given the priority to expand the database to generate additional efficacy and safety data in care facilities, and subject to funding, we are re-evaluating the timing for initiating TRANQUILITY At Home.

On September 5, 2024, we submitted to the FDA the proposed protocol for our TRANQUILITY In-Care Phase 3 trial designed to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 for agitation associated with Alzheimer's dementia. On November 12, 2024, we announced that we had received FDA feedback on the proposed protocol**.**

Adjunctive treatment in Major Depressive Disorder ("MDD")

We were previously evaluating BXCL501 as an adjunctive treatment for MDD. The initial clinical study in this program was a double-blind, placebo-controlled, multiple ascending dose ("MAD") trial to evaluate the safety and tolerability of daily doses of BXCL501 in healthy volunteers.

As part of the Reprioritization announced on August 14, 2023, we paused our plan to develop a Phase 2 human proof-of-concept trial design to investigate BXCL501 as a potential adjunctive treatment and its potential accelerant effect in combination with first-line selective serotonin reuptake inhibitors or serotonin-norepinephrine reuptake inhibitors.

Pediatric Study

In June 2021, we initiated a global clinical trial designed to evaluate the safety and efficacy of BXCL501 in the acute treatment of agitation associated with pediatric schizophrenia and bipolar disorders, in part to fulfill pediatric study requirements agreed to with the FDA in connection with the approval of IGALMI®. The trial protocol has been reviewed by the FDA, as well as by the European Medicines Agency, to fulfill potential commitments to study the effects of BXCL501 in pediatric patients ages 13 to 17 with schizophrenia and ages 10 to 17 with bipolar disorders. Enrollment of patients with schizophrenia, schizoaffective disorder, bipolar I, and bipolar II disorder is ongoing in this multisite, double-blind, placebo-controlled parallel group trial. Approximately 63% of the 150 total subjects have been enrolled in the U.S. and 95 of such subjects have completed the clinical trial. In July 2023, we stopped activities in the European region as enrollment and site recruitment was unproductive. Similar to our registration trials in schizophrenia and bipolar disorder (SERENITY I and II), the primary endpoint is the change from baseline PEC total score at two hours. The U.S. portion of this program remains active following the Reprioritization.

In October 2024, we submitted a request to the FDA for an extension and plan to submit an updated trial protocol to complete enrollment requirements for pediatric patients with schizophrenia or schizoaffective disorder. The FDA granted a 3-year extension to complete the pediatric study.

IGALMI® Post-Marketing Requirement Study

On June 25, 2024, we announced positive topline results from our post-marketing requirement study evaluating whether tolerance, tachyphylaxis, or withdrawal occur following repeat dosing of the 180 mcg (highest approved dose) of IGALMI®. This study was a single-arm, open-label study of 28 inpatient adults with frequent episodes of agitation associated with bipolar disorders or schizophrenia who self-administered 180 mcg dose of IGALMI® as needed over seven days. A total of 83 episodes were treated. The study achieved its objective and demonstrated no evidence of tachyphylaxis, tolerance, or withdrawal, and IGALMI® was generally well tolerated during the study.

Additional Neuroscience Opportunities

BXCL501 Pipeline Opportunities for Franchise Expansion

Given the differentiated design of BXCL501 and its selective mechanism of action, we believe BXCL501 has the potential for broad applicability across several indications where agitation is a symptom of a condition or underlying disease.

Government-Supported Investigator-Sponsored Trial Programs

The Company has been awarded key opportunities for the development of BXCL501 in post-traumatic stress disorder ("PTSD"), alcohol use disorder ("AUD"), and opioid use disorder ("OUD"). These are being funded through Cooperative Agreements with the U.S. Department of Defense Congressionally Directed Medical Research Program and National Institute on Drug Abuse ("NIDA"). Clinical and regulatory responsibilities are led by clinical researchers and regulatory staff at the Veterans Affairs Connecticut Healthcare System, Yale University Medical School, RTI International, Columbia University New York State Psychiatric Institute, and NIDA.

Opioid Use Disorder Program

As previously announced, NIDA awarded a grant to Columbia University to fund clinical testing of BXCL501 as a potential treatment for opioid withdrawal in patients diagnosed with OUD. The original 160-patient, three-site, four-arm study is a randomized, double-blind, double-dummy inpatient study comparing BXCL501 (180 mcg and 240 mcg BID), lofexidine (as a positive control), and placebo. The study's goal is to evaluate the safety and efficacy of BXCL501 relative to lofexidine and placebo in subjects with OUD. A majority of OUD patients participating in the study are anticipated to be exposed to fentanyl adulterated or associated with xylazine. To date, all three initial sites have recruited, enrolled, and dosed patients diagnosed with OUD who are physically dependent on opioids, including prescription opioids. The Company is supplying BXCL501 for the conduct of this study, which is sponsored by Columbia University. We expect that the results from current study will be used to select a recommended dose of BXCL501 to compare to placebo in a later outpatient Phase 3 study sponsored by NIDA.

On November 6, 2023, we announced that NIDA requested Columbia University, the trial coordinator, to add a fourth site to expedite trial completion. The patient screening and enrollment process for the fourth site commenced in March 2024, a potential mid-study readout anticipated in the first half of 2025. Subject to favorable results and available funding, we plan to seek FDA feedback on potential registrational paths.

Alcohol Use Disorder with Comorbid Post-traumatic Stress Disorder Program

In December 2020, the Veterans Affairs Connecticut Healthcare System and Yale University Medical School were awarded a grant by the U.S. Department of Defense's Congressionally Directed Medical Research Program with the overall objective to evaluate BXCL501 in patients who suffer from AUD with comorbid PTSD. The Company provided BXCL501 for the inpatient Alcohol Interaction Study, which has been completed. We understand Yale is currently seeking approval from its Institutional Review Board ("IRB") and allowance from the FDA to proceed with a trial

evaluating the effects of up to 80 mcg BID of BXCL501 per day for 28 days on alcohol consumption, PTSD symptoms, cognitive function, memory, sleep, and mood in patients diagnosed with mild, moderate, or severe AUD and who meet Criterion A for comorbid PTSD. The new outpatient study has received funding approval from the Pharmacotherapies for Alcohol and Substance Use Disorders Alliance (funded through a Cooperative Agreement between the U.S. Department of Defense Congressionally Directed Medical Research Program and RTI International). Patient screening and enrollment began in the fourth quarter of 2024. We believe the results from this study may be used to inform a Phase 3 study intended to commence with support by the alliance.

Acute Stress Disorder (ASD) Program

On October 15, 2024, we announced a U.S. Department of Defense grant to the University of North Carolina ("UNC") to fund a study of BXCL501 for treating ASD. The award provides $2,800 to the UNC Institute for Trauma Recovery from September 15, 2024 through September 14, 2026 to evaluate the potential efficacy of BXCL501 to reduce ASD symptom severity and/or posttraumatic neuropsychiatric symptoms. The double-blind, placebo-controlled trial is expected to enroll 100 patients experiencing ASD resulting from motor vehicle collisions, beginning in the first half of 2025. We intend to supply BXCL501 for the trial.

BXCL502 Development

We identified a second neuropsychiatric drug candidate, BXCL502 − Latrepirdine (Dimebon) − through our AI-based platform. We plan to evaluate BXCL502 initially as a monotherapy and possibly in combination with BXCL501 for the chronic treatment of agitation in patients with dementia and acute stress disorder. The active pharmaceutical ingredient ("API") underlying BXCL502 affects serotonergic signaling in the brain. Our preclinical data suggests BXCL502 has the potential to treat stress-related neuropsychiatric symptoms in dementia and other stress-related disorders. In previously published third-party clinical trial data, daily administration of the API of BXCL502 demonstrated improvement in behaviors using a well-established, clinically validated symptom scale. Formulation and further clinical development planning for BXCL502 was paused as part of the Reprioritization.

Other Product Candidates Leveraging the AI Platform

Our AI platform is comprised of a series of customized and specific AI applications aimed at identifying, predicting efficacy and testing of late-stage assets with known mechanisms of action and associated pharmacology and safety data. We target neuropsychiatric and neurological rare disorders, where the compounds are either disease-modifying or symptom-mitigating. Compounds are tested in relevant models of disease and rank-ordered based on the potential to enter the clinic and ease of development. Disease areas of interest are stress related such as agitation, or neuropsychiatric symptoms associated with dementia and responsible for increased levels of healthcare burden. For example, our pipeline concepts BXCL503 and BXCL504 putatively have the potential to address apathy and aggression in dementia, respectively. These programs were also paused as part of the Reprioritization.

Neuroscience Competition

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. The neuroscience and rare disease segments of the industry are highly competitive. While we believe that our technology, development experience, and scientific knowledge provide competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, and biotechnology companies, academic institutions, governmental agencies, and public and private research institutions.

Many of our competitors may have significantly greater financial resources, and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals, and marketing approved medicines than we do. Mergers and acquisitions in the pharmaceutical, biotechnology, and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and in establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies

complementary to or necessary for our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, if any, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, more convenient, less expensive, or have fewer or less severe side effects than any medicines we may develop. Our competitors also may obtain FDA or other regulatory approval for their medicines more rapidly than us, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic medicines. There are many generic medicines currently on the market for certain indications that we are pursuing, and additional generics are expected to become available over the coming years. We expect that any of our therapeutic product candidates that are approved will be priced at a significant premium over competitive generic medicines.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. IGALMI® and any of our other product candidates that are approved, if any, will compete with the drugs discussed below, in addition to any other drugs currently in development.

Drugs used for the acute treatment of agitation related to schizophrenia and bipolar disorder are antipsychotics frequently administered via IM injection that typically requires patient restraint. These include IM aripiprazole, olanzapine, ziprasidone, and haloperidol. Oral products include the sublingually administered atypical antipsychotic Asenapine, as well as benzodiazepines, lorazepam, and midazolam. The typical antipsychotic Adasuve® (loxapine) from Alexza is delivered via inhalation.

Neuroscience Manufacturing

We do not have manufacturing facilities. We currently rely on strategic manufacturing partners, in particular ARx, LLC ("ARx"), and expect to continue to rely on third parties for the manufacture of our product candidates for clinical research and our products for commercialization efforts. ARx has agreed to exclusively manufacture and supply our supply of film formulation of dexmedetomidine to be used for the commercial supply of IGALMI® and for ongoing clinical trials of BXCL501, subject to certain alternative supply provisions.

BXCL501 drug product is manufactured using commercially available components and packaging materials. The equipment employed for manufacturing and analysis is consistent with standard pharmaceutical production.

Neuroscience Commercialization

We plan to retain worldwide commercialization rights for IGALMI® and other approved product candidates, if any, but could consider collaboration opportunities to maximize returns or facilitate commercialization efforts in foreign jurisdictions. For additional information regarding our commercialization efforts for IGALMI®, see above under "IGALMI® Commercial Strategy."

As product candidates advance through our pipeline, our commercialization plans may change. Clinical data, the size of the development programs, the size of the target market, the required commercial infrastructure, and manufacturing needs may all influence global commercialization strategies.

Neuroscience Intellectual Property

Our policy is to protect and enhance the proprietary technologies, inventions, and improvements that are commercially important to our business by filing patent applications in the U.S. and other jurisdictions related to our proprietary technology, inventions, improvements, and product candidates. We also rely on trademarks, trade secrets,

and know-how relating to our proprietary technologies and product candidates, continuing innovation, and in-licensing technology and products. This reliance is expected to develop, maintain, and strengthen our proprietary position for novel therapeutics and novel formulations of existing therapeutics across multiple therapeutic areas. We also plan to rely on data exclusivity, market exclusivity, and patent term extensions when available.

We have multiple patent families filed to protect our Neuroscience program, including BXCL501. As of February 20, 2025, our neuroscience patent portfolio included five Patent Cooperation Treaty ("PCT") applications not yet in national phase, 13 U.S. utility applications, 16 issued U.S. utility patents, 76 pending non-U.S. utility applications, 24 allowed or granted non-U.S. patents (including four in Japan), one pending U.S. design patent application, and 39 allowed or registered design patents (including two in Japan). Thirteen U.S. utility patents, directed to our proprietary sublingual film formulation of Dex and methods of treating agitation, are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") for IGALMI® with expiration dates between 2037 and 2043. In the formulation family, we have granted or allowed patents in China, Europe, Eurasia, Japan, Mexico, and the U.S., and pending applications in the U.S., China, and other major markets. We expect that patents issued in this family will expire no earlier than 2039. We have also filed applications in additional patent families that are relevant to BXCL501. We have one granted European patent and applications pending in the U.S. and Japan directed to methods of treating insomnia using sublingual Dex. We expect that patents issued from these applications, will expire no earlier than 2035. We also have granted patents and pending applications filed in major markets, including the U.S., Europe, Japan, and China, directed to methods of treating agitation. We expect that patents issued from these applications, will expire between 2039 and 2043. We also have four PCT applications directed to treating mania, depression, stress and agitation. If patents are issued from those cases, we expect them to expire in 2043 or 2044.

In August 2024, the Company received a Notice of Allowance from the U.S. Patent and Trademark Office ("USPTO") for U.S. Patent Application No. 18/600,431 (the "'431 Application"). The '431 Application claims methods of treating agitation using an oromucosal formulation of dexmedetomidine. The '431 Application issued as U.S. Patent No. 12,138,247 (the '247 Patent) patent, issued on November 2024, and is expected to expire no earlier than January 12, 2043. The '247 Patent is listed in the Orange Book for IGALMI®.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. Depending upon the timing, duration, and specifics of FDA approval of our product candidates, a U.S. patent that we own or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a., the "Hatch-Waxman Act"). The act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the drug approval regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND, and the submission date of a new drug application ("NDA"), plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension, and the application for extension must be made prior to patent expiration. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

The term of a patent can also be extended by PTA established in 35 U.S.C. 154(b). The intention of the PTA is to accommodate for delays caused by the USPTO during the prosecution of a US utility or plant patent application. Under PTA, the USPTO delay is divided into three types: type A (delays after 14 months from the filing date of the application until the USPTO issues a first Office Action and delays after four months from the filing of certain actions by the applicant until the USPTO responds to such actions); type B (delays after three years from the earliest effective filing date until a patent is granted); and type C (delays due to interferences, secrecy orders, and successful appeals). The total amount of PTA is calculated by adding the types A, B, and C delays, and then subtracting any delay that is overlapped among three types or that is attributable to the applicant.

The term of a patent can also be shortened by a terminal disclaimer. A terminal disclaimer is a statement filed by a patent owner in which the owner disclaims or dedicates to the public the terminal part of the term of a patent. Often, the terminal disclaimer is filed in cases where at least one claim of a pending application would have been obvious in light of at least one claim in an earlier-filed patent, (or non-statutory obviousness-type double patenting rejection).

The patent positions of companies such as ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of method of use patents or reformulation patents has emerged in the U.S. patent laws and their interpretation outside of the U.S. are also uncertain. Changes in either the patent laws or their interpretation in the U.S. and other countries may diminish our ability to protect our technology or product candidates and enforce the patent rights that we license, and also could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions, and improvements. With respect to both licensed and company owned intellectual property, we cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use, or the manufacture of those products. In addition, if a pending patent application is granted, it is possible that only a subset of the claims that are currently contained in the pending patent application will be issued. Further, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing our product candidates and practicing our proprietary technology, and the issued patents that we in-license and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies outside the scope of the rights granted under any issued patents that we own or exclusively in license. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides. For additional information regarding intellectual property regulations and risks, see below under “Immuno-Oncology Intellectual Property” and Part I, Item 1A, “Risk Factors - Risks Related to Our Intellectual Property.”

Immuno-Oncology

On April 19, 2022, we announced the formation of a wholly owned subsidiary, OnkosXcel to develop potentially transformative medicines in oncology. OnkosXcel uses proprietary AI capabilities to drive the capital-efficient development of innovative anti-cancer therapeutics. On March 14, 2023, we announced that OnkosXcel had confidentially submitted a draft registration statement on Form S-1 with the SEC relating to the proposed initial public offering of its common stock following its conversion into a corporation. The Company is continuing to evaluate strategic options for OnkosXcel. With the Company’s Reprioritization announcement on August 14, 2023, further work on the immuno-oncology programs described below has generally been paused, except as noted below.

Our approach to drug discovery leverages the application and methodology of our proprietary AI-based research and development platform, complemented by EvolverAI, utilized in the successful development of IGALMI® with the aim of efficiently identifying and developing immuno-oncology product candidates. We believe that BXCL701 reflects the potential of this discovery approach in immuno-oncology. BXCL701 is an investigational, oral innate immune activator which demonstrated a 25% composite response rate in a Phase 2a clinical trial to treat patients with small cell neuroendocrine carcinoma (“SCNC”) phenotype metastatic castration-resistant prostate cancer (“mCRPC”). On February 12, 2024, the Company announced that the FDA has designated as a Fast Track development program the investigation of BXCL701 in combination with a checkpoint inhibitor for the treatment of patients with metastatic SCNC with progression on chemotherapy and no evidence of microsatellite instability. We have finalized a potential

registrational trial design in mCRPC patients with SCNC phenotype, however in light of our Clinical Prioritization, we have not met with the FDA to discuss this, nor plan at the current time to initiate this trial.

mCRPC is often characterized as a “cold” tumor, which is a tumor with an immunosuppressive tumor microenvironment (“TME”) and poor immune cell infiltration. Currently approved checkpoint inhibitors (“CPIs”) that target programmed cell death 1 (“PD-1”) or cytotoxic T-lymphocyte-associated protein 4 (“CTLA-4") have failed to demonstrate meaningful single-agent activity against such difficult-to-treat tumor types, including mCRPC. BXCL701 is designed to promote an immune-induced inflammatory response in the TME primarily via inhibition of dipeptidyl peptidases (“DPP”) 8 and 9, which we believe can provide enhanced CPIs therapeutic utility. We believe BXCL701 can potentially provide significant benefits for the approximately 20% of the estimated 299,010 men who will be diagnosed with prostate cancer in the U.S. in 2024 and are expected to progress to the more aggressive mCRPC form of the disease, including approximately 20%, or 11,960, of those patients who will develop the SCNC phenotype, for which there are currently limited treatment options. Immune checkpoints represent a myriad of inhibitory pathways that act to regulate the duration and intensity of an antigen-induced immune response and factor prominently in mediating immune tolerance. They function as critical gatekeepers that prevent the indiscriminate attack of normal host cells by components of the immune system. Certain cancers co-opt these pathways and overexpress immune checkpoint molecules to camouflage themselves to avoid detection and destruction. CPIs, designed to harness the intrinsic power resident in the immune system, work by disabling the suppressive function of immune checkpoints, allowing the immune system to bypass such cancers’ shield of immune tolerance. CPIs are expected to generate sales of more than $50 billion worldwide by 2025, up from sales of approximately $29 billion in 2020. While CPIs have proven to be a significant advancement in cancer therapy, those currently approved by the FDA do not produce meaningful results in a majority of patients, as the clinical benefit is generally viewed to be limited to between 13% and 30% of cancer patients, and the duration of response is relatively short.

We believe the limited efficacy of approved CPIs results primarily from their intervention at later stages of the immune response. As a result, other targets and pathways can be exploited by the tumor to create a TME that can evade the enhanced immunological response enabled by approved CPIs. While numerous agents designed to target the earlier stages of an immune response are in development for use in combination with CPIs, their activity is restricted to a single component of the immune response. In contrast, we have developed BXCL701 to simultaneously address multiple components of the immune response, including:

- *Cancer antigen presentation by dendritic cells*: stimulation of dendritic cell trafficking to tumor draining lymph nodes.
- *Priming and activation of T cells*: acceleration of tumor-induced priming of T cells and the formation of potent cytotoxic T lymphocytes (“CTLs”).
- *Infiltration of immune cells into the tumor*: stimulation of release of chemokines that attract effector T cells but block regulatory T cells, and also induce NK cell and neutrophil migration.
- *Killing of tumor cells*: induction of formation of CTLs and NK cells expressing tumor-killing perforins and granzymes, as well as the formation of memory T cells that can selectively kill returning tumor cells.

Accordingly, we believe BXCL701 may have utility in stimulating increased activation, proliferation, and infiltration of tumor cells by immune effector cells, enabling its potential application in combination with currently approved CPIs, across a range of solid tumors and hematological malignancies, to potentially:

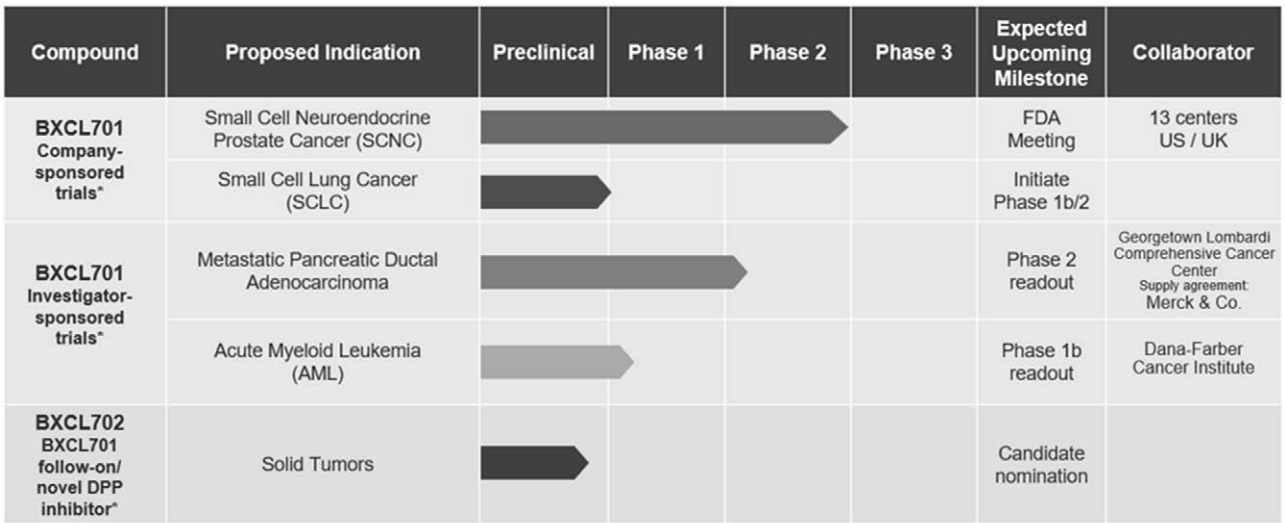
- *Convert immunological cold tumors into ones sensitive to CPIs;*
- *Enhance hot tumors’ response rate and depth of response to CPIs; and*
- *Restore CPI sensitivity to tumors that were previously responsive.*

Central to our drug discovery initiatives are proprietary, AI-driven platform technologies we employ to identify novel therapeutic uses for approved therapeutics and candidates in clinical evaluation. The first and most advanced of

our AI-driven discovery programs is our innate immune modulation program, which supported the pursuit of BXCL701 as a development candidate. We believe the application of this program provides us actionable insights into the inflammasome, a component of the innate immune system responsible for activation of the inflammatory response.

Our Immuno-Oncology Programs

Below is a summary of the status of our immuno-oncology clinical development programs as of the date of this Annual Report on Form 10-K. We believe our product candidates, if successfully developed and approved, have the potential to become compelling treatment options for their respective indications. With our Reprioritization announced on August 14, 2023, further work on our immuno-oncology program has been paused, other than as noted below.



*The safety and efficacy of these investigational agents have not been established.

Immuno-Oncology Clinical Trials

Leveraging the insights enabled by the application and methodology of our proprietary AI-based platform complemented by EvolverAI, which was used to identify novel therapeutic uses for our approved therapeutics and product candidates in clinical evaluation, and our industry expertise, we are pursuing two proprietary discovery programs to advance our goal of developing anti-cancer therapeutics. The first program, which encompasses BXCL701 across a range of indications, is based on the application of innate immune modulation technology. This program has been constructed to embrace key distinguishing characteristics of the innate immune system and we believe it is supported by our development efforts. This approach has driven the development of BXCL701, which we are currently evaluating in a Phase 1b/2a clinical proof-of-concept trial as a potential treatment for mCRPC with either SCNC or adenocarcinoma phenotype. Fundamental to the innate immune modulation program is BXCL701's potential to:

- Convert cold tumors into ones sensitive to CPIs;
- Enhance hot tumors' response rate and depth of response to CPIs; and
- Restore CPI sensitivity to tumors which had previously been responsive.

BXCL701 as a Potential Treatment for mCRPC

Prostate cancer is the most common malignancy and the second-leading cause of cancer-related deaths in men in the U.S. According to the American Cancer Society, approximately 299,010 men will be diagnosed with, and 35,250 men will die of, prostate cancer in 2024. The majority of these cases are classified as adenocarcinomas and involve low risk, localized or regional disease for which the five-year survival rate ranges from 60% to 99%. However, an estimated 20%

of these newly diagnosed cases will progress to the more aggressive metastatic disease. The five-year survival rate for men with metastatic prostate cancer drops significantly, to approximately 30%. Approximately 20% of patients with mCRPC will develop the SCNC phenotype, which is characterized by poor prognosis and low survival rate with a five-year life expectancy of 14%.

Prostate function requires the presence of various androgens, such as testosterone. Early cancerous prostate cells typically also require androgens to proliferate. Accordingly, aggressive forms of prostate cancer can initially be treated using androgen deprivation therapy ("ADT"). While ADT offers temporary therapeutic benefit, in almost all patients the treatment eventually loses efficacy, referred to as "castration resistance." Cases of castration-resistant prostate cancer ("CRPC") are generally treated with a second-generation androgen receptor ("AR") inhibitor, such as XTANDI® (enzalutamide), or an androgen synthesis inhibitor, such as ZYTIGA® (abiraterone), which targets the enzyme CYP17 to block the production of testosterone. These therapeutics have widely become the standard of care, though only ZYTIGA has been approved to treat mCRPC, as well as metastatic high-risk castration-sensitive prostate cancer. XTANDI has been approved to treat CRPC and metastatic castration-sensitive prostate cancer.

Virtually all patients who initially respond to ZYTIGA and XTANDI are expected to progress to even more aggressive forms of prostate cancer requiring further treatment. Patients whose disease has progressed after treatment with these second-generation targeted endocrine therapies are administered a docetaxel containing drug regimen that provides a survival benefit of only 10 months. The poly-ADP ribose polymerase ("PARP") inhibitors LYNPARZA® (olaparib) and RUBRACA® (rucaparib) are approved for the treatment of mCRPC in patients whose disease has progressed after receiving XTANDI or ZYTIGA, but their approval is limited to instances of mCRPC linked to a BRCA gene mutation. As such, an unmet medical need remains for patients with mCRPC who are not eligible for PARP inhibitor treatment after treatment with the targeted endocrine therapy and docetaxel.

In addition, a number of men, both newly diagnosed patients and men whose disease has progressed after second-generation targeted endocrine therapy, will develop an aggressive tumor that typically expresses very little AR and accordingly does not respond to therapeutics targeting the AR signaling pathway. Prostate cancer with this phenotype is referred to as SCNC, for which there is currently no effective treatment. The incidence of SCNC is increasing with the widespread use of AR inhibitor therapy. Treatment protocols for patients with SCNC typically involve cytotoxic chemotherapies despite their short duration of response and considerable toxicities. These patients represent an additional unmet medical need among men with prostate cancer. We believe BXCL701 may prove efficacious in addressing the unmet needs of both adenocarcinoma and SCNC prostate cancer phenotypes.

mCRPC is often characterized as a cold tumor, or a tumor with an immunosuppressive TME and poor immune cell infiltration. Currently approved CPIs, which target PD-1 and CTLA-4, have not demonstrated significant single-agent therapeutic activity. For instance, a Phase 2 investigator sponsored trial ("IST") to assess the efficacy of the PD-L1 inhibitor avelumab, marketed by EMD Serono and Pfizer as BAVENCIO®, to treat mCRPC with SCNC phenotype, as well as aggressive variant prostate cancer with adenocarcinoma histology, generated an ORR of 6.7% (representing 1 of 15 patients who was known to be microsatellite instability-high, an established marker of response to CPIs).

We believe the limited efficacy of CPIs results primarily from their intervention at later stages of the immune response. As a result, other targets and pathways can be exploited by the tumor to create a TME that can evade the enhanced immunological response enabled by approved CPIs. BXCL701 is designed to act on multiple components of immune system functioning, including:

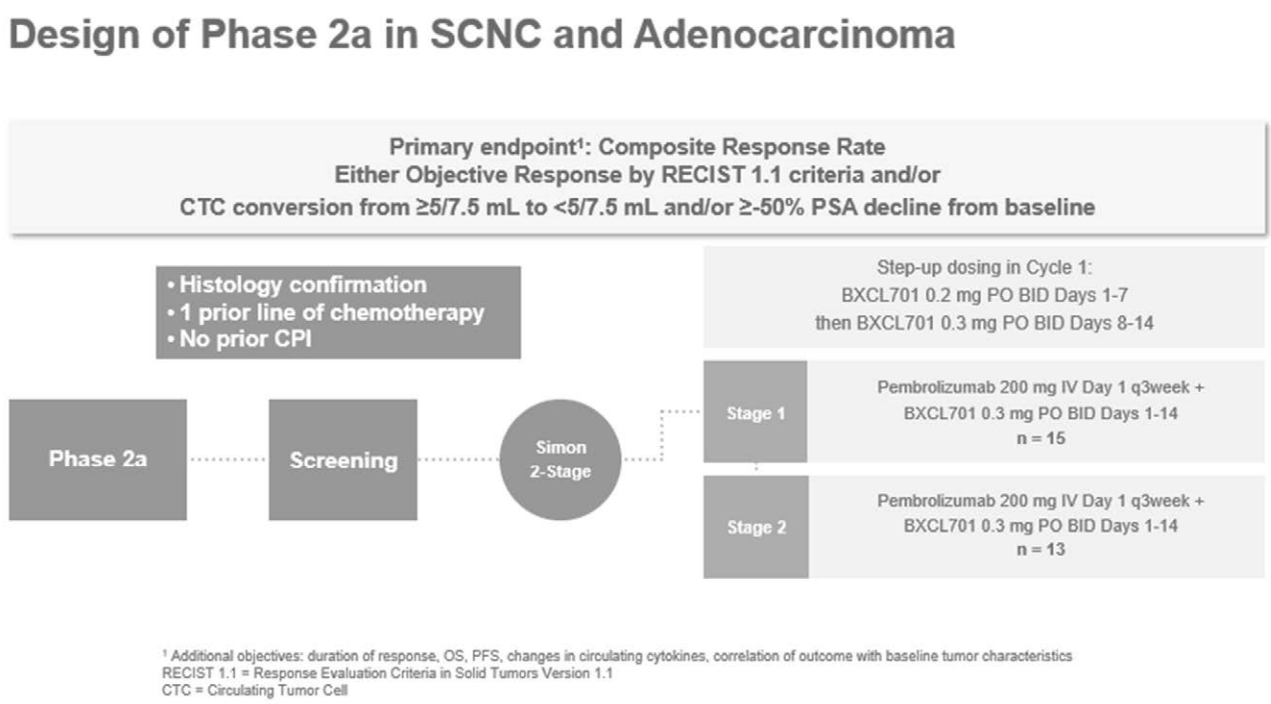
- *Cancer antigen presentation by dendritic cells*: stimulation of dendritic cell trafficking to tumor draining lymph nodes.
- *Priming and activation of T cells*: acceleration of tumor-induced priming of T cells and the formation of potent CTLs.
- *Infiltration of immune cells into the tumor*: stimulation of release of chemokines that attract effector T cells but block regulatory T cells and also induce NK cell and neutrophil migration.

- *Killing of tumor cells*: induction of formation of CTLs and NK cells expressing tumor-killing perforins and granzymes as well as the formation of memory T cells that can selectively kill returning tumor cells.

We believe BXCL701 may have utility in stimulating increased activation, proliferation, and infiltration of tumor cells by immune effector cells, enabling its potential use in combination with currently approved CPIs to treat cold tumors, such as mCRPC. We elected to pursue mCRPC as an indication for BXCL701 due to its enrichment for DPP mutations, which are especially prevalent in tumors with SCNC phenotype.

BXCL701 has been evaluated in a Phase 1b/2a clinical proof-of-concept trial that we sponsored to investigate its potential efficacy when used in combination with pembrolizumab. Enrollment in this trial is complete, and the data are described below.

We received initial comments from the FDA on our proposed clinical development plan and received feedback regarding dose-optimization for use in future studies. However, the start of any such additional trial is paused following the Company's Reprioritization. The Phase 1b portion of our Phase 1b/2 clinical trial was a dose escalation safety lead-in which employed a standard 3 x 3 trial design to determine the recommended Phase 2 dose ("RP2D"). During each 21-day treatment cycle, 200 mg of pembrolizumab were administered intravenously on day one, with BXCL701 taken twice daily on days one through 14, for a minimum of two cycles. The results of this Phase 1b trial, which were presented at The Society for Immunotherapy of Cancer's 35th Anniversary Annual Meeting, allowed us to identify 0.3 mg, taken twice daily, as the RP2D.

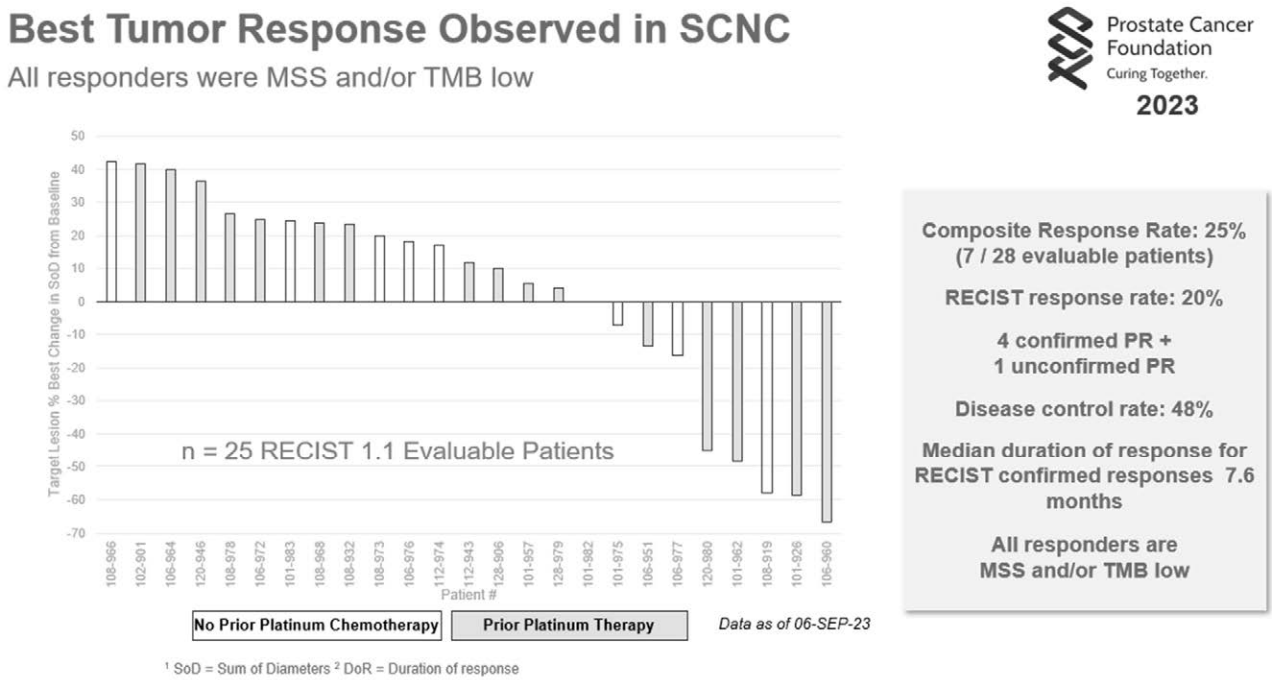


The Phase 2a portion of the trial was segregated into two 28-patient trial cohorts, one cohort consisting of mCRPC patients with SCNC phenotype and a second cohort consisting of mCRPC patients with adenocarcinoma phenotype. Initially, we focused on mCRPC with SCNC phenotype as the primary patient population for BXCL701, since DPP9 is amplified in approximately 17% of treatment-emergent mCRPC with SCNC phenotype, compared to 5% or less in the broader prostate cancer population. However, we also observed responses in mCRPC patients with adenocarcinoma phenotype who were microsatellite stable in the Phase 1b portion of the trial. On this basis, we widened our Phase 2a trial to include relapsed mCRPC patients with either SCNC or adenocarcinoma phenotype. Both cohorts employed a Simon two-stage trial design of 15 trial participants followed by 13 additional patients. The primary endpoint of the Phase 2a portion of this trial was a composite response rate, determined as either a RECIST 1.1 response (defined as a

reduction in RECIST score of 30% or more), and/or a reduction in prostate specific antigen ("PSA") level of 50% or more, and/or a conversion in circulating tumor cells ("CTCs") from 5 or more CTCs/7.5 milliliter ("ml") to less than 5 CTCs/7.5 ml. Secondary endpoints included duration of response, progression-free survival, overall survival, changes in circulating cytokines, and certain disease-specific biomarkers.

We believe the results observed in the Phase 2a trial of BXCL701 administered in combination with pembrolizumab support further development.

We were particularly encouraged by the results observed in the cohort consisting of mCRPC patients with SCNC phenotype. Updated Phase 2a results for the SCNC cohort were presented at the 30th Annual Prostate Cancer Foundation Scientific Retreat (PCF 2023). BXCL701 in combination with pembrolizumab demonstrated a 25% (seven out of 28 evaluable patients) composite response rate in mCRPC patients with SCNC phenotype, for whom there is no standard of care. As of a data cutoff of September 6, 2023, five of these responders were RECIST 1.1 responders (four confirmed responses and one unconfirmed response) with decreases in tumor size ranging from -45% to -67% and a median duration of response of 7.6 months.



AEs consistent with cytokine activation, including fever, nausea, chills, fatigue, headache, and dizziness were observed during the trial and were generally mild to moderate. SAEs experienced by six trial participants - one patient hospitalized with Grade 1 orthostatic hypotension, one patient hospitalized with Grade 3 hypotension and acute kidney injury ("AKI"), which resolved, one patient with Grade 3 hypothyroidism which resolved, one patient with Grade 3 colitis, one patient with Grade 3 generalized oedema, and one patient hospitalized with Grade 4/5 tumor lysis syndrome/AKI, which resulted in fatality after the patient voluntarily discontinued dialysis - were reported as related or possibly related to BXCL701 or pembrolizumab, though there was no evidence that BXCL701 potentiated immune-related AEs associated with CPIs. The table below summarizes treatment-related AEs observed in the SCNC cohort as of December 19, 2022.

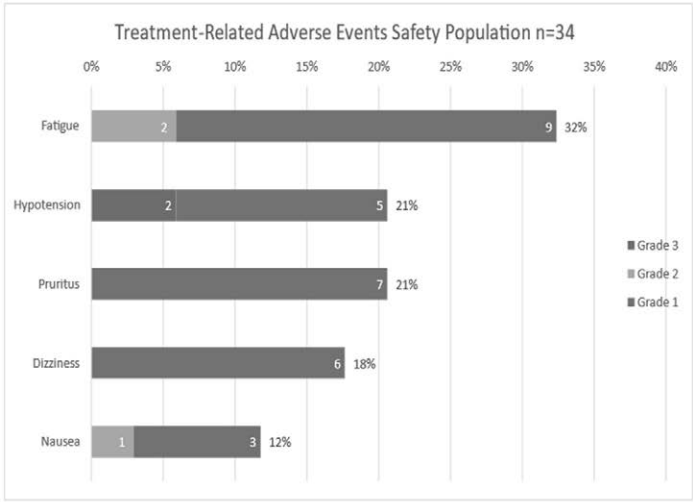
SCNC Safety Results

Prostate Cancer Foundation
Curing Together.
2023

Treatment-Emergent Adverse Events	n = 34 n (%)
Any Grade	**33** (97)
Attributed to BXCL701	***29** (85)*
Attributed to Pembrolizumab	***23** (68)*
Grade 3	**16** (47)
Grade 4	**0** (0)
Grade 5	**1** (3)*
AE Leading to Treatment Discontinuation	**6** (18)
Attributed to BXCL701	***6** (18)*
Attributed to Pembrolizumab	***5** (15)*
Immune Related Adverse Events	
Any Grade	**14** (41%)
*Grade ≥ 3^*	***1** (7%)*

* Grade 5 tumor lysis
^ Grade 3 colitis (resolved)

n = number of patients experiencing an AE

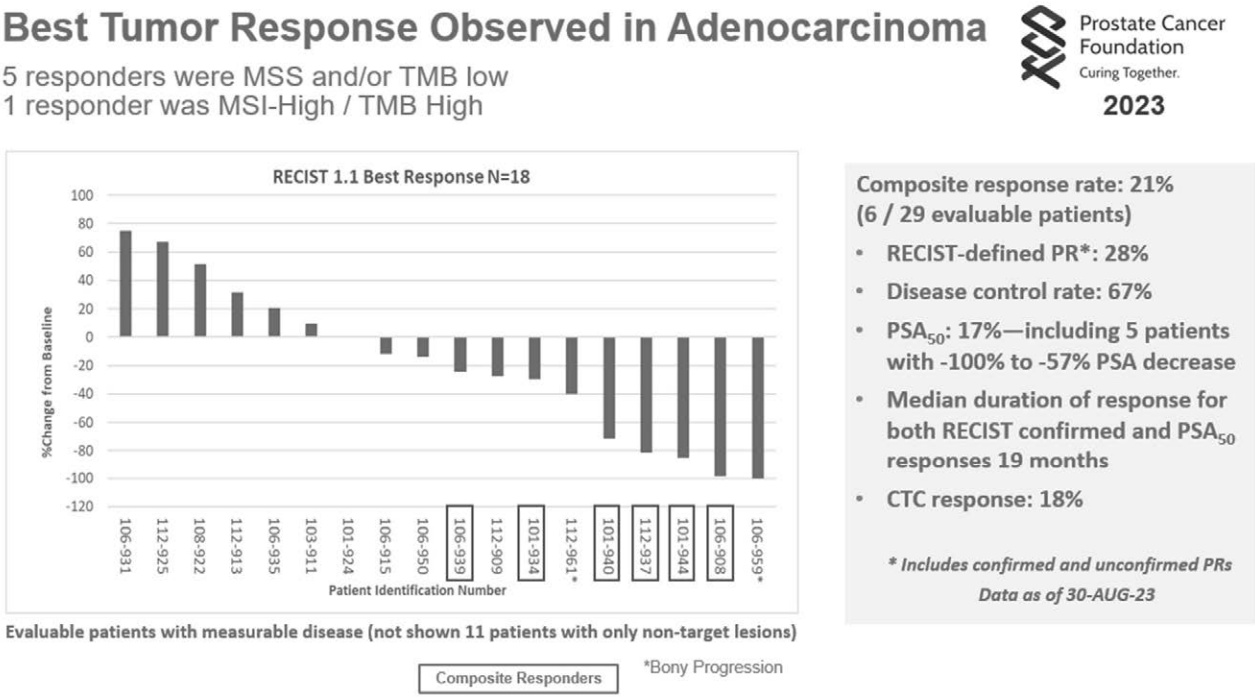


TRAEs at least possibly related to BXCL701 or pembrolizumab, occurring in >10% of patients

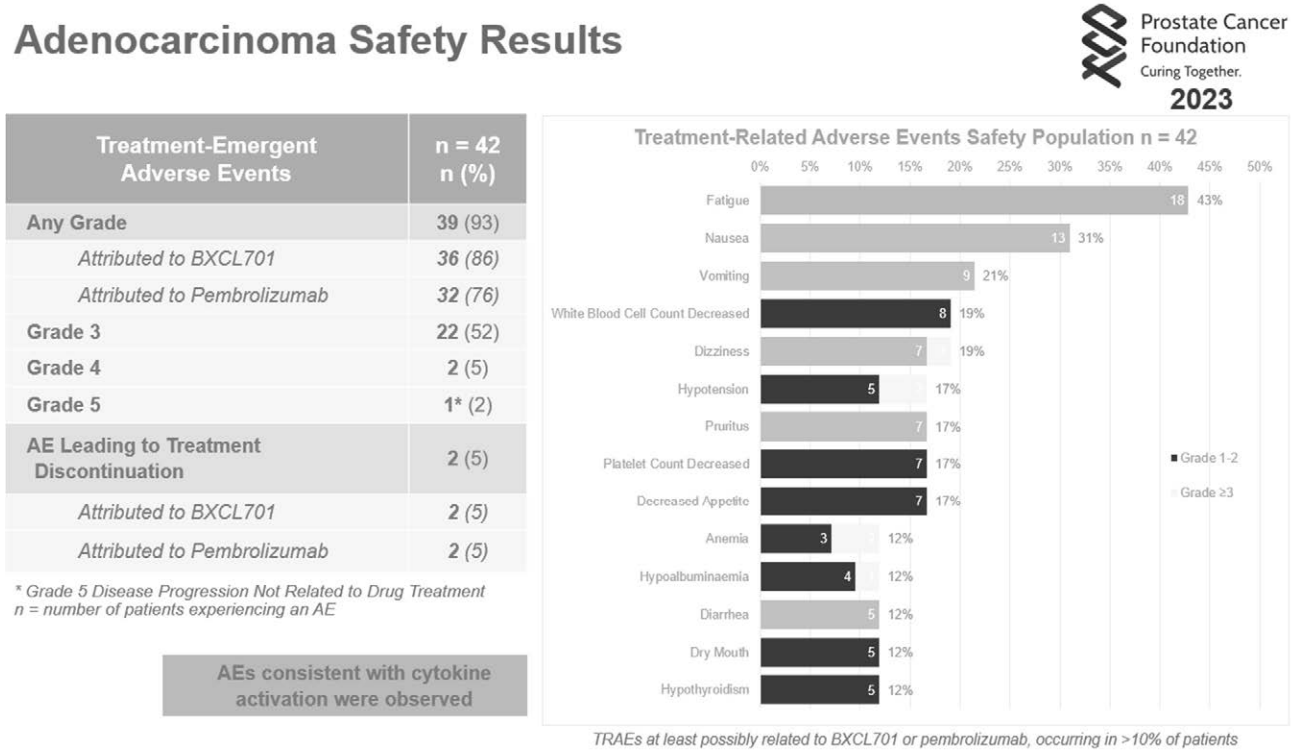
On October 10, 2023, we reported positive overall survival (OS) results from the Phase 2a portion of the trial in SCNC patients. BXCL701 in combination with pembrolizumab demonstrated a compelling median OS and 12-month survival rate. As of a data cutoff of September 6, 2023, evaluable patients with SCNC (n = 28) showed a median OS of 13.6 months (95% CI 10.9–NR), and a 12-month survival rate of 56.5%.

On February 12, 2024 the Company announced that the FDA designated as a Fast Track development program the investigation of BXCL701 in combination with a checkpoint inhibitor for treatment of patients with metastatic SCNC with progression on chemotherapy and no evidence of microsatellite instability.

The Phase 2a trial has also been completed for the adenocarcinoma cohort. Updated results for this trial cohort were also presented at PCF 2023. BXCL701 in combination with pembrolizumab demonstrated a 21% (six out of 29 evaluable patients) composite response rate in mCRPC patients with adenocarcinoma phenotype, for whom there are limited treatment options. As of a cutoff date of September 6, 2023, five of these composite responders were RECIST 1.1 responders (four confirmed responses and one unconfirmed response) with decreases in tumor size ranging from -30% to -99% and a median duration of response to 19 months.



As of the cutoff date of December 19, 2022, the majority of AEs experienced by patients in the adenocarcinoma cohort were low grade. AEs consistent with cytokine activation were observed, including fever, myalgia, nausea, chills, fatigue, dyspnea, headache and dizziness. SAEs experienced by five patients (12%) were reported as possibly related to BXCL701 or pembrolizumab: two reports of hypotension; one report of dizziness; one report of peripheral edema; one report of pyrexia; one report of Myasthenia Gravis; and one report of Cytokine Release Syndrome. Two patients (5%) discontinued therapy due to AEs. There was no evidence that BXCL701 potentiated immune-related AEs related to CPIs. The table below summarizes treatment-related AEs observed in the adenocarcinoma cohort.



On November 8, 2023, we reported positive OS results from the Phase 2a portion of the trial in patients with adenocarcinoma. As of a data cutoff of September 6, 2023, among evaluable patients with adenocarcinoma (n = 29) BXCL701 in combination with pembrolizumab demonstrated a median OS of 15.5 months (95% CI 9.6–NR), and a 12-month survival rate of 59.3%.

BXCL701 as a Potential Treatment for Small Cell Lung Cancer ("SCLC")

The American Cancer Society estimates that in 2024, about 35,187 cases of SCLC will be diagnosed in the U.S. Approximately 60-70% of these patients present with extensive disease, and first-line therapy for a majority of these patients involves the combination of a CPI with platinum-based chemotherapy or etoposide.

We are encouraged by the therapeutic potential of BXCL701 for SCLC given the activity it has demonstrated in the ongoing SCNC clinical trial. We are preparing the protocol for a Phase 1b/2 trial design to be a dose-escalation safety lead-in to establish a RP2D. However, the start of any such trial is paused following the Reprioritization.

BXCL701 as a Potential Treatment for Other Cancers

In addition to its potential use in combination with CPIs to treat mCRPC, an immunologically cold tumor, we are developing BXCL701 as a therapeutic for pancreatic cancer, and other solid tumors with greater, or "non-cold," immunological activity that are nonetheless regarded as difficult-to-treat, and hematological malignancies. We believe the synergistic potential of BXCL701 and CPIs, when administered in combination, could increase cancer cell susceptibility to an enhanced immune response, potentially increasing the clinical benefit of CPIs, whose single-agent efficacy in treating these tumor types is generally viewed to be limited to between 13% and 30% of cancer patients and the duration of response to treatment is often short. As such, we envision the potential therapeutic benefit of BXCL701 increasing the sensitivity of cold tumors to CPI therapy, enabling the potential treatment of a range of cancers including pancreatic cancer, breast cancer, colorectal cancer, and ovarian cancer, as well as enhancing the depth of response to CPIs in other cancers. In addition, based on the preclinical observation that BXCL701 showed direct cytotoxic activity

against certain leukemic cells, we have initiated clinical development targeting relapsed or refractory acute myeloid leukemia ("AML").

Pancreatic Cancer

The American Cancer Society estimated that in 2024, approximately 66,440 cases of pancreatic cancer were expected to be diagnosed in the U.S. We are supporting a Phase 2 investigator-sponsored trial ("IST") sponsored by Georgetown Lombardi Comprehensive Cancer Center ("Georgetown Lombardi"), designed to evaluate the use of BXCL701 along with pembrolizumab to treat pancreatic cancer. Few therapeutic options are available for patients with this disease, which has a five-year survival rate of less than 10%, among the lowest of all cancers. Pancreatic cancer has among the highest levels of overexpression and amplification of DPPs. Preclinical models demonstrated synergy between DPP inhibition with BXCL701 and anti-PD-1 antibody in the pancreatic cancer tumor microenvironment. Based on these preclinical observations, Georgetown Lombardi has initiated a Phase 2 IST to assess the safety of BXCL701 when administered in combination with pembrolizumab (safety lead-in), as well as to estimate the 18-week progression-free survival rate (primary objective of the efficacy phase) in previously treated metastatic pancreatic ductal adenocarcinoma. This trial started in the third quarter of 2023. On February 6, 2024, we announced the completion of patient enrollment in the safety lead-in portion of the trial. As part of the trial's safety lead-in, the first six patients have been enrolled and will be observed for a six-week safety window period. The trial is then expected to enroll approximately 39 patients in its efficacy phase in a Simon 2-stage single-arm, open-label design (19 patients in stage 1 and 20 patients in stage 2). Patients will be monitored radiographically and by tumor markers for response assessment. Tumor biopsies and blood samples will also be collected over the course of treatment to better understand the potential mechanism of action for the combination. The human proof of concept portion of the trial started in the first half of 2024. On April 24, 2024, we announced that an abstract entitled "Phase II trial of BXCL701 and pembrolizumab in patients with metastatic pancreatic ductal adenocarcinoma (EXPEL-PANC): Preliminary findings," was selected for presentation at the poster session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting that took place in Chicago, Illinois from May 31 to June 4, 2024. Investigators reported that, as of the applicable cutoff date, one patient was progression-free at 18 weeks, three patients showed substantial reductions in serum CA19-9, a tumor marker that may correlate with increased T-cell infiltration, and one patient showed a best response of partial responses, out of six patients that had been treated with the combination.

Relapsed or Refractory AML

The American Cancer Society estimated that in 2024, approximately 20,800 new cases of AML were expected to be diagnosed in the U.S. We are supporting a Phase 1b IST sponsored by the Dana-Farber Cancer Institute ("Dana-Farber") designed to evaluate the use of BXCL701, along with the current standard of care to treat relapsed or refractory AML. We believe that pyroptosis triggered by BXCL701 may provide potent single agent cytotoxicity directed towards AML. We also believe that DPP9 copy number may provide an actionable biomarker, as high copy number has been observed to correlate with BXCL701 toxicity in human AML cell lines. DPP8/9 inhibition has been shown to be cytotoxic to THP-1 cells, monocytic cancer cells cultured from a patient with AML, but not other cell lines, suggesting a specific vulnerability of AML to these inhibitors which we believe can be exploited for therapeutic benefit. Based on these preclinical observations, Dana-Farber has initiated a Phase 1b trial to assess the safety of BXCL701 and to determine the maximum tolerated dose or the RP2D of BXCL701 as a single agent. This trial started in the first quarter of 2023. Subject to successful completion of this Phase 1b trial, we anticipate that Dana-Farber will conduct further studies to determine BXCL701's objective response rate in AML in combination with the standard of care.

Other Potential Anti-cancer Programs

We collaborated with the University of Texas MD Anderson Cancer Center in a Phase 2a IST to evaluate the potential efficacy of BXCL701 administered in combination with pembrolizumab in patients with advanced solid cancer. The design of this open label trial included two cohorts and incorporated a two-stage configuration, which allowed for an expansion of patient enrollment to a total of 17 patients in each cohort if a RECIST 1.1 complete response or partial response was observed in at least one of the initial nine patients. The first cohort enrolled patients who previously had not received CPI therapy, with a second cohort consisting of patients that were either refractory to CPI therapy or had relapsed while on CPI therapy, meaning that no further response to CPI treatment is anticipated among patients in the second cohort. Trial participants received 200 mg of pembrolizumab on day 1 of a 21-day cycle, with 0.2 mg of

BXCL701 administered twice-daily ("BID") on days 1 through 7 during the first cycle, the dose increasing to 0.3 mg BID on Days 8 through 14 during the first and the subsequent cycles. Evaluable trial participants were required to receive a minimum of two treatment cycles. A preliminary assessment of BXCL701 dosed in combination with a CPI, as of completion of the first stage, noted responses in one patient in each of the CPI naïve and CPI refractory/relapsed cohorts, including a partial response in CPI-naïve, microsatellite stable endometrial carcinoma, PD-L1 negative (CPS <1) and a partial response in CPI-refractory uveal melanoma. These preliminary results were presented at the 2021 American Society of Clinical Oncology annual meeting (ASCO 2021). Patient enrollment in this trial was completed in the third quarter of 2022.

We believe BXCL701 may have potential application in breast cancer, as its use in combination with monoclonal antibody therapy generated encouraging in vivo data in a preclinical disease model where enhanced antibody-dependent cellular cytotoxicity was observed.

The FDA has granted BXCL701 orphan drug designation for the treatment of AML, stage IIb to IV melanoma, pancreatic cancer, and soft tissue sarcoma. As we consider BXCL701's therapeutic potential for additional indications that represent unmet medical needs, we intend to apply for additional orphan drug designations for BXCL701.

Biomarker Development Initiatives Intended to Complement BXCL701 Administration

We are also actively engaged in the identification and development of predictive biomarkers that we believe could be used in conjunction with BXCL701 to predict the likelihood of patient response to therapy across the range of targeted indications. Based on preliminary data from AML patients, we believe DPP9 copy number could correlate to BXCL701 response rate, with a greater likelihood of BXCL701 cytotoxicity in patients with increased DPP9 copy number. We are pursuing its use in our biomarker discovery activities as a potential companion diagnostic. At the Society for Immunotherapy of Cancer's 38th Annual Meeting (SITC 2023), we presented data from the Phase 2a trial in SCNC patients, which indicated DPP9 overexpression is a potential response-predictive biomarker of BXCL701 and pembrolizumab combination treatment in mCRPC patients with SCNC phenotype.

Immuno-Oncology Manufacturing

We rely on third party contract manufacturing organizations to support development and manufacture of product candidates for our clinical trials, and, if any of our current or future product candidates receives marketing approval, we expect to rely on such manufacturers to meet commercial demand. We expect this strategy will enable us to maintain a more efficient infrastructure, avoiding dependence on our own manufacturing facility and equipment, while simultaneously enabling us to focus our expertise on the clinical development and future commercialization of our products. Drug substance is produced by Aptuit (Oxford) Ltd, an Evotec Company, and drug product by Pharma Services (Patheon) by Thermo Fisher Scientific. We expect to enter into commercial supply agreements with these manufacturers prior to any potential approval of BXCL701.

BXCL701 drug product is manufactured via conventional pharmaceutical processing procedures, employing commercially available excipients and packaging materials. The procedure and equipment employed for manufacture and analysis are consistent with standard organic synthesis or pharmaceutical production, and are transferable to a range of manufacturing facilities, if needed. We have selected a larger third-party drug product manufacturer and will be executing technology transfer of drug product manufacture to a larger manufacturer. We also plan to maintain the current drug substance and product manufacturer as part of our supply chain strategy.

Immuno-Oncology Competition

The biotechnology and pharmaceutical industries have made substantial investments in recent years into the rapid development of novel immunotherapies for the treatment of a range of pathologies, including infectious diseases and cancers, making this a highly competitive market. We believe BXCL701 is the only innate immune system activator in clinical development specifically addressing the cold tumor problem in immuno-oncology.

We face substantial competition from multiple sources, including large and specialty pharmaceutical, biopharmaceutical and biotechnology companies, academic research institutions and governmental agencies, and public

and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development, and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunotherapy and, furthermore, within the treatment of infectious diseases and cancers.

In addition to the current standard of care treatments for patients with infectious diseases or cancers, numerous commercial and academic preclinical studies and clinical trials are being undertaken by a large number of parties to assess novel technologies and product candidates in the field of immunotherapy. Results from these studies and trials have fueled increasing levels of interest in the field of immunotherapy.

Large pharmaceutical companies that have commercialized or are developing immunotherapies to treat cancer include AstraZeneca AB, Bristol-Myers Squibb Company, Merck & Co., Inc., Novartis AG, Pfizer Inc., and F. Hoffmann-La Roche Ltd.

We face significant competition from pharmaceutical and biotechnology companies that target specific tumor-associated antigens using immune cells or other cytotoxic modalities. These generally include immune cell redirecting therapeutics such as T cell engagers, adoptive cellular therapies such as CAR-Ts, antibody drug conjugates, targeted radiopharmaceuticals, targeted immunotoxin, and targeted cancer vaccines.

Clinical stage companies that compete with us directly on the level of the development of product candidates targeting the innate immune system include Amgen Inc., Mirati Therapeutics, Inc., Bristol- Myers Squibb Company, Ryvu Therapeutics, Merck & Co., Inc., Replimune Group Inc., Nektar Therapeutics, Novartis AG, Xbiotech Inc., Stingthera, Inc., AstraZeneca AB, F. Hoffmann-La Roche Ltd and Aravive, Inc. Clinical stage companies that compete with us directly on the level of the development of product candidates targeting the mCRPC include Astellas Pharma Inc., Pfizer Inc., Bayer AG, Janssen, Sanofi S.A., Clovis Oncology, Inc., AstraZeneca AB, Merck & Co., Inc., GSK plc, Tempest Therapeutics, Inc., Zenith Epigenetics Ltd. and Gossamer Bio, Inc. Clinical stage companies that compete with us directly on the level of the development of product candidates utilizing the therapeutic potential of synthetic lethality include Repare Therapeutics Inc., IDEAYA Biosciences, Inc. and Tango Therapeutics, Inc.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if one or more of our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than our proposed product offerings. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Immuno-Oncology Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, enforcing, and defending patent and other intellectual property rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through

inclusion in expedited development and review, data exclusivity, market exclusivity, and patent term extensions where available.

As of February 20, 2025, we have multiple patent families filed to protect our immuno-oncology program, including our core patent family directed to methods of using BXCL701 with immune checkpoint inhibitors, which is granted in the U.S., Japan, Australia, Canada, Russia, China, India, Taiwan, South Africa, Mexico, New Zealand, Europe and United Arab Emirates. Additional applications in this family are pending in major markets. Patents issued from this family are expected to expire no earlier than 2036. We have an additional patent issued in the U.S. directed to a method of selecting patients based on a biomarker and methods of treating certain cancers, with an expected expiration date no earlier than 2039. A corresponding European Patent case directed to selecting patients is issued and is expected to expire no earlier than 2039.

Additional applications are directed to administering BXCL701 in combination with various other molecules, biomarkers, and dosing regimens. We also have three PCT applications directed to novel formulations of BXCL701, various dosing regimens, methods of use, combination therapies, and to methods of treating small cell lung cancer. We expect that any patents issuing from the PCT and provisional applications will expire no earlier than 2043 to 2044.

We expect to file additional patent applications in support of current and new immuno-oncology clinical candidates as well as new platform and core technologies. For additional information regarding intellectual property regulations and risks, see above under "—Neuroscience—Neuroscience Intellectual Property" and Part I, Item 1A, "Risk Factors - Risks Related to Our Intellectual Property."

Our Relationship with BioXcel LLC

As of March 21, 2025, BioXcel LLC holds an ownership interest of approximately 8.8% in the Company and our pipeline compounds were identified by applying our growing internal AI capabilities, along with BioXcel LLC's EvolverAI, a proprietary pharmaceutical discovery and development engine, for drug re-innovation.

We entered into the Amended and Restated Asset Contribution Agreement (the "Contribution Agreement"), pursuant to which BioXcel LLC, agreed to contribute BioXcel LLC's rights, title and interest in BXCL501, BXCL701, BXCL502 and BXCL702, and all of the assets and liabilities associated in consideration for (i) 592,500 shares of our common stock, (ii) $1 million upon completion of an initial public offering, (iii) $500,000 upon the later of the 12-month anniversary of an initial public offering and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program, (iv) $500,000 upon the later of the 12 month anniversary of an initial public offering and the first dosing of a patient in the Phase 2 proof of concept open-label monotherapy or combination trial with Keytruda for the BXCL701 program and (v) a one-time payment of $5 million within 60 days after the achievement of $50 million in cumulative net sales of any product or combination of products resulting from the development and commercialization of any one of the contributed product candidates or a product derived therefrom. As of December 31, 2024, all of the foregoing have been paid except for (v).

We entered into a Separation and Shared Services Agreement with BioXcel LLC that took effect on June 30, 2017, as amended and restated thereafter (the "Services Agreement"), pursuant to which services provided by BioXcel LLC through its subsidiaries in India and the U.S. will continue indefinitely, as agreed upon by the parties. These services include certain intellectual property prosecution and management and research and development activities. The Company had an option, exercisable until December 31, 2024, to enter into a collaborative services agreement with BioXcel LLC pursuant to which BioXcel LLC shall perform product identification and related services for us utilizing EvolverAI, its proprietary pharmaceutical discovery and development engine. To maintain the ability to exercise the foregoing option, pursuant to an amendment to the Services Agreement effective as of April 19, 2022, the Company agreed to pay BioXcel LLC $18,000 per month from March 13, 2023 to December 31, 2024. This option was not exercised. However, BioXcel LLC continues to perform certain administrative services under the terms of the expired contract.

The parties were obligated to negotiate the collaborative services agreement in good faith and to incorporate reasonable market-based terms, including consideration for BioXcel LLC reflecting a low, single-digit royalty on net sales and reasonable development and commercialization milestone payments, provided that (i) development milestone

payments did not exceed $10 million in the aggregate and were not to be payable prior to proof of concept in humans and (ii) commercialization milestone payments were to be based on reaching annual net sales levels, were to be limited to 3% of the applicable net sales level, and were not exceed $30 million in the aggregate. However, subsequent to December 31, 2024 no development activity has been carried out by BioXcel LLC and none is contemplated.

Service charges recorded under the Services Agreement were $1.3 million for each of the years ended December 31, 2024 and 2023.

Government Regulation

Government Regulation and Product Approval

Government authorities in the U.S., 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 U.S. 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 U.S. federal, state, and local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the U.S., the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests, animal studies, and formulation studies in accordance with FDA's Good Laboratory Practice requirements and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board ("IRB") or ethics committee at each clinical site before each clinical 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 clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements to assure that the facilities, methods, and controls are adequate to preserve the drug's identity, strength, quality and purity, and potential inspection 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 specified indications for use in the U.S.

Prior to beginning the first clinical trial with a product candidate in the U.S., a sponsor must submit an IND to the FDA. An IND is a request for allowance 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 any clinical trials can begin. Submission of an IND may or may not result in FDA allowance 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 among other things, 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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and its investigators for actual or suspected serious and adverse events, along with any findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs and findings from animal or in vitro testing suggesting a significant risk to humans, as well as any clinically important increased incidence of a suspected serious adverse reaction compared to that listed in the protocol or investigator brochure.

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 a study can move forward at designated check points, based on access to data from the study, and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other for other grounds, such as no demonstration of efficacy. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

- Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2: The product candidate is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule, and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3: The product candidate is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product labeling.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be conducted after initial marketing approval and may be used to gain additional experience from the treatment of patients in the intended

therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

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

In addition, during the development of a drug, sponsors are given opportunities to periodically meet with or seek feedback from the FDA. These interactions may be requested, for example, prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. These interactions 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 alignment on the next phase of development.

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, including results from 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 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, and of ten months from the date of NDA receipt to complete a standard review of an NDA for a drug that is not a new molecular entity.

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 review, evaluate and provide a recommendation as to whether the NDA 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 comply with cGMP and are 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 trial sites to assure compliance with GCPs.

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 and sale of the product with specific prescribing information for specific indications. A CRL usually describes the specific deficiencies in the NDA identified by the FDA

and may require additional clinical data, including additional clinical trials, or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA or, address all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If regulatory approval of a product is granted, such approval will be granted for specific 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, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. The FDA may also require one or more post-market studies and additional surveillance programs to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

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

Expedited Development and Review Programs

The FDA offers 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 product candidates 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 candidate and the specific indication for which it is being studied. The sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the NDA may be eligible for priority review. An NDA for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

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

Any 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 FDA review programs intended to expedite the FDA review and approval process, such as priority review. An NDA is eligible for priority review if the product candidate 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 application within six months of the 60-day filing date, or with respect to non-new-molecular-entity NDAs, within six months of the NDA receipt date.

Additionally, depending on the design of the applicable clinical studies, 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 confirmatory clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit, and may require that such confirmatory studies be underway prior to granting accelerated approval. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required confirmatory studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the relevant product.

Fast Track designation, Breakthrough Therapy designation, priority review, and accelerated approval do not change the standards for approval, but such designations 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 to qualify for such program or may 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 U.S., or a patient population greater than 200,000 individuals in the U.S. and when there is no reasonable expectation that the cost of developing and making available the drug in the U.S. will be recovered from sales in the U.S. for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

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

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the disease or condition for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the U.S. may be lost if the FDA later determines that the request for designation was materially defective or, 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

events, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. 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 health care 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 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 manufacturers' 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.

Hatch-Waxman Act

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("ANDA"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's drug or a method of using the drug. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Upon submission of an ANDA or a 505(b)(2) NDA, an applicant must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification (a "paragraph IV certification"). If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification to the FDA, the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The Hatch-Waxman Act establishes periods of non-patent regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For example, the holder of an NDA, including a 505(b)(2) NDA, may obtain five years of non-patent data exclusivity upon approval of a new drug containing new chemical entities that have not been previously approved by the FDA. 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 therapeutic activity 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 that contains the previously approved active moiety. However, an ANDA or 505(b)(2) NDA may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The Hatch-Waxman Act also provides three years of non-patent exclusivity to the holder of an NDA (including a 505(b)(2) NDA) for a

particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted or sponsored by the applicant. This three-year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDAs for the condition of the new drug's approval. As a general matter, the three-year exclusivity does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for generic versions of the original, unmodified drug product. 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 efficacy.

FDA Approval and Regulation of Medical Devices and Companion Diagnostics

If safe and effective use of a therapeutic depends on an in vitro diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that apply to approval of therapeutic products and in vitro companion diagnostics. According to the guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population.

Under the FDCA, in vitro diagnostics, including companion diagnostics, are regulated as medical devices. In the U.S., the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, medical devices, including companion diagnostic tests, require marketing clearance or approval from the FDA prior to commercial distribution.

The two primary types of FDA marketing authorization applicable to a medical device are premarket notification ("510(k) clearance") and premarket approval ("PMA"). To obtain 510(k) clearance, a manufacturer must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed predicate device. The FDA's 510(k) clearance process usually takes from three to twelve months but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III (i.e., high-risk) device. The device sponsor must then fulfill more rigorous PMA requirements or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or depending on the modification, approval of a PMA application or de novo classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), de novo classification or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until it receives 510(k) clearance, approval of a PMA application, or issuance of a de novo classification. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive

preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the QSR which imposes elaborate testing, control, documentation and other quality assurance requirements.

Approval of a PMA is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained, or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which currently cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

In January 2024, the FDA announced that it intends to initiate the process to reclassify most in vitro diagnostic tests ("IVDs") that are currently Class III into Class II, including companion diagnostics. If such reclassification efforts occur, any companion diagnostics that are the subject of the down-classification may no longer require premarket approval, but rather may become subject to the generally less burdensome 510(k) clearance process.

International Regulations

In addition to regulations in the U.S., we are and will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, marketing authorization, post-marketing requirements, and any commercial sales and distribution of our products. We must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of any products in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. Failure to comply with applicable foreign regulatory requirements, may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Non-Clinical Studies and Clinical Trials

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

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice ("GLP") as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular

medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

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

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation ("CTR") which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application ("CTA") to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB, respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the EU Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the EU Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR.

During the development of a medicinal product, the EMA and national regulators provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use ("CHMP"). A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding to any future MA application ("MAA") of the product concerned.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal products candidates can only be placed on the market after obtaining a MA. To obtain regulatory approval of a product candidate in the EU, we must submit a MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- "Centralized MA": are issued by the European Commission through the centralized procedure based on the opinion of the EMA's CHMP and are valid throughout the EU. The centralized procedure is compulsory for

certain types of medicinal products such as (i) medicinal products derived from biotechnology processes, such as genetic engineering, (ii) medicinal products containing a new active substance indicated for the treatment of certain diseases, such as HIV or AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) designated orphan medicinal products, and (iv) advanced therapy medicinal products ("ATMPs") such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure is optional for product candidates containing a new active substance not yet authorized in the EU, or for product candidates that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- "National MA": are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized MAs. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure, an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the European Commission may then adopt a decision to grant an MA. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the Breakthrough Therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme, facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the European Commission or the national competent authority decides on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

Data and Marketing Exclusivity

The EU also provides opportunities for market exclusivity. Upon receiving an MA, reference product generally receives eight years of data exclusivity and an additional two years of market exclusivity. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of 11 years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the U.S. A medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention, or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition.

The application for orphan drug designation must be submitted before the MAA. Orphan designation entitles a party to incentives such as fee reductions or fee waivers, protocol assistance, and access to the Centralized MA process. Upon grant of a MA, orphan medicinal products are entitled to 10 years of market exclusivity for the approved therapeutic indication. During the 10-year market exclusivity period, the competent authorities cannot accept a MAA, or grant a MA, or accept an application to extend a MA, for the same indication, in respect of a similar medicinal product. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan ("PIP"). No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, a MA may be granted to a similar product for the same indication at any time if (1) the second applicant can establish that its product, although similar, is safer, more effective, or otherwise clinically superior; (2) the applicant consents to a second orphan medicinal product application; or (3) the applicant cannot supply enough orphan medicinal product.

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

The aforementioned EU rules are generally applicable in the European Economic Area ("EEA"), which consists of the 27 EU member states plus Iceland, Liechtenstein, Norway, Switzerland and Turkey, as well as cooperating countries Albania, Bosnia and Herzegovina, Kosovo, Montenegro, North Macedonia, and Serbia.

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws, however under the terms of the Ireland/Northern Ireland Protocol, EU laws generally apply to Northern Ireland. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain, however new legislation such as the EU CTR is not applicable in Great Britain ("GB").

The Trade and Cooperation Agreement ("TCA") became effective on January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of Good Manufacturing Practice ("GMP") inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

Other Foreign Regulations

For other countries outside of Europe, such as countries in Eastern Europe, Latin America, or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Regulation of Companion Diagnostics

In the EU, in vitro diagnostic medical devices were regulated by Directive 98/79/EC, which regulated the placing on the market, the CE marking, the essential requirements, the conformity assessment procedures, the registration obligations for manufacturers and devices, as well as the vigilance procedure. In vitro diagnostic medical devices had to comply with the requirements provided for in the Directive, and with further requirements implemented at national level (as the case may be).

The regulation of companion diagnostics is subject to further requirements since in-vitro medical diagnostic devices Regulation (No 2017/746) ("IVDR") became applicable on May 26, 2022. The IVDR applies since May 26, 2022, but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the Regulation.

The IVDR introduced a new classification system for companion diagnostics, which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue an EU certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure process for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure process, or an MAA for the medicinal product has been submitted through the centralized procedure process. For other substances, the notified body can seek the opinion from a national competent authority or the EMA.

The aforementioned EU rules are generally applicable in the EEA.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of drug products for which we obtain regulatory approval. In the U.S. and other countries, sales of products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third-party payors. Third-party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the

FDA-approved drugs for a particular indication. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, new products are facing increasingly high barriers to entry. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, an increasing emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is secured for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

To raise sufficient financial resources to commercialize our approved products and continue to advance our product candidates, we will need to address pricing pressures and potential third-party reimbursement coverage for our approved products and product candidates. In the U.S. and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government payors, like Medicare and Medicaid, and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It is and will continue to be time consuming and expensive for us or our strategic collaborators to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

Healthcare Reform

We participate in the Medicaid Drug Rebate Program and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. The U.S. government and other governments have shown significant interest in pursuing health care reform, which has resulted in changes to these programs and impacts IGALMI® and our product candidates that may be approved. For example, in March 2010, the Patient Protection and Affordable Care Act ("ACA") was enacted and substantially changed the way health care is financed in the U.S. by both government and private insurers. Among other cost containment measures, the ACA established:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents;
- a Medicare Part D coverage gap discount program, in which pharmaceutical manufacturers who wish to have their drugs covered under Part D must offer discounts to eligible beneficiaries during their coverage gap period, or the "donut hole"; and

- a new formula that increases the rebates a manufacturer must pay under the Medicaid Drug Rebate Program.

Since its enactment, there have been judicial, executive and congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. In addition, we expect that federal, state, and local governments in the U.S. will continue to consider legislation to limit the growth of health care costs, including the cost of prescription drugs. Future legislation could limit payments for pharmaceuticals such as IGALMI® and the product candidates that we are developing.

Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate reductions of Medicare payments to providers, which will remain in effect through 2032, absent additional congressional action. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, in March 2021, Congress enacted the American Rescue Plan Act of 2021, which, among other things, eliminated the statutory Medicaid drug rebate cap, effective January 1, 2024. The rebate was previously capped at a drugs average manufacturer price.

Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. HHS has issued and will continue to issue guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined, it is likely to be significant.

In addition, individual U.S. states have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

Future legislation could limit payments for pharmaceuticals such as IGALMI® and the product candidates that we are developing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures. The implementation of cost-containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

Other Health Care Laws and Compliance Requirements

For approved products, we may be subject to various federal, state, and foreign laws targeting fraud and abuse in the health care industry. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, consumer fraud, and transparency laws and regulations with respect to drug pricing and payments and other transfers of value made to physicians and other health care professionals, as well as similar foreign laws in jurisdictions outside the U.S.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal health care program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of this statute

or specific intent to violate it in order to have committed a violation. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program. 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 False Claims Act. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal health care program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus significant civil penalties for each separate false claim.

Also, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The Physician Payment Sunshine Act (the "Sunshine Act"), which was enacted as part of the ACA, requires applicable manufacturers of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or the Children's Health Insurance Program, to report annually to the Secretary of the Department of Health and Human Services payments or other transfers of value made by that entity, or by a third-party as directed by that entity, to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain non-physician providers including physician assistants and nurse practitioners, and teaching hospitals, or to third parties on behalf of such providers, as well as ownership and investment interests held by physicians and their immediate family members during the course of the preceding calendar year. Failure to comply with the reporting requirements can result in significant civil monetary penalties for any payment or other transfer of value that is not reported.

Moreover, analogous state and foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant federal government compliance guidance; require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers, many of which differ from each other in significant ways, thus further complicating compliance efforts; and restrict marketing practices or require disclosure of marketing expenditures and pricing information.

Violations of any of these laws or any other governmental laws and regulations that may apply include, without limitation, significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded health care programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations.

Data Privacy & Security

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health-related information. In the U.S., numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In addition, certain state and non-U.S. laws, such as the California Consumer Privacy Act ("CCPA"), the California Privacy Rights Act ("CPRA"), and the EU General Data Protection Regulation ("GDPR"), govern the privacy and security of personal

information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing. Additionally, our use of AI and machine learning may be subject to laws and evolving regulations regarding the use of AI or machine learning, controlling for data bias, and anti-discrimination.

Human Capital

Our Employees

In August 2023, our Board of Directors approved the Reprioritization. Following a comprehensive review of the business, we determined to focus on high-potential agitation-market opportunities using our innovative, AI-based clinical drug development platforms. Our goal was to reduce more than 50% of our cash burn, as compared to our cash burn levels during the second quarter of 2023, to approximately $80 million on a go-forward annualized basis. As part of the Reprioritization, our Board of Directors approved a reduction of approximately 60% of our workforce, from approximately 190 to 80 employees. These actions also included a shift in commercial strategy for IGALMI® in the institutional setting, a reduction of in-hospital commercialization expenses, a suspension of programs no longer deemed core to our business, and a shift in focus to develop BXCL501 for use in the at-home setting in the treatment of agitation in schizophrenia, bipolar disorders, and in patients with mild to moderate dementia due to probable Alzheimer's disease.

In May, 2024 the Company took additional actions as part of its continued efforts to preserve cash and prioritize investment in its core clinical programs. As part of these actions, the Company initiated a further reduction of approximately 15% of the Company's then current workforce. The Company recorded total restructuring costs of $0.9 million for the three months ended June 30, 2024. These costs consisted of severance and benefit costs, all of which were paid during the three month period ended June 30, 2024.

In September, 2024, the Company approved a plan for an additional reduction its workforce by 15 employees, or approximately 28% of the Company's headcount (the "Clinical Prioritization"), in order to extend its cash runway and prioritize investment on the clinical development of its lead neuroscience asset, BXCL501. The Company recorded total restructuring costs of $1.6 million for the three months ended September 30, 2024. These costs also consisted of severance and benefit costs. The Company completed the Clinical Prioritization in October 2024, and commenced payments which are expected to be completed in the first quarter of 2025.

We recorded restructuring costs of $2.4 million and $4.2 million in the years ended December 31, 2024 and 2023, respectively, including severance and benefit costs of $4.1 million and contract termination costs of $0.1 million, substantially all of which were paid in 2023. As of December 31, 2024 and 2023, respectively, we had 37 and 74 full-time employees.

Our Culture

We believe that the success of our human capital management investments is evidenced by our low employee turnover, despite the difficult restructuring actions recently taken, and is regularly reviewed by our Board of Directors as part of their oversight of our human capital strategy.

Employee Engagement, Talent Development & Benefits

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. We provide our employees with competitive salaries, bonuses, opportunities for equity ownership and other comparable benefits for our industry.

Employee and Visitor Safety Protocols

We follow health and safety guidelines to protect the well-being of our employees and visitors.

Diversity & Inclusion

Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels and continue to focus on extending our diversity and inclusion initiatives across our entire workforce. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values.

Our Corporate Information

The Company was incorporated as a Delaware corporation on March 29, 2017. Our principal executive offices are located at 555 Long Wharf Drive, New Haven, CT 06511 and our telephone number is (475) 238-6837.

Available Information

Our website address is www.bioxceltherapeutics.com. The contents of, or information accessible through, our website are not part of this Annual Report on Form 10-K. We make our filings with the SEC, including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports, available free of charge on our website as soon as reasonably practicable after we file such reports with, or furnish such reports to, the SEC.

We may use our website as a distribution channel of material information about the Company. Financial and other important information regarding the Company is routinely posted on and accessible through the Investors & Media sections of our website at www.bioxceltherapeutics.com. In addition, you may automatically receive email alerts and other information about the Company when you enroll your email address by visiting the "Email Alerts" option under the News / Events menu of the Investors & Media section of our website at www.bioxceltherapeutics.com.

The reference to our website address does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider such information to be a part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10-K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Financial Position and Need for Additional Capital

We have a limited operating history and have not generated substantial product revenues to date, which may make it difficult to evaluate the success of our business and to assess our future viability.

We were incorporated in March 2017 and our operations to date have been largely focused on staffing our Company, raising capital, advancing the development of our product candidates, including conducting clinical and preclinical studies and establishing our commercial organization. We have only one product approved for commercial sale, and have limited experience in obtaining marketing approvals, manufacturing products on a commercial scale, and conducting sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully commercializing products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We are focused primarily on research and development while continuing to support IGALMI® commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was $59.6 million and $179.1 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had a stockholders' deficit of approximately $93.1 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We have only one product candidate approved for marketing in the U.S., none in any other jurisdiction, and may never receive approval beyond the one product approved to date. It could be several years, if ever, before we have a commercialized product that generates significant revenues through sales of IGALMI® or our product candidates, if approved. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses may increase in the long term as we:

- evaluate the development of our product candidates;
- conduct preclinical studies and clinical trials for our current product candidates and any future product candidates that we may pursue;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials;
- develop an appropriate sales, marketing, and distribution infrastructure to commercialize IGALMI® and any other product candidates for which we may obtain marketing approval;
- potentially hire additional clinical, commercial, regulatory, scientific and finance personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must develop and commercialize more products or product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing, and selling IGALMI® and any current and future product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

Although we have obtained U.S. FDA approval for IGALMI®, because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any additional product candidates. If we are required by the FDA, or other regulatory authorities such as the European Medicines Agency ("EMA") to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future product candidates, our expenses could increase and profitability could be further delayed. For example, developments with respect to our TRANQUILITY program evaluating BXCL501 in patients with dementia due to probable Alzheimer's disease may increase the likelihood that we experience such costs or delays, as discussed in the risk factor below entitled: "*Developments relating to our TRANQUILITY II Phase 3 trial may impact the timing of our development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease*."

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our Company also could cause you to lose all or part of your investment.

Our strategic reprioritization and other workforce reductions may not achieve our intended outcome.

In August 2023, we announced a broad-based strategic reprioritization (the "Reprioritization") and have taken further restructuring actions since then. As part of these efforts, we have taken actions to reduce certain operational and workforce expenses that are no longer deemed core to our ongoing operations in order to extend our cash runway and drive innovation and growth in high potential clinical development and value creating opportunities. These actions include a shift in commercial strategy for IGALMI® in the institutional setting, a reduction of in-hospital commercialization expenses, a suspension of programs no longer determined to be core to ongoing operations, and a prioritization on at-home treatment setting opportunities for BXCL501. As part of this strategy, we reduced our workforce in 2023 by approximately 60%.

In May and September 2024, we initiated further workforce reductions, and we may undertake further similar cost-saving initiatives, which may include additional restructuring or workforce reductions. These types of cost-reduction activities can be complex and result in unintended consequences and costs, including decreased employee morale, loss of institutional knowledge and expertise and adversely impact our business. We completed these additional restructuring actions to further reduce the workforce by 50%, ending the year ended December 31, 2024 with 37 full-time employees.

The reduction in force may result in unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. The workforce reduction could also harm our reputation, making our ability to recruit skilled personnel difficult. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, our business, financial condition, and results of operations may be materially adversely affected.

In addition, we may not realize the benefits of or there may be unanticipated costs associated with our Reprioritization. As a result of the Reprioritization, including our strategic refocus, we may not generate material revenues from IGALMI® in the near term because our commercial force will be significantly reduced. If we are unable to commercialize IGALMI® in a different setting or unable to develop, receive marketing approval for and successfully commercialize BXCL501, BXCL701 and any of our other product candidates on our own or with any future collaborator, or experience delays because of any of these factors or otherwise, our business could be materially and substantially harmed.

In addition, because we have limited financial and managerial resources, under our Reprioritization, we intend to focus on specific product candidates, indications and development programs. We may also conduct several clinical trials for our product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other product candidates or other indications that could have had greater commercial potential or likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. If we are not successful in increasing our efficiency as a result of this Reprioritization, our efforts to develop and commercialize our product candidates may be delayed or halted and our business could be materially adversely impacted.

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts or otherwise seek strategic alternatives. In addition, the failure to raise additional financing in accordance with the minimum capital raising requirements of our Credit Agreement (as defined herein) would trigger an event of default thereunder.

We will require additional future funding to support current and anticipated future expenses. We currently anticipate continuing to develop and conduct clinical trials with respect to our current and any future product candidates; seek to identify and develop additional product candidates; acquire or in-license other product candidates or technologies; seek regulatory approvals for our product candidates that successfully complete clinical trials, if any; establish sales, marketing, distribution and other commercial infrastructure to support the commercialization of products for which we may obtain marketing approval; require the manufacture of larger quantities of product candidates for clinical development and, potentially, commercialization; maintain, expand and protect our intellectual property portfolio; hire and retain limited additional personnel, such as clinical, quality control and scientific personnel; add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company; and add equipment and physical infrastructure to support our research and development programs.

We have been and may continue to be required to expend significant funds to continue to commercialize IGALMI® in the U.S. and advance the development of BXCL501, BXCL701, BXCL502 and our other product candidates. In addition, while we may seek one or more collaborators for future development of our current product candidates or any future product candidates that we may develop for one or more indications, we may not be able to enter into a collaboration for any of our product candidates for such indications on suitable terms, on a timely basis or at all. In any event, our existing cash will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of our product candidates or our other preclinical programs. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We may also seek third-party investments in or other strategic options for our subsidiary, OnkosXcel. Further financing may not be available to us on acceptable terms, or at all. In addition, we are reliant on the financial institutions with which we hold our cash and cash equivalents. If such institutions were to close, we may not be able to recover all of our cash or cash equivalents held at such institutions. Moreover, market volatility, credit crises, adverse macroeconomic conditions, such as high interest or inflation rates, or other factors, as well as Company-specific factors such as the progress of our development pipeline, adverse clinical events or results, regulatory investigations, or ongoing or potential legal proceedings, could also adversely impact our ability to access capital as and

when needed. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Management believes that the Company's cash and cash equivalents of $29.8 million as of December 31, 2024, together with approximately $14.0 million gross proceeds received from the registered direct offering in March 2025, will allow the Company to fund its operations and meet its liquidity requirements into the third quarter of 2025. However, there can be no assurance that we will be able to extend our cash runway by meeting the conditions for additional funding under the terms of our Credit Agreement (defined below) or otherwise. In addition, the failure to raise additional financing in accordance with the minimum capital raising requirements of our Credit Agreement would trigger an event of default thereunder. The Fifth Amendment to our Credit Agreement included a new capital raising covenant requiring that the Company receive (A) after the effective date of the Fifth Amendment and on or prior to November 27, 2024, at least $7.0 million in gross cash proceeds from the issuance of the Company's common stock, warrants and/or pre- funded warrants ("Raise 1"), (B) after the effective date of the Fifth Amendment and on or before March 15, 2025 (provided that the Company was required to use its commercially reasonable efforts to satisfy the requirement by February 15, 2025), at least $18.0 million in net cash proceeds (including the proceeds of Raise 1) from (i) the issuance of the Company's common stock, warrants and/or pre-funded warrants, (ii) non-refundable cash consideration from partnering transactions entered into after the effective date of the Fifth Amendment (so long as such partnering transactions would not require the Company or any of its subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made), (iii) the issuance of the Company's subordinated debt (subject to terms set forth in the Fifth Amendment), and/or (iv) asset sales permitted pursuant to the Credit Agreement or consented to by the Lenders (such capital raise, "Raise 2"), and (C) after the effective date of the Fifth Amendment and on or prior to the earlier of (x) August 15, 2025 and (y) the date that is 30 days after the final data readout of the SERENITY At-Home Phase 3 trial, at least $29.0 million in net cash proceeds ("Raise 3") (including the proceeds from Raise 1 and Raise 2) from the same permitted capital raising activities listed in the preceding clause (B).The Company has met the requirements of Raise 1 and Raise 2, but has not met the requirements of Raise 3.

In connection with the Fifth Amendment and the required capital raises described in the preceding paragraph, the Lenders agreed to modify the Credit Agreement's minimum liquidity covenant to require minimum cash liquidity of $7.5 million (instead of $25.0 million) from and after the closing of Raise 1 until March 30, 2025. On March 31, 2025, the minimum liquidity amount will increase to $10.0 million, and on September 30, 2025, the minimum liquidity amount will further increase to $15.0 million.

Furthermore, our estimate as to how long we expect our existing cash 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. Further, 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. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs, and results of clinical trials of our product candidates, including any delays that have occurred or may occur due to the recent developments with the TRANQUILITY program;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;
- the costs, timing and outcome of seeking regulatory approvals;
- the costs of commercialization activities for IGALMI® and for any of our product candidates that receive marketing approval, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- revenue received from commercial sales of IGALMI® and our current and future product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;

- the number of future product candidates that we pursue and their development requirements;
- changes in regulatory policies or laws that may affect our operations;
- changes in physician acceptance or medical society recommendations that may affect commercial efforts;
- the costs of acquiring potential new product candidates or technology;
- the costs of operating as a public company;
- the extent to which our operations continue;
- the costs of legal proceedings and investigations; and
- costs associated with any adverse market conditions or other macroeconomic factors.

As we continue our research and development activities, we will require additional resources to continue as a going concern. We can provide no assurance that we will successfully obtain additional resources to improve our financial condition. If we are unable to obtain necessary additional capital, we could be compelled to pursue alternative options, including, without limitation, implementing further workforce reductions, reducing or ceasing product development programs and advancement of our clinical trials and product candidates, selling our assets or seeking other strategic alternatives.

We have significant indebtedness and other contractual obligations that could impair our liquidity, restrict our ability to do business and thereby harm our business, results of operations and financial condition. We may not have sufficient cash flow from operations to satisfy our obligations under the Credit Agreement.

As of December 31, 2024, we had aggregate principal indebtedness of $106.7 million outstanding under our Credit Agreement and Guaranty (as amended, the "Credit Agreement") by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto (the "Lenders"), and Oaktree Fund Administration LLC ("OFA") as administrative agent.

Restrictive covenants in the Credit Agreement place limits on our ability to conduct our business. The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions, including specific exceptions with respect to product commercialization and development activities. In addition, certain events, including receipt of a warning letter from the FDA, may constitute an event of default. We must also comply with certain covenants under the Credit Agreement, including a financial covenant that requires we maintain certain minimum cash liquidity amounts. In addition, certain events, including certain regulatory events and any "going concern" or similar qualification in a report of the Company's independent registered public accountants relating to the Company's annual financial statements (except for the years ended December 31, 2024 and 2023, respectively), constitute an event of default under the Credit Agreement. The report of our independent registered public accounting firm included in this Annual Report on Form 10-K contains a "going concern" explanatory paragraph. The Credit Agreement also includes other covenants relating to certain change of control events can also trigger an event of default under the Credit Agreement, including control by any entity or group of entities, other than BioXcel LLC and its affiliates, that acquires 35% or more of our voting capital stock.

Our ability to make scheduled payments or payments to maintain compliance with covenants or to restructure or refinance these and other outstanding debt obligations depends on our financial and operating performance, including growth in revenue from IGALMI® and BXCL501, which will be affected by prevailing economic, industry and competitive conditions and by financial, business and other factors beyond our control. A failure to pay our debt, fixed costs and other obligations or a breach of our contractual obligations or other event of default could result in a variety of adverse consequences, including the acceleration of our obligations or the exercise of remedies by our creditors and lessors. In such a situation, it is unlikely that we would be able to cure our breach, fulfill our obligations, make required

payments or otherwise cover our fixed costs, which would have a material adverse effect on our business, results of operations and financial condition.

In addition, historically we have relied on debt and equity financings as our primary sources of liquidity. If our future cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay expenditures, sell assets, seek additional capital or seek to restructure or refinance our indebtedness. Any refinancing or restructuring of our indebtedness could be at higher interest rates and may require us to comply with more onerous covenants. These alternative measures may not be successful and may not permit us to meet our scheduled or any accelerated debt service obligations. In the absence of such cash flows and resources, we could face substantial liquidity problems and might be required to sell material assets or pursue other strategic alternatives to attempt to meet our debt service obligations.

We have identified conditions and events that raise substantial doubt regarding our ability to continue as a going concern.

As of December 31, 2024, we had $29.8 million in cash and cash equivalents. Based on our existing cash, cash equivalents and lack of current availability under our funding facilities, we do not believe we have sufficient cash on hand to support current operations and service our debt obligations for at least one year from the date of issuance of the audited consolidated financial statements appearing in this Annual Report on Form 10-K. This condition raises substantial doubt about our ability to continue as a going concern for at least one year from the date that our financial statements for the year ended December 31, 2024 are issued. In order to mitigate the current and potential future liquidity issues, we have undertaken the Reprioritization and other restructuring actions, and may, among other things, seek to raise capital through the issuance of common stock, or by restructuring, refinancing, and/or amending the terms of the Credit Agreement (including with respect to regulatory related events of default that do not contain a cure period) or pursue other strategic alternatives. However, such transactions may not be successful and we may not be able to raise additional equity and/or financing necessary to meet our obligations. Moreover, our Credit Agreement contains covenants that we may be unable to comply with and which could result in the acceleration of our debt service obligations, further reducing our capital resources and ability to fund our operations. As such, there can be no assurance that we will be able to continue as a going concern and we may be forced to delay, reduce or discontinue our product development programs or commercialization efforts in order to preserve cash. For additional cost-saving and other strategic initiatives we may be compelled to pursue, see the risk factor entitled, *"We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts or otherwise seek strategic alternatives."*

We could be delisted from The Nasdaq Capital Market, which could seriously harm the liquidity of our stock and our ability to raise capital or complete a strategic transaction.

As previously reported, on September 20, 2024, we received a letter from Nasdaq Staff notifying us that for the 30 consecutive business days prior to the date of the letter, the Company's market value of listed securities closed below the minimum $35 million requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company was granted a period of 180 calendar days, or until March 19, 2025, to regain compliance.

As anticipated, on March 20, 2025, the Company received another letter from the Staff stating that, as a result of the Company's continued non-compliance with the MVLS Requirement, its securities would be delisted from Nasdaq unless the Company appeals the Staff's delisting determination by requesting a hearing before the Nasdaq Panel. The Company made timely request for a hearing before the Panel to appeal the Staff's determination. The Company's common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process; however, there can be no assurance that the Company will ultimately regain compliance and remain listed on Nasdaq.

If our common stock is delisted by Nasdaq, the price of our common stock may decline and our common stock may be eligible to be quoted on the OTC Bulletin Board, another over-the-counter quotation system, or on the pink sheets, which would negatively affect the liquidity of our common stock and an investor may find it more difficult to dispose of

their common stock or obtain accurate quotations as to the market value of our common stock. Any such delisting action may materially adversely affect our ability to raise capital or pursue strategic transactions on acceptable terms, or at all.

In addition, if our common stock is delisted from the Nasdaq Capital Market and the trading price remains below $5.00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker-dealers in connection with any trade involving a stock defined as a "penny stock" (generally, any equity security not listed on a national securities exchange that has a market price of less than $5.00 per share, subject to certain exceptions).

We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter.

Risks Related to the Discovery and Development of Product Candidates

We have limited experience in drug discovery and drug development.

Prior to the acquisition of our product and product candidates, we were not involved in and had no control over their preclinical and clinical development. In addition, we are relying upon the parties we acquired our product candidates from to have conducted research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable product candidate, and correctly collected and interpreted the data from these studies and trials. To the extent any of these activities did not occur, our expected development time and costs could increase, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these product candidates.

Developments relating to our TRANQUILITY II Phase 3 trial may impact the timing of our development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease.

Following our discovery of principal investigator misconduct at one of the clinical sites in our TRANQUILITY II Phase 3 clinical trial, we initiated an investigation into the issues associated with the trial. This principal investigator had previously been subject to a December 2022 FDA inspection of her clinical site in connection with the TRANQUILITY II clinical trial. At the conclusion of this inspection, the FDA issued an FDA Form-483 identifying three inspectional observations. These observations related to the principal investigator's failure to adhere to the informed consent form approved by the Institutional Review Board for a limited number of subjects whose records the FDA reviewed, maintain adequate case histories for certain patients whose records the FDA reviewed, and adhere to the investigational plan in certain instances. For example, the FDA cited the principal investigator's delay in informing the sponsor's medical monitor or pharmacovigilance safety vendor of an SAE, for one of the subjects, which report was made to our vendor outside of the 24 hour time period prescribed by the clinical trial protocol. The principal investigator for this clinical site responded to the FDA observations within the time period requested. The FDA concluded that the inspection of a single site in its TRANQUILITY II Phase 3 trial is closed under 21 C.F.R.20.64(d)(3) and released the Establishment Inspection Report. The FDA has designated "Voluntary Action Indicated" for the site.

In May 2023, it came to our attention that this same principal investigator in the TRANQUILITY II clinical trial may have fabricated email correspondence around the time of the FDA inspection, purporting to demonstrate that the investigator timely submitted to our pharmacovigilance safety vendor a report of an SAE from a different subject than the one cited in the FDA Form-483, and purporting to show that the vendor had confirmed receipt. Upon receipt of this information, we promptly initiated an investigation and received confirmation that the principal investigator fabricated the email correspondence related to the timing of the reporting of this SAE to our pharmacovigilance vendor to make it appear as though this SAE had been timely reported as required by the clinical trial protocol. This principal investigator has not participated in any other clinical trial sponsored or conducted by us. Both we and the principal investigator's employer have reported this incident to the FDA.

Since that time, we have taken steps to further investigate and evaluate the conduct of the TRANQUILITY II trial at this clinical site. Based on these steps to date, we believe that there have been no further instances of misconduct or fraud or other findings that adversely impact the data integrity or reliability of the eligibility, safety, and efficacy data obtained at the clinical trial site in question.

The primary efficacy endpoint in TRANQUILITY II was the change in PEC score, which is a measurement of agitation severity captured by trained raters during an agitation episode. While change in PEC score has been used to support the approval of IGALMI® for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults, it has not been used as a primary endpoint to support the approval of a drug candidate for the treatment of agitation associated with Alzheimer's Disease. Prior to initiating our TRANQUILITY II trial, we believe we reached alignment with FDA regarding the use of PEC scores as a primary endpoint to assess individual agitation episodes in dementia patients. In the normal course, we have been in communication with the FDA regarding the data and information needed to further support the consistency of the measurement of PEC ratings, and we believe that we have generated sufficient data to demonstrate such consistency. Following submission of certain data on PEC score from a separate study of raters assessing video vignettes, the FDA expressed certain concerns with respect to the reliability of PEC scores in that study. The FDA has requested that we provide additional information to support the consistency of the measurement of PEC ratings to assess the treatment of agitation associated with Alzheimer's Disease. While we believe that we have generated sufficient data to demonstrate such consistency, and we plan to submit these data and analyses to the FDA, if the FDA disagrees, it may require that we provide more information to demonstrate reliability in the measurement of PEC scores and/or may require that we generate additional data to support the reliability of PEC score measurements in our TRANQUILITY II trial. There can be no assurances that any information or and data we provide to FDA will sufficiently demonstrate the consistency and reliability of the PEC-score data from our TRANQUILITY II trial, or that our PEC-score data will not represent a potential review issue in connection with any application we may submit to FDA.

In addition, we are continuing to seek feedback from the FDA with respect to our TRANQUILITY program. For example, on February 20, 2024, we held a Type B/Breakthrough Therapy designation meeting with the FDA. The original purpose of this meeting was to obtain feedback on the design of a proposed at-home study that did not include caregiver-collected efficacy endpoints, based on our belief that obtaining caregiver assessments of efficacy would be challenging. We believe there are no validated caregiver endpoints for assessing efficacy in Alzheimer's disease patients in the at-home setting. As a result, we focused on requesting feedback from the FDA regarding our proposal for an at-home clinical study with safety as the primary objective, and to better understand what additional data would be required to submit an sNDA to support labeling for BXCL501 to include the acute treatment of agitation associated with dementia in probable Alzheimer's disease or, in the alternative, in this population in the care setting only. In its preliminary responses, the FDA reiterated its prior comments that we generate additional efficacy data, including repeat-dose efficacy data, to support an sNDA submission, as the FDA indicated that our proposed efficacy database, which currently includes the 70 patients who have been treated with 60 mcg of BXCL501 in TRANQUILITY I and TRANQUILITY II, would not contain substantial evidence of effectiveness absent additional data. The FDA advised that we generate the necessary efficacy data in care facilities prior to conducting any trials in the at-home setting. In addition, the FDA indicated the need to generate long-term safety data to support an sNDA submission, including from probable Alzheimer's disease patients exposed to BXCL501, for up to one year. We have received the final meeting minutes from the FDA, which we believe are consistent with the FDA's preliminary responses and the subsequent meeting discussion. Based on the FDA's feedback, we are currently planning to generate additional Phase 3 efficacy and safety data, in a variety of relevant care-facility settings and across severity of dementia, including through, among other things, conducting our planned TRANQULITY In-Care Phase 3 trial. In addition, we plan to discuss the details of the requirement for long-term safety data at a future meeting with the FDA. Also, although we announced in November 2023 that we were planning to conduct a Phase 3 trial in the at-home setting, with safety as the primary objective (TRANQUILITY At Home), given the priority to expand the database to generate additional efficacy and safety data in care facilities, we are re-evaluating the timing for initiating TRANQUILITY At Home. Conducting any new clinical trial can take significant time, funding and resources, and there are no assurances we could raise sufficient capital or have the liquidity and resources to conduct further clinical trials in our TRANQUILITY program, including our planned TRANQUILITY In-Care Trial. Any new clinical trials conducted in our target patient populations may have different safety or efficacy results from the topline data the Company previously announced for the TRANQUILITY II clinical trial. Further, any government investigation, disqualification, or debarment of, or proceeding or action against the principal investigator, or any government investigation, proceeding or action against us, could further delay development

and approval of BXCL501 for this indication, and otherwise have a material adverse effect on us, our financial condition (including triggering a potential event of default under our Credit Agreement), results of operations and prospects.

We have limited clinical data supporting potential safety or efficacy of BXCL501 for use in the at-home setting in the acute treatment of agitation in patients with dementia due to probable Alzheimer's disease.

In August 2023, we announced our intention to pursue the Reprioritization, including among other things, a shift in focus to primarily develop BXCL501 for use in expanded settings, including the at-home setting and care facilities, for the acute treatment of agitation in patients with dementia due to probable Alzheimer's disease and the acute treatment of agitation in schizophrenia and bipolar patients in the at-home setting. Although we have conducted several clinical trials that evaluated BXCL501 in the institutional setting, and we are conducting the SERENITY At-Home Phase 3 trial evaluating the safety of BXCL501 for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting, but we have not conducted a clinical trial evaluating the at-home use of BXCL501 in the acute treatment of agitation in patients with dementia due to probable Alzheimer's disease.

Although we will seek additional feedback from the FDA regarding the potential of its ongoing or completed clinical trials to support submission of one or more sNDAs and to support a label for use in the home, it is possible that the FDA may not consider our available data adequate to support such submissions. For example, on October 11, 2023, we received feedback from the FDA that TRANQUILITY I and TRANQUILITY II alone are not sufficient to support an sNDA submission for the use of BXCL501 to treat acute agitation (non-daily) in patients with dementia due to probable Alzheimer's disease in either the at-home setting or care facilities, and the FDA indicated that we should, among other things, conduct a further clinical trial to evaluate safety and collect efficacy data of BXCL501 before we are able to submit an sNDA seeking approval of BXCL501 for use in such populations.

For a description of recent developments relating to our TRANQUILITY program, please see the prior risk factor, "*Developments relating to our TRANQUILITY II Phase 3 trial may impact the timing of our development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease.*" We cannot provide assurance that we will be able to seek or obtain approval of BXCL501 for treatment of agitation in patients with dementia due to probable Alzheimer's disease in the at-home setting based on this updated development plan.

Although we continue to seek feedback from the FDA with respect to our TRANQUILITY program, the FDA may not agree that any trial designs we propose are sufficient to establish both the safety and efficacy of BXCL501 for the acute treatment of agitation associated with dementia due to probable Alzheimer's disease in either a care setting or an at-home setting. For example, to assess safety, the FDA has indicated that we need to expose more patients to BXCL501 for a longer period of time and that an efficacy trial of a shorter duration, combined with the patients in its previous trials, would not support submissions of an sNDA. Further, to assess efficacy in the home setting, the FDA may determine that we cannot rely on our previous studies of BXCL501 for this proposed indication since those studies were conducted in assisted living facilities and they are not comparable to the at-home setting. The FDA may also require us to seek approval for BXCL501 for use in care facilities prior to seeking any approval for at-home use in the targeted AD patient population. In particular, we are planning to generate additional Phase 3 safety and efficacy data in a variety of relevant care-facility settings, but even if our planned clinical efforts are successful and even if we are able to obtain approval of BXCL501 for use in patients with dementia due to probable Alzheimer's disease, we cannot provide assurance that we will be able to seek or obtain approval of BXCL501 for the treatment of agitation in patients with dementia due to probable Alzheimer's disease in the at-home setting based on this data and we will be required to generate additional data to evaluate the at-home use of BXCL501 in our targeted Alzheimer's dementia population before we are able to seek approval for such at-home use in this population, if ever. In addition, the FDA may determine that we cannot rely on the data from our prior TRANQUILITY II Phase 3 trial to support an sNDA as a result of potential data integrity issues at the trial site, as the FDA may not agree with our belief that data reliability and integrity remain intact. See Part II, Item 1A, "Risk Factors—Risks Related to the Discovery and Development of Product Candidates—*Developments relating to its TRANQUILITY II Phase 3 trial may impact the timing of its development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease*" for additional information. If the FDA does not accept the data from our prior TRANQUILITY II Phase 3 trial, we could be required to conduct additional

clinical trials beyond those we currently contemplate, which would increase our costs and delay potential submission of an sNDA for BXCL501 which in turn would adversely affect our financial position and operations.

Accordingly, if the FDA reaches these conclusions or otherwise finds that our proposed clinical studies would not adequately evaluate the safety and efficacy of BXCL501 for the acute treatment of agitation associated with dementia due to probable Alzheimer's disease in an at-home setting and/or care setting, we may need to evaluate more patients for a longer period of time to demonstrate the safety and efficacy of BXCL501.

With respect to our SERENITY program, we also held a Type C Meeting with the FDA on March 6, 2024 to obtain further feedback on our proposed changes to the design of SERENITY III Part 2, including with respect to the trial endpoints, and to discuss the content and format of a potential sNDA submission to expand the label of IGALMI® 120 micrograms to the acute treatment of agitation associated with schizophrenia and bipolar disorders in the outpatient setting. IGALMI® is already approved at the 120 mcg dose based on efficacy data that we previously generated in treating a single episode of agitation. Consistent with the data generated to date, the label for IGALMI® currently includes a limitation on use ("LOU"), noting the lack of efficacy or safety data beyond 24 hours following the first dose. During our March 6, 2024 Type C meeting with the FDA, we discussed, among other things, whether evaluating the at-home use of BXCL501 120 mcg, with safety as the primary objective and efficacy measures as exploratory endpoints, if successful, could support the submission of an sNDA seeking expansion of the current label for IGALMI® 120 mcg to allow at-home use and labeling without the current LOU. Based on current FDA feedback, we have amended the Part 2 of the SERENITY III protocol to evaluate the safety and efficacy of the 120 mg dose in the at-home setting, and now refer to this revised trial as the SERENITY At-Home trial. We believe that our ability to seek labeling without the current LOU will depend, in part, on the number of agitation episodes we observe during our planned study period. Even if our planned SERENITY At-home trial is successful in demonstrating safety in the at-home setting, and even if the IGALMI® 120 mcg label is expanded to allow outpatient use, there is no guarantee that we will observe and/or treat a sufficient number of agitation episodes during the study period to support removal of the current LOU.

Any modifications to our proposed trial designs, whether by us or by the FDA would delay our initiation of such proposed trials, increase the costs of any trial that we do conduct and delay any potential submission of an sNDAs for BXCL501. Requirements to conduct additional clinical trials evaluating BXCL501 in support of our planned sNDAs seeking approvals for BXCL501 for our targeted patient populations in at-home settings would increase our costs, and in either case, such modifications or requirements could have a material adverse effect on our prospects and results of operations.

In the near term, we are dependent on the success of IGALMI®, and the development of four of our product candidates, BXCL501, BXCL502, BXCL701 and BXCL702. If we are unable to complete the clinical development of or obtain marketing approval for our product candidates or successfully commercialize IGALMI® and our other product candidates, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

We currently have only one product that has received regulatory approval and may never be able to develop additional marketable product candidates. We are continuing to invest a significant portion of our efforts and financial resources in the commercialization of IGALMI® and development of our four product candidates, BXCL501, BXCL502, BXCL701 and BXCL702, as well as other product candidates. In connection with the Reprioritization, we have significantly reduced the resources devoted to commercialization of IGALMI® and it is possible that will have adverse consequences on the revenue that we are able to generate from IGALMI® in the near term. As part of the Company's Reprioritization, the IGALMI® commercial team shifted focus to a hospital/Integrated Delivery Network ("IDN") contracting strategy with a Corporate Account Director (CAD) team. The goal of the realigned CAD team is to work with large IDNs and drive sales utilizing a top-down approach. Over time, the revised commercial effort is expected to allow the Company to continue to make inroads into the institutional market in a more cost-efficient manner. However, we have limited experience in drug development and commercialization, and our prospects are substantially dependent on our ability, or that of any future collaborator, to develop, obtain marketing approval for and successfully commercialize product candidates in one or more additional disease indications.

The success of IGALMI®, and of BXCL501, BXCL701, BXCL502 and our other product candidates will depend on several factors, including the following:

- acceptance of an investigational new drug application ("IND") by the FDA or acceptance of comparable applications by foreign regulatory authorities allowing us to conduct clinical trials of our product candidates in the U.S. or in foreign jurisdictions;
- initiation, progress, timing, costs and results of clinical trials of our product candidates and potential product candidates, including any delays caused by the developments relating to the TRANQUILITY program, and any additional trials we may need to conduct prior to seeking approvals for BXCL501 in at-home and/or care facilities;
- demonstration of safety and efficacy of our product candidates to the satisfaction of the FDA, or any comparable foreign regulatory authority, and sufficient for marketing approval;
- the timing and performance of our current and future collaborators;
- the nature of any required post-marketing clinical trials or other commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the U.S. and internationally;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

Many of these factors are beyond our control, including the results of clinical trials, the time required for the FDA, or any comparable foreign regulatory authorities, to review any regulatory submissions we may make, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to commercialize IGALMI® or develop, receive marketing approval for and successfully commercialize BXCL501, BXCL701 and our other product candidates, on our own or with any future collaborator, or experience delays because of any of these factors or otherwise, our business could be substantially harmed.

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

From time to time, we may publicly disclose top-line or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data. The results and related findings and conclusions based on such preliminary data are subject to change, and have in the past changed, 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 or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim data and final data could significantly harm 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 harmed, which could harm our business, operating results, prospects or financial condition.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, expensive and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to nonclinical findings made while clinical studies are underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our future clinical trial results may not be successful, and notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. The historical failure rate for product candidates in our industry is high. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. We obtained regulatory approval for our first product candidate for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder, which is in the early stages of commercialization. It is possible that none of our other product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval.

Our current product candidates, or any that may be developed in the future, could fail to receive regulatory approval for many reasons, including the following:

- the FDA, or comparable foreign regulatory authorities, may disagree with the design or implementation of our clinical trials;
- 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;

- 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 U.S. or elsewhere;

- the FDA, or comparable foreign regulatory authorities, may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or comparable foreign regulatory pathways;

- the FDA, or comparable foreign regulatory authorities, may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; 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.

We have limited experience in completing clinical trials of product candidates. Consequently, we may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of clinical trials we initiate in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all. This 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 significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, 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 or may restrict its distribution. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have only submitted one NDA to the FDA and have not submitted any similar marketing applications to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates currently in development, or any than may be developed in the future, will be successful in clinical trials or receive regulatory approval. Further, our product candidates currently in development, or any that may be developed in the future, may not receive regulatory approval even if we believe they are successful in clinical trials. If we do not receive regulatory approvals for additional product candidates, we may not be able to continue our operations. For any regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for IGALMI® or our other product candidates are not as significant as we estimate, we may not generate significant revenues from sales of IGALMI® or such other product candidates, if approved.

We plan to seek regulatory approval to commercialize our product candidates in the U.S., the European Union ("EU") and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation ("CTR"), which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application ("CTA"), to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision

per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors could choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those are governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Clinical trials are expensive, time-consuming, difficult to design, difficult to conduct, and involve an uncertain outcome.

Before obtaining marketing approval from the FDA, or other comparable foreign regulatory authorities, for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates, in accordance with applicable law and regulations. Failure can occur at any time during the clinical trial process. Although we are planning for certain clinical trials relating to BXCL501, BXCL701, BXCL502 and our other product candidates, there can be no assurance that the FDA, or other comparable foreign regulatory authorities, will accept our proposed trial designs as sufficient to establish the safety and/or efficacy of our product candidates.

We may experience delays in our clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, or comparable foreign regulatory authorities, disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory allowances or authorizations to commence a trial or consensus with regulatory authorities on trial designs;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining institutional review board approval at each site, or independent ethics committee approval at any sites outside the U.S.;
- dependence on the needs and timing of third-party collaborators;
- changes to clinical trial protocols;
- recruiting suitable patients to participate in a trial in a timely manner and in sufficient numbers;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing patient safety concerns that arise during the course of a trial;
- having patients complete a trial or return for post-treatment follow-up;
- imposition of a clinical hold by regulatory authorities, including as a result of unforeseen safety issues or side effects or failure of trial sites to adhere to regulatory requirements;

- the occurrence of SAEs in trials of the same class of agents conducted by other companies or institutions;
- subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing trials;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- lack of adequate funding to continue the clinical trial;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA, or comparable foreign regulatory authorities, to temporarily or permanently shut down due to violations of current good manufacturing practice ("cGMP") regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCPs or other regulatory requirements; or
- third-party contractors not performing data collection or analysis in a timely or accurate manner; third-party contractors not complying with training and trial protocol; or third-party contractors becoming debarred or suspended or otherwise penalized by the FDA, such as in the case of the recent events relating to the TRANQUILITY II clinical trial, or other government or regulatory authorities, for violations of regulatory requirements, in which case, we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB") for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we have agreements governing their committed activities, we have limited influence over their actual performance, which increases the risk that such CROs or trial sites may fail to perform in accordance with regulatory requirements, clinical trial protocols or with the agreements governing their services to us. For example, investigator misconduct affecting our TRANQUILITY II trial, which evaluated BXCL501 in patients with probable Alzheimer's disease, may have a material adverse impact on our development program for BXCL501 in these patients, as described more fully in the risk factor above entitled: "*Developments relating to our TRANQUILITY II Phase 3 trial may impact the timing of our development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease*."

Further, conducting clinical trials in foreign countries, as we may do for our current and future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol due to differences in health care services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. For example, current geopolitical conflicts in Eastern Europe and the Middle East may adversely impact our ability to conduct trials in those regions and elsewhere.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. 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.

We depend on enrollment and evaluation of patients in our clinical trials to continue development of our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll and evaluate a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or evaluation in our clinical trials for a variety of reasons. Patient enrollment and evaluation is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the size of the patient population required for analysis of the trial's primary endpoints, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, the risk that patients enrolled in clinical trials will drop out of the trials before evaluation or completion, the frequency of acute agitation symptoms in enrolled patients, the opportunity for evaluation of patients enrolled in our trials, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our product candidates are designed to target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. The delay or inability to meet planned patient enrollment may result in increased costs and delay or termination of our trials, which could have a harmful effect on our ability to develop products.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The clinical evaluation of BXCL501, BXCL502, BXCL701, BXCL702 and our other product candidates in patients, in many cases, is ongoing and it is possible that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. For example, in our Phase 2 clinical trial of BXCL701 for the treatment of emergent neuroendocrine prostate cancer, one patient experienced acidosis with a fatal outcome. Although the clinical investigator could not determine that the fatality was related to treatment with BXCL701, it is possible that BXCL701 could be tied to unacceptable side effects in the future.

If we observe drug-related AEs or other unacceptable safety concerns in clinical trials, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials or the FDA, or comparable foreign regulatory authorities, could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. For example, the FDA placed Point Therapeutics, Inc.'s IND for BXCL701 on clinical hold following an increase in observed mortality in patients receiving BXCL701 in a Phase 3 trial in patients with non-small cell lung cancer. Though we believe that this result was caused by, among other things, an imbalance in the disease severity of patients enrolled in the active arm of the clinical trial, there is no guarantee that excess mortality will not be observed in future clinical studies. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train

medical personnel using our product candidates to understand the side effect profiles observed in our clinical trials and upon commercialization of any of our product candidates that may receive regulatory approval. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if we or others later identify undesirable side effects caused by IGALMI® or any other product candidate that receives marketing approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products;
- we may be required to recall a product or change the way such a product is administered to patients;
- additional restrictions may be imposed on the marketing or distribution of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or contraindication;
- we may be required to implement Risk Evaluation and Mitigation Strategies ("REMS") or create a medication guide outlining the risks of such side effects for distribution to patients, or similar risk management measures;
- we could be sued and held liable for harm caused to patients;
- our product may become less competitive; and
- our reputation may suffer.

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

The discovery and development of product candidates based on EvolverAI, BioXcel LLC's proprietary pharmaceutical discovery and development engine, and our artificial intelligence ("AI") platform is novel and unproven, and we do not know whether we will be able to develop any products of commercial value.

We are leveraging our own AI platform and BioXcel LLC's EvolverAI, a proprietary pharmaceutical discovery and development engine, to create a pipeline of neuroscience and immuno-oncology product candidates for patients whose diseases have not been adequately addressed to date by other approaches and to design and conduct efficient clinical trials with a higher likelihood of success. While we believe that applying our AI platform and BioXcel LLC's EvolverAI to create medicines for defined patient populations may potentially enable drug research and clinical development that is more efficient than conventional drug research and development, our approach is novel. Although we obtained FDA approval for IGALMI®, because our approach is novel, the cost and time needed to develop our product candidates is difficult to predict, and our efforts may not result in the discovery and development of commercially viable medicines. We may also be incorrect about the effects of our product and product candidates on the diseases of our defined patient populations, which may limit the utility of our approach or the perception of the utility of our approach. Furthermore, our estimates of our defined patient populations available for study and treatment may be lower than expected, which could adversely affect our ability to conduct clinical trials and may also adversely affect the size of any market for medicines we may successfully commercialize. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively as expected and therefore we may not be able to commercialize our approach as originally expected.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many

technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Additionally, our use of AI and machine learning may be subject to laws and evolving regulations regarding the use of AI or machine learning, controlling for data bias, and anti-discrimination, and we may not always be able to anticipate how to respond to these laws or regulations. Further, there is an increase in litigation in a number of jurisdictions, including the United States, relating to the use of AI, particularly generative AI.

Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our operations, financial performance and business.

The Company's AI platform and BioXcel LLC's EvolverAI may fail to help us discover and develop additional potential product candidates.

Any drug discovery that we are conducting using the Company's AI platform and BioXcel LLC's EvolverAI may not be successful in identifying compounds that have commercial value or therapeutic utility. The Company's AI platform and BioXcel LLC's EvolverAI may initially show promise in identifying potential product candidates, yet fail to yield viable additional product candidates for clinical development or potential commercialization for a number of reasons, including:

- research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price;

- compounds found through the Company's AI platform and BioXcel LLC's EvolverAI may not demonstrate efficacy, safety or tolerability;

- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance;

- competitors may develop alternative therapies that render our potential product candidates non-competitive or less attractive; or

- a potential product candidate may not be capable of being produced at an acceptable cost.

Regulators may limit our ability to develop or implement our proprietary AI algorithms and/or may eliminate or restrict the confidentiality of our proprietary technology, which could have an adverse effect on our business, results of operations, and financial condition.

Our future success depends on our ability to continue to develop and implement our proprietary AI algorithms and models, and to maintain the confidentiality of this technology. Changes to existing regulations, their interpretation or implementation, or new regulations could impede our use of this technology or require that we disclose our proprietary technology to our competitors, which could impair our competitive position and result in an adverse effect on our business, results of operations and financial condition.

We obtained Fast Track designation for certain of our product candidates, and we may seek Fast Track designation for other indications or for our other product candidates, but we might not receive such designations, and even if we do, such designations may not actually lead to a faster development or regulatory review or approval process.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for FDA Fast Track designation. The sponsor of a Fast Track product candidate 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 if the relevant criteria are met. An NDA for a Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We obtained Fast Track designation for BXCL501 for the acute treatment of mild-to-moderate agitation associated with schizophrenia, bipolar disorder, and dementia, and we further obtained Fast Track designation for BXCL701, in combination with a checkpoint inhibitor, for the treatment of patients with metastatic SCNC with progression on chemotherapy and no evidence of microsatellite instability, and we may seek additional Fast Track designation for BXCL501 or BXCL701 or for one or more of our other product candidates, but we might not receive such designations from the FDA. However, even if we receive Fast Track designation, Fast Track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. We may not experience a faster development or regulatory review or approval process with Fast Track designation compared to conventional FDA procedures. In addition, 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.

A Breakthrough Therapy designation by the FDA, even if granted for any of our 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 marketing approval.

We obtained Breakthrough Therapy Designation for BXCL501 for the acute treatment of agitation associated with dementia, and we may seek additional Breakthrough Therapy designations for our product candidates if the clinical data support such a designation for one or more 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 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. Product candidates designated as Breakthrough Therapies by the FDA also receive the benefits associated with Fast Track designation, including the potential for rolling review of an NDA.

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 drugs considered for approval under non-expedited FDA review 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 the product no longer meets the conditions for qualification or decide that the period for FDA review or approval will not be shortened.

If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for certain of our product candidates. The Hatch-Waxman Act added Section 505(b)(2) to the Federal Food, Drug and Cosmetic Act ("FDCA"). Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

If we are required by the FDA, or similar regulatory authorities, to obtain approval (or clearance, or certification) of a companion diagnostic device in connection with approval of one of our product candidates, and we do not obtain, or face delays in obtaining approval (or clearance, or certification) of a companion diagnostic device, we will not be able to commercialize the product candidate, and our ability to generate revenue will be materially impaired*.*

According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to regulatory approval requirements. For example, we may decide to collaborate with patient diagnostic companies during our clinical trial enrollment process for BXCL701 to help identify patients with tumor gene alterations that we believe may be most likely to respond to treatment with BXCL701. The process of obtaining or creating such diagnostic is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and, to date, the FDA has generally required premarket approval of companion diagnostics for cancer therapies. Generally, when a companion diagnostic is essential to the safe and effective use of a therapeutic product, the FDA requires that the companion diagnostic be approved before or concurrent with approval of the therapeutic product and before a product can be commercialized. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect. In January 2024, the FDA announced that it intends to initiate the process to reclassify most in vitro diagnostic tests ("IVDs") that are currently Class III into Class II, including companion diagnostic IVDs. If such reclassification efforts occur, any companion diagnostics that are the subject of the down-classification may no longer require premarket approval, but rather may be marketed pursuant to the generally less burdensome 510(k) clearance process. However, there is no assurance that any companion diagnostic required for our pharmaceutical development programs will benefit from the reclassification, or that the reclassification, even if it does occur, will result in a shorter timeline to development or marketing of the companion diagnostic.

If the FDA, or a comparable foreign regulatory authority, requires approval (or certification or clearance) of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains marketing approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval (or clearance, or certification) for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval (or clearance, or certification) of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

Approval, clearance or certification of companion diagnostics may be subject to further legislative or regulatory reforms notably in the EU. On May 25, 2017, the new In Vitro Medical Devices Regulation No. 2017/746 ("IVDR") entered into force. The IVDR repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, regulations are directly applicable (i.e., without the need for adoption of EU member states laws implementing them) in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. The IVDR became effective in May 2022. However, on October 14, 2021, the European Commission proposed a "progressive" roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. The European Parliament and Council adopted the proposed regulation on December 15, 2021. The IVDR has applied since May 26, 2022, but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation.

The regulation of companion diagnostics in the EU is subject to further requirements since the IVDR became applicable as it introduced a new classification system for companion diagnostics. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue an EU certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a marketing authorization ("MA") application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national competent authority or the EMA.

These modifications may make it more difficult and costly for us to obtain regulatory clearances, approvals or certifications for our companion diagnostics or to manufacture, market or distribute our products after clearance, approval or certification is obtained.

Although the FDA has approved IGALMI® for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder, we will still face extensive and ongoing regulatory requirements and obligations for IGALMI® and for any product candidates for which we obtain approval.

Any regulatory approvals that we may receive for IGALMI® or any of our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA-approved label for IGALMI® includes certain warnings and precautions regarding hypotension, orthostatic hypotension, bradycardia, somnolence, and QT interval prolongation. The FDA may also require a REMS to approve a product candidate, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

In addition, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for IGALMI® are and will remain subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and on-going compliance with cGMPs, and GCPs for any clinical trials that we conduct post-

approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory authority discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, discovery of previously unknown AEs or other problems with our products, manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on manufacturing such products;
- restrictions on the labeling or marketing of products;
- restrictions on product manufacturing, distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Further, the policies of the FDA and other regulatory authorities may change, and additional government regulations may be enacted that could impose extensive and ongoing regulatory requirements and obligations on any product candidate for which we obtain marketing approval. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad.

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

The FDA and other regulatory authorities strictly regulate marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA or any other regulatory authority may grant is limited to those specific diseases and indications for which a product is deemed to be safe and effective. For example, the FDA-approved label for IGALMI® is currently limited to the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults to be self-administrated by patients under the supervision of a health care provider.

While physicians in the U.S. may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate

treatment for some patients in varied circumstances. For example, other formulations of Dex, the active ingredient in IGALMI®, have been approved for uses beyond those authorized in IGALMI® approved labeling, such as for use in sedation of surgical patients, and we are continuing to develop BXCL501 for potential use in patients with dementia, MDD, Alzheimer's disease and other indications. We do not market or promote IGALMI® for these uses.

Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on off-label use. If we are found to have promoted our products for any off-label uses, the U.S. federal government (and other foreign governments) could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA, or other regulatory authorities, could also require that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of IGALMI® or our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or staffing reductions could prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result of some of these aforementioned issues. In addition, government funding of other government agencies 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, such as the EMA, following its relocation to Amsterdam and corresponding staff changes, may also slow the time necessary for new drug or modifications to approved drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Additionally, recent actions by the United States federal government have caused concern in the industry that this may occur. For example, beginning on February 13, 2025, the Department of Health and Human Services began firing a large number of its probationary employees, a category that includes new federal employees and employees recently promoted or transferred to new positions or agencies. Larger layoffs may follow, according to a memorandum issued by the Office of Personnel Management on February 26, 2025. These terminations, if they withstand legal challenges, may significantly delay and impede our interactions with FDA. Similar results may stem from the recent confirmed resignations of some senior FDA employees with responsibility for regulation of drugs and biologics, as well as possible future layoffs and resignations. There are also reports that the United States federal government intends to request Congress to reduce FDA funding in upcoming budgets. Such funding cuts may also delay the development and approval of our product candidates.

We may conduct certain of or portions of our clinical trials for our product candidates outside of the U.S. and the FDA may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We may choose to conduct one or more of our clinical trials or a portion of our clinical trials for our product candidates outside the U.S. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign

study data are not intended to serve as the sole basis for approval, if the clinical trial was not otherwise subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an on-site inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and could result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

We may be subject to extensive regulations outside the U.S. and may not obtain marketing approvals for products in Europe and other jurisdictions.

In addition to regulations in the U.S., should we or our collaborators pursue marketing approvals for IGALMI®, and for BXCL501, BXCL502, BXCL701, BXCL702 and our other product candidates internationally, we and our collaborators will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we, or our collaborators, obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country.

We expect to pursue marketing approvals for IGALMI®, and may pursue marketing approvals for BXCL501, BXCL502, BXCL701, BXCL702 and our other product candidates in Europe and other jurisdictions outside the U.S. with collaborative partners. The time and process required to obtain regulatory approvals and reimbursement in Europe and other jurisdictions may be different from those in the U.S. Also, regulatory approval in one jurisdiction does not ensure approvals in any other jurisdiction; however, negative regulatory decisions in any jurisdiction may have a negative impact on the regulatory process in other jurisdictions.

Following a national referendum and enactment of legislation by the government of the United Kingdom ("UK"), the UK formally withdrew from the EU on January 31, 2020 and ratified a trade and cooperation agreement governing its future relationship (commonly referred to as "Brexit"). The agreement, which was applied provisionally from January 1, 2021 and entered into force on May 1, 2021, addresses trade, economic arrangements, law enforcement, judicial cooperation and a governance framework including procedures for dispute resolution, among other things. Because the agreement merely sets forth a framework in many respects and requires complex additional bilateral negotiations between the UK and the EU as both parties continue to work on the rules for implementation, significant political and economic uncertainty remains about how the precise terms of the relationship between the parties will differ from the terms before withdrawal.

Since January 1, 2021, the UK operates under a distinct regulatory regime to the EU. EU pharmaceutical laws only apply in respect of the UK to Northern Ireland (as set out in the Protocol on Ireland/Northern Ireland). EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". While the UK has indicated a general intention that new laws regarding the development, manufacture and commercialization of medicinal products in the UK will align closely with EU law, there are limited detailed proposals for future regulation of medicinal products. The trade and cooperation agreement includes specific provisions concerning medicinal products, which include the mutual recognition of cGMP, inspections of manufacturing facilities for medicinal products and cGMP documents issued (such mutual recognition can be rejected by either party in certain circumstances) but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. For example, it is not clear to what extent the UK will adopt legislation aligned with, or similar to, the EU CTR which became applicable on January 31, 2022 and which significantly reforms the assessment and supervision processes for clinical trials throughout the EU. On January 17, 2022, the UK Medicines and Healthcare products Regulatory Agency ("MHRA") launched an eight-week consultation on reframing the UK legislation for clinical trials which aimed to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The MHRA responded to the consultation on March 21, 2023 and confirmed that it would bring forward changes to the legislation. The final legal texts introduced by the UK Government will ultimately

determine the extent to which the UK clinical trials framework aligns with or diverges from the EU CTR. A decision by the UK not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries.

Therefore, there remains political and economic uncertainty regarding to what extent the regulation of medicinal products will differ between the UK and the EU in the future. Any divergences will increase the cost and complexity of running our business, including with respect to the conduct of clinical trials. Brexit also materially impacted the regulatory regime with respect to the approval of our product candidates. Great Britain is no longer covered by the EU's procedures for the grant of MAs (Northern Ireland is covered by the centralized authorization procedure and can be covered under the decentralized or mutual recognition procedures). As of January 1, 2021, all existing centralized MAs were automatically converted into UK MAs effective in Great Britain and issued with a UK MA number on January 1, 2021 (unless MA holders opted out of this scheme). A separate MA is now required to market drugs in Great Britain. It is currently unclear whether the regulator in the UK, the MHRA, is sufficiently prepared to handle the increased volume of MA applications that it is likely to receive. Any delay in obtaining, or an inability to obtain, any regulatory approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in Great Britain and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in Great Britain for our product candidates, which could significantly and materially harm our business. Any of these factors could have a significant adverse effect on our business, financial condition, results of operations and prospects.

If we are found in violation of federal, state or foreign health care "fraud and abuse" laws, we may be required to pay significant fines and penalties, including, without limitation, debarment, suspension or exclusion from participation in federal, state or similar health care programs, which may adversely affect our business, financial condition and results of operations.

In the U.S., we are subject to various federal and state health care "fraud and abuse" laws, including anti- kickback laws, false claims laws and other laws intended to reduce fraud and abuse in federal and state health care programs, which could affect us, and our ability to successfully commercialize our products in the U.S. We may have to comply with similar laws and regulations outside the U.S. These laws include:

- the federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a federal health care program, such as Medicare or Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

- false claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, claims for reimbursed drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the provision of kickbacks has resulted in the submission of false claims to governmental health care programs. 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 false claims laws. Further, private individuals have the ability to bring actions on behalf of the government under the federal False Claims Act;

- the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") prohibits persons or entities from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;

- federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows, or should know, it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the federal physician sunshine requirements under the Patient Protection and Affordable Care Act ("ACA"), which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to 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 applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to health care providers and other potential referral sources; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures and pricing information; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to health care providers.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state or foreign health care programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, any of which could adversely affect our ability to market our products and adversely impact our financial results.

We may be unable to maintain sufficient clinical trial liability insurance.

Our inability to retain sufficient clinical trial liability insurance at an acceptable cost to protect against potential liability claims could prevent or inhibit our ability to conduct clinical trials for product candidates we develop. We may be unable to obtain appropriate levels of such insurance. Even if we do secure clinical trial liability insurance for our programs, we may not be able to achieve sufficient levels of such insurance. Any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that exceeds the limits of our insurance coverage. We have supplemented our clinical trial coverage with product liability coverage in connection with the commercial launch of IGALMI® and expect that we would similarly supplement our coverage for any of our other product candidates that may receive regulatory approval, but we may be unable to obtain such increased coverage on acceptable terms or at all. If we are found liable in a clinical trial lawsuit or a product liability lawsuit in the future, we will 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.

Risks Related to Commercialization of Our Product Candidates

If our products do not gain market acceptance or if we fail to accurately forecast demand or manage our inventories, our business will suffer because we might not be able to fund future operations.

A number of factors may affect the market acceptance of our products or any other products or product candidates we develop or acquire, including, among others:

- the price of our products relative to other products for the same or similar treatments;
- the perception by patients, physicians and other members of the health care community of the effectiveness, utility and safety of our products for their indicated applications and treatments;
- our ability to fund our sales and marketing efforts; and
- the effectiveness of our sales and marketing efforts, including our strategic refocus to hospital/IDNs as part of the Reprioritization.

If our products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for new product candidates and expanding our sales and marketing efforts for our approved products, which would cause our business to suffer.

We plan to continue to commercialize IGALMI® sublingual film for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder, to be self-administered by patients under the supervision of a healthcare provider, which is our only approved product to date. However, in connection with the Reprioritization, we significantly reduced the resources devoted to commercialization of IGALMI ® and it is possible that will have adverse consequences on the revenue that we are able to generate from IGALMI®. Revenues for IGALMI® for the year ended December 31, 2024 were $2.3 million. If our commercial products do not gain market acceptance, we may not be able to fund future operations, including developing, testing and obtaining regulatory approval for an sNDA for other BXCL501 indications, including in the at-home setting for the acute treatment of agitation (non-daily) associated with dementia due to probable Alzheimer's disease, or for other product candidates that it may develop. Our results of operations could be materially harmed if we are unable to successfully commercialize IGALMI® for any currently or additionally approved indications or any future product candidates that we may have approved.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for IGALMI® and manage our inventory. To ensure adequate inventory supply, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for IGALMI®. Our ability to accurately forecast demand for IGALMI® could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for IGALMI® or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for IGALMI®, our third-party contract manufacturer may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or our third-party manufacturers may not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for IGALMI® and our results of operations.

We seek to maintain sufficient levels of inventory to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

Our estimated number of episodes of agitation and our corresponding estimated total addressable market are subject to inherent challenges and uncertainties. If we have overestimated the number of episodes or the size of our total addressable market for our current and potential future products or product candidates, or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability may be harmed.

We have based our potential market opportunity on a number of internal and third-party estimates and resources, including, without limitation, management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties, which may be incorrect. Our estimated potential market opportunity is based on estimates of episodes of agitation across our indications, and these estimated episodes of agitation are also based on internal and third-party estimates and market resources using data self-reported by patients. The conditions supporting our assumptions or estimates and the market data supporting these assumptions and estimates may change at any time or otherwise be inaccurate, thereby reducing the predictive accuracy of these underlying factors. Our total addressable market will ultimately depend upon, among other things, the number of actual treatable episodes, the diagnosis criteria included in the final label for each of our product candidates, if approved for sale for these indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients and treatable episodes in the United States and other major markets and elsewhere may turn out to be materially lower than expected, the number of treatable episodes may be significantly fewer than total episodes experienced, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would harm our results of operations and our business. For example, our estimates of the monthly average episodes for patients diagnosed with bipolar disorder and patients diagnosed with schizophrenia and, therefore, our estimated total addressable market are based on third-party market surveys which differ from an observational study in the EU of inhaled loxapine for the treatment of agitation in patients with schizophrenia or bipolar disorder conducted which found that only 40% of enrolled patients reported agitation episodes in the six-month study period. If third-party or internally generated data prove to be inaccurate or we make errors in our assumptions based on that data, our total addressable market may be meaningfully smaller than we have estimated, our future growth opportunities and sales growth may be impaired, any of which could have a material adverse effect on our business, financial condition and results of operations.

We obtained Orphan Drug Designation for BXCL701 for the treatment of pancreatic cancer, melanoma, acute myeloid leukemia and soft tissue sarcoma and we may seek Orphan Drug Designation for other indications or product candidates, and we may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity, and may not receive Orphan Drug Designation for other indications or for our other product candidates.

Regulatory authorities in some jurisdictions, including the U.S. and EU, may designate drugs intended for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient population greater than 200,000 individuals in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S. In the EU, orphan drug designation is granted by the European Commission based on a scientific opinion of the EMA's Committee for Orphan Medicinal Products. A medicinal product may be designated as orphan if its sponsor can establish that (i) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (ii) either (a) such condition affects no more than 5 in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (iii) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the medicinal product will be of significant benefit to those affected by the condition. The application for orphan designation must be submitted before the application for MA.

In the U.S., orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, 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 drug exclusivity. Orphan drug exclusivity in the U.S. provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same disease or condition for

seven years. In limited circumstances, the applicable exclusivity period is 10 years in the EU. The EU exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

In January 2021, the FDA granted Orphan Drug Designation to BXCL701 for the treatment of soft tissue sarcoma. In September 2019, the FDA granted Orphan Drug Designation to BXCL701 for the treatment of acute myeloid leukemia. Prior to 2019, the FDA granted Orphan Drug Designation to BXCL701 for the treatment of pancreatic cancer and melanoma. We may seek Orphan Drug Designations for BXCL701 in other diseases or conditions or for other product candidates. There can be no assurances that we will be able to obtain such designations.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, 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 orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products, and it is possible that another company also holding orphan drug designation for the same product candidate will receive marketing approval for the same disease or condition before we do. If that were to happen, our applications for that disease or condition may not be approved until the competing company's period of exclusivity expires. In addition, exclusive marketing rights in the U.S. and abroad may be limited if we seek approval for an indication broader than the orphan-designated disease or condition or may be lost if the FDA or foreign regulatory authorities later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active ingredients may be approved for the same disease or condition. Even after an orphan drug is approved, the FDA or foreign regulatory authorities can subsequently approve the same drug with the same active ingredient for the same condition if the FDA or foreign regulatory authorities conclude 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 or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process and does not prevent competitors from obtaining approval of the same product candidate as ours for indications other than those in which we have been granted orphan drug designation.

If we are unable to develop satisfactory sales and marketing capabilities, we may not succeed in commercializing IGALMI® or any product candidate for which we may obtain regulatory approval.

We have limited experience in marketing and selling drug products. We have not entered into arrangements for the sale and marketing of IGALMI®, BXCL501, BXCL502, BXCL701, BXCL702 or any other product candidate. Typically, pharmaceutical companies would employ groups of sales representatives and associated sales and marketing staff numbering in the hundreds to thousands of individuals to call on the large number of physicians and hospitals. Following our Reprioritization, we may need to rebuild a commercial sales and marketing team if we seek to modify our commercial strategy for IGALMI® or initiate commercial sales for any product candidate in the future, which will likely require significant cost. We may seek to collaborate with a third-party to market our drugs or may seek to market and sell our drugs by ourselves. If we seek to collaborate with a third-party, we cannot be sure that a collaborative agreement can be reached on terms acceptable to us. We may also need to hire additional personnel skilled in marketing and sales for our direct marketing and selling efforts. We cannot be sure that we will be able to acquire, or establish third-party relationships to provide, any or all of these marketing and sales capabilities. The maintenance and expansion of our direct sales force or establishment of a contract sales force, or a combination thereof, as applicable, to market our products is expensive and time-consuming and could delay any product launch. In addition, reputational harm from the Reprioritization may adversely impact our efforts to hire personnel skilled in marketing and sales. Further, we can give no assurances that we will be able to maintain a direct and/or contract sales force for any period of time or that our sales efforts will be sufficient to grow our revenues or that our sales efforts will ever lead to profits. A direct sales force has in the past subjected and may in the future subject us to higher fixed costs than those of companies that market competing products through independent third parties, due to the costs that we bear associated with employee benefits, training, and managing sales personnel. As a result, we could be at a competitive disadvantage. Additionally, these fixed costs may slow our ability to reduce costs if needed, which could have a material adverse effect on our business, financial condition, and results of operations.

We operate in a highly competitive and rapidly changing industry.

Biopharmaceutical product development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the U.S., the EU and other jurisdictions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop.

Established biopharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for products and product candidates, if any, that we commercialize. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

Although we obtained FDA approval for IGALMI®, our products and product candidates may not be accepted by physicians or the medical community in general, and there may be insufficient insurance coverage and reimbursement.

There can be no assurance that IGALMI®, or BXCL501, BXCL502, BXCL701, BXCL702 and our other product candidates or any other product candidate successfully developed by us, independently or with partners, if approved, will be accepted by physicians, hospitals and other health care facilities. IGALMI® competes, and BXCL501, BXCL502, BXCL701, BXCL702 and any future product candidates we develop will compete, with a number of products manufactured and marketed by major pharmaceutical and biotechnology companies. The degree of market acceptance of IGALMI® and any drugs we develop depends on a number of factors, including:

- our demonstration of the clinical efficacy and safety of our products and product candidates;
- timing of market approval and commercial launch of our products and product candidates;
- the clinical indication(s) for which our products and product candidates are approved;
- product label and package insert requirements;
- advantages and disadvantages of our products and product candidates compared to existing therapies;
- continued interest in and growth of the market for anti-cancer or anti-agitation drugs;

- strength of sales, marketing, and distribution support;
- product pricing in absolute terms and relative to alternative treatments;
- future changes in health care laws, regulations, and medical policies; and
- availability of coverage and reimbursement in select jurisdictions, and future changes to coverage and reimbursement policies of government and third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of IGALMI® or any product candidate for which we obtain regulatory approval. In the U.S. and other countries, sales of IGALMI® and any other products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government health administrative authorities, such as Medicaid and Medicare, managed care providers, private health insurers and other organizations.

Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time consuming and expensive for us to go through the process of seeking coverage and reimbursement from Medicare and private payors. IGALMI® and any other products for which we receive regulatory approval may not be considered cost-effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our proposed products on a profitable basis. Further federal, state and foreign government proposals and health care reforms are likely which could limit the prices that can be charged for IGALMI®and the product candidates that we develop and may further limit our commercial opportunities. Our results of operations could be materially adversely affected by proposed health care reforms, by the Inflation Reduction Act and other drug pricing legislation in the U.S., by the possible effect of such current or future legislation on amounts that private insurers will pay and by other health care reforms that may be enacted or adopted in the future.

Health care reform measures could hinder or prevent our product candidates' commercial success.

The U.S. government and other governments have shown significant interest in pursuing health care reform. Any government-adopted reform measures could adversely impact the pricing of health care products and services in the U.S. or internationally and the amount of reimbursement available from governmental agencies or other third-party payors for IGALMI® and the product candidates that we develop. The continuing efforts of the U.S. and foreign governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce health care costs may adversely affect our ability to set prices for our products, which we believe are fair, and our ability to generate revenues and achieve and maintain profitability.

New laws, regulations and judicial decisions, or new interpretations of existing laws, regulations and decisions, that relate to health care availability, methods of delivery or payment for products and services, or sales, marketing or pricing, may limit our potential revenue, and we may need to revise our research and development programs. The pricing and reimbursement environment may change in the future and become more challenging due to several reasons, including policies advanced by the current executive administration in the U.S., new health care legislation or fiscal challenges faced by government health administration authorities. Specifically, in both the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the health care system in ways that could affect our ability to sell our products profitably.

For example, in the U.S., the ACA, which was enacted in 2010, has substantially changed the way health care is financed by both government health plans and private insurers, and significantly impacts the pharmaceutical industry. For example, the ACA imposed a non-deductible excise tax on pharmaceutical manufacturers or importers that sell branded prescription drugs to government programs. In addition, as part of the ACA's provisions closing a funding gap that existed in the Medicare Part D prescription drug program, manufacturers are required to provide a discount on branded prescription drugs for drugs provided to certain beneficiaries who fall within the "donut hole." Similarly, the ACA increased the level of Medicaid rebates payable by manufacturers of brand-name drugs from 15.1% to 23.1% of the average manufacturer price and required collection of rebates for drugs paid by Medicaid managed care organizations. The ACA also included changes to the Public Health Service's 340B drug pricing program (the "340B program") including expansion of the list of eligible covered entities that may purchase drugs under the program.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form.

In addition, other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. These changes include the Budget Control Act of 2011, which resulted in aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. Furthermore, the American Taxpayer Relief Act of 2012, further reduced Medicare payments to several types of providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, beginning January 1, 2024.

Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services ("HHS") to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. HHS has issued and will continue to issue guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined, it is likely to be significant.

The cost of prescription pharmaceuticals in the U.S. will likely continue to be the subject of considerable discussion. Members of Congress and the Biden Administration have indicated they will continue to pursue further legislative or administrative measures to control prescription drug costs. There have been several Congressional inquiries, as well as legislative and regulatory initiatives and executive orders designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

Individual states in the U.S. continue to consider and have enacted legislation to limit the growth of health care costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

It is likely that federal and state legislatures within the U.S. and foreign governments will continue to consider changes to existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of governments, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect the demand for IGALMI® and any other drug products for which we may obtain

regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain adequate coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the U.S. and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment ("HTA") amending Directive 2011/24/EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

If we fail to comply with reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, results of operations and financial condition.

We participate in the Medicaid Drug Rebate Program ("MDRP") and other federal and state government pricing programs in the U.S., and we may participate in additional government pricing programs in the future. These programs generally require manufacturers to pay rebates or otherwise provide discounts to government payors in connection with drugs that are dispensed to beneficiaries of these programs. As a condition of having federal funds being made available for covered outpatient drugs under Medicaid and Medicare Part B, a manufacturer must enroll in the MDRP. Under this program, we must pay a rebate to state Medicaid programs for each unit of our covered outpatient drug dispensed to a Medicaid beneficiary and paid for by a state Medicaid program. Medicaid drug rebates are based on pricing data that we must report on a monthly and quarterly basis to CMS. For the MDRP, this data includes the average manufacturer price ("AMP") for each drug and, in the case of an innovator product, like IGALMI®, the best price. If we become aware that our MDRP price reporting submission for a prior period was incorrect or has changed as a result of recalculation of the pricing data, we must resubmit the corrected data for up to three years after the data originally was due. Further, under the IRA, AMP figures we report will also be used to calculate a rebate on Medicare Part D utilization, triggered by price increases that outpace inflation. If we fail to provide information timely or are found to have knowingly submitted false information to the government, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP, which would result in payment not being available for our covered outpatient drugs under Medicaid or,

if applicable, Medicare Part B. Failure to make necessary disclosures and/or to identify overpayments additionally could result in allegations against us under the Federal False Claims Act and other laws and regulations.

Federal law requires that a manufacturer that participates in the MDRP also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B, and we participate in the 340B program. The 340B program is administered by the Health Resources and Services Administration ("HRSA") and requires us to charge statutorily defined covered entities no more than the 340B "ceiling price" for our covered outpatient drugs used in an outpatient setting. These 340B program covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. We must report 340B ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B covered entities. HRSA has finalized regulations regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B eligible drugs. HRSA has also finalized an administrative dispute resolution process through which 340B covered entities may pursue claims against participating manufacturers for overcharges, and through which manufacturers may pursue claims against 340B covered entities for engaging in unlawful diversion or duplicate discounting of 340B drugs. In addition, legislation may be introduced that, if passed, would further expand the 340B program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B program discounted pricing on drugs used in an inpatient setting.

In order to be eligible to have drug products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we also must participate in the U.S. Department of Veterans Affairs ("VA") Federal Supply Schedule ("FSS") pricing program. Under the VA/FSS program, we must report the Non-Federal Average Manufacturer Price ("Non-FAMP") for our covered drugs to the VA and charge certain federal agencies no more than the Federal Ceiling Price, which is calculated based on Non-FAMP using a statutory formula. These four agencies are the VA, the U.S. Department of Defense, the U.S. Coast Guard, and the U.S. Public Health Service (including the Indian Health Service). We must also pay rebates on products purchased by military personnel and dependents through the TRICARE retail pharmacy program. If we fail to provide timely information or are found to have knowingly submitted false information, we may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of health care costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with drug price transparency requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations are complex, vary among products and programs, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. The terms, scope and complexity of these government pricing programs change frequently, as do interpretations of applicable requirements for pricing and rebate calculations. Responding to current and future changes may increase our costs and the complexity of compliance will be time-consuming. Any required refunds to the U.S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. Price recalculations under the MDRP also may affect the ceiling price at which we may be required to offer products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we fail to submit required price data on a timely basis, or if we are found to have charged 340B program covered entities more than the statutorily mandated ceiling price. In the event that CMS were to terminate our Medicaid rebate agreement, pursuant to

which we participate in the MDRP, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs. We cannot assure you that price data submissions we make will not be found to be incomplete or incorrect.

Risks Related to Our Relationship with BioXcel LLC

BioXcel LLC has significant influence over the direction of our business, and the concentrated ownership of our common stock will prevent you and other stockholders from influencing significant decisions.

As of December 31, 2024, BioXcel LLC owned approximately 15.5% of the economic interest and voting power of our outstanding common stock and BioXcel LLC is controlled by BioXcel Holdings, Inc. Our Chief Executive Officer and member of our board of directors, Vimal Mehta, Ph.D., is the Chief Executive Officer, President, Treasurer and Secretary and a member of the board of managers of BioXcel LLC and Chief Executive Officer, President, Treasurer and Secretary and the sole member of the board of directors of BioXcel Holdings, Inc. See "*The management of and beneficial ownership in BioXcel LLC by our executive officers and our directors may create, or may create the appearance of, conflicts of interest.*" below. Even though BioXcel LLC controls less than a majority of the voting power of our outstanding common stock, it may influence the outcome of such corporate actions so long as it owns a significant portion of our common stock.

Approval of commercial terms between us and BioXcel LLC does not preclude the possibility of stockholder litigation, including but not limited to derivative litigation nominally against BioXcel LLC and against its directors and officers and also against us and our directors and officers.

The commercial terms of the Separation and Shared Services Agreement (as amended and/or restated and in effect as of the date hereof, the "Services Agreement"), and the Amended and Restated Asset Contribution Agreement (as amended and/or restated and in effect as of the date hereof, the "Contribution Agreement"), that we entered into with BioXcel LLC have not been negotiated by persons consisting solely of disinterested directors.

No assurance can be given that any equity or debt holder of BioXcel LLC or the Company will not claim in a lawsuit that such terms in fact are not in the best interests of BioXcel LLC or the Company and its applicable equity holders, that the directors and officers of BioXcel LLC or the Company breached their fiduciary duties in connection with such agreements and that any disclosures by the Company to its stockholders regarding these agreements and the relationship between BioXcel LLC and us did not satisfy applicable requirements. In any such instance, we and our directors and officers may also be named as defendants and we would have to defend ourselves and our directors and officers. While we would seek indemnification from BioXcel LLC under the terms of these agreements against any damages or other costs, which could be substantial, no such indemnification has yet been agreed to or may be agreed to and be in effect. Further, any such litigation would be time-consuming and would divert focus and resources from the development of our product candidates and our business, including but not limited to possibly delaying our clinical trials due to our management having to spend time and attention on such litigation.

We continue to depend on BioXcel LLC to provide us with certain services for our business.

We rely, in part, on BioXcel LLC and access to its EvolverAI, to complement our in-house, uniquely integrated AI-to-drug-development capability. EvolverAI is a research and development engine created and owned by BioXcel LLC, to identify, research and develop potential product candidates in neuroscience and immuno-oncology. We negotiated the Services Agreement with BioXcel LLC pursuant to which BioXcel LLC agreed to perform certain intellectual property prosecution and management and research and development activities for us utilizing its EvolverAI.

Under the Services Agreement, we had an option, exercisable until December 31, 2024, to enter into a separate collaborative services agreement with BioXcel LLC pursuant to which BioXcel LLC shall perform product identification and related services for us utilizing its EvolverAI. We agreed to pay BioXcel LLC $18,000 per month from March 13, 2023, to December 31, 2024 in exchange for this option. We agreed to negotiate any such collaborative services agreement in good faith and to incorporate reasonable market-based terms, including consideration for BioXcel LLC reflecting a low, single-digit royalty on net sales and reasonable development and commercialization milestone payments, provided that (i) development milestone payments shall not exceed $10 million in the aggregate and not be

payable prior to proof of concept in humans and (ii) commercialization milestone payments shall be based on reaching annual net sales levels, be limited to 3% of the applicable net sales level, and not exceed $30 million in the aggregate. We did not exercise this option, which expired on December 31, 2024.

In addition, at the time of our initial public offering ("IPO"), BioXcel LLC granted us (i) a first right to negotiate exclusive rights to any additional product candidates in the fields of neuroscience and immuno-oncology that BioXcel LLC may identify on its own and not in connection with BioXcel LLC's provision of services to us under the Services Agreement and (ii) an exclusivity agreement in the neuroscience and immuno-oncology fields whereby BioXcel LLC agreed not develop drugs, or engage in preclinical discovery for the purpose of developing drugs, in the neuroscience and immuno-oncology fields for or on behalf of a third party, utilizing EvolverAI or otherwise. This first right to negotiate and exclusivity period expired on March 12, 2023, and there is no assurance that we will extend the terms of the agreement. We are continuing to assess our ongoing business needs.

On September 19, 2023, the Company, Krishnan Nandabalan, Ph.D., InveniAI LLC ("Inveni") and Invea Therapeutics, Inc. ("Invea") and the other parties thereto entered into a non-compete agreement pursuant to which Dr. Nandabalan, Inveni and Invea agreed not to compete with the Company and its controlled affiliates in the fields of neuroscience and immuno-oncology for a period of five years from September 19, 2023 and not to solicit employees of the Company or its controlled affiliates for a period of two years from September 19, 2023. Inveni and Invea are subsidiaries of BioXcel LLC.

If our rights under the Services Agreement were to become limited or if we are otherwise precluded from conducting research and development using EvolverAI, or if BioXcel LLC, Inveni or Invea do not fulfill their obligations under the agreements, such development could materially adversely affect our future operating results, financial condition, and prospects. Furthermore, certain individuals conducting services on our behalf are not our employees, and we cannot control whether they devote sufficient time, skill and resources to our ongoing development programs. We also cannot ensure that BioXcel LLC retains sufficient resources or personnel or otherwise to conduct its operations. BioXcel LLC may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting research and development activities, which could impede their ability to devote appropriate time to our research and development programs. BioXcel LLC is not currently restricted from using EvolverAI to perform drug discovery services for our direct competitors, and if we do not extend the exclusivity period in the neuroscience and immuno-oncology fields, this could harm our competitive position and adversely affect our future operating results and financial condition.

The management of and beneficial ownership in BioXcel LLC may create, or may create the appearance of, conflicts of interest.

Our Chief Executive Officer and member of our board of directors, Vimal Mehta, Ph.D., is the Chief Executive Officer, President, Treasurer and Secretary and a member of the board of managers of BioXcel LLC and Chief Executive Officer, President, Treasurer and Secretary and the sole member of the board of directors of BioXcel Holdings, Inc. Additionally, as of December 31, 2024, Dr. Mehta, through his beneficial ownership of BioXcel LLC, beneficially owned approximately 15.5% of the Company. The management and ownership of BioXcel LLC by Dr. Mehta may create the appearance of conflicts of interest when Dr. Mehta is faced with decisions that could have different implications for BioXcel LLC than the decisions have for us, including decisions that relate to our Services Agreement and Contribution Agreement, as well as potential agreements relating to future product candidates and AI-related services or collaborations. Any perceived conflicts of interest resulting from investors questioning the independence of our management or the integrity of corporate governance procedures may materially affect our stock price and expose us to litigation risk.

Any disputes that arise between us and BioXcel LLC with respect to our past and ongoing relationships could harm our business operations.

Disputes may arise between BioXcel LLC and us in a number of areas relating to our past and ongoing relationships, including:

- intellectual property, technology and business matters, including failure to make required technology transfers and failure to comply with contractual provisions applicable to BioXcel LLC and us;
- labor, tax, employee benefit, indemnification and other matters arising from the separation of BTI from BioXcel LLC;
- distribution and supply obligations;
- employee retention and recruiting;
- business combinations involving us;
- sales or distributions by BioXcel LLC of all or any portion of its ownership interest in us;
- the nature, quality and pricing of services BioXcel LLC has agreed to provide us; and
- business opportunities that may be attractive to both BioXcel LLC and us.

We entered into the Services Agreement with BioXcel LLC related to the separation of our business operations from those of BioXcel LLC that contains certain limitations on BioXcel LLC's ability to control various aspects of our business and operations, notwithstanding BioXcel LLC's substantial ownership position. This agreement may be amended upon agreement between us and BioXcel LLC.

BioXcel LLC may experience challenges with the acquisition, development, enhancement, or deployment of technology necessary for EvolverAI. We may face similar challenges with other AI platforms that we utilize, including our own in-house proprietary platform.

BioXcel LLC operates in businesses that require sophisticated computer systems and software for data collection, data processing, cloud-based platforms, analytics, statistical projections and forecasting, mobile computing, social media analytics and other applications and technologies. BioXcel LLC seeks to address its technology risks by increasing its reliance on the use of innovations by cross-industry technology leaders and adapt these for their pharmaceutical, biotechnology, biopharmaceutical, diagnostic, medical device and contract research and manufacturing clients. Some of the technologies supporting the industries they serve are changing rapidly and we must continue to adapt to these changes in a timely and effective manner at an acceptable cost. They also must continue to deliver data to their clients in forms that are easy to use while simultaneously providing clear answers to complex questions. We also utilize our own in-house AI platform.

There can be no guarantee that we or BioXcel LLC will be able to develop, acquire or integrate new technologies, that these new technologies will meet our and BioXcel LLC's needs or achieve our expected goals, or that we will be able to do so as quickly or cost-effectively as our competitors. Significant technological change could render BioXcel LLC's EvolverAI or other AI platforms that we utilize obsolete. BioXcel LLC's and our continued success will depend on the ability to adapt to changing technologies, manage and process ever-increasing amounts of data and information and improve the performance, features and reliability of these services in response to changing client and industry demands. If EvolverAI or other AI and machine learning models that we use are incorrectly designed, do not operate properly, the data we use to train them is incomplete, inadequate or biased in some way, or if we do not have sufficient rights to use the data on which our AI and machine learning models rely, the performance of our products, services and businesses, as well as our reputation, could suffer or we could incur liability through the violation of laws, third-party privacy rights or contracts to which we are a party. BioXcel LLC or we may experience difficulties that could delay or prevent the successful design, development, testing, and introduction of advanced versions of EvolverAI, limiting our

ability to identify new product candidates. New services, or enhancements to existing EvolverAI services, may not adequately meet our requirements. Any of these failures could have a material adverse effect on our operating results and financial condition.

Risks Related to Our Reliance on Third Parties

We are substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates and our commercial supplies of IGALMI®, and we intend to rely on third parties to produce commercial supplies of any other approved product candidate. Therefore, our development of our products could be stopped or delayed, and our commercialization of any future product could be stopped, delayed or made less profitable if third-party manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us with drug product in sufficient quantities or at acceptable prices.

We entered into a commercial supply agreement with ARx, LLC ("ARx") pursuant to which ARx has agreed to exclusively manufacture and supply us with all of our worldwide demand of film formulation of Dex to be used for the commercial supply of IGALMI® and for ongoing clinical trials of our product candidate BXCL501, subject to certain alternative supply provisions. If ARx is unable or ceases to produce our supply of Dex in sufficient quantities as and when needed or if the ARx agreement becomes too costly, our business would be harmed because there can be no assurance that we will be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. An interruption in our ability to sell our products to customers could occur if we encounter delays or difficulties in securing Dex, or if the quantity or quality supplied does not meet our specifications, or if we cannot then obtain an acceptable substitute. If any of these events occur, our business and operating results could be harmed. Our specified minimum annual payment could adversely affect our cash flows in the future, such as in times when we have sufficient inventory and would otherwise be able to use our cash for other purposes.

The manufacture of biotechnology and pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in biotechnology and pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We do not currently have nor do we plan to acquire the infrastructure or capability internally to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of our products or to produce our products in accordance with cGMP prescribed by the FDA or similar foreign requirements. Drug manufacturing facilities are subject to inspection before the FDA or foreign regulatory authorities will issue an approval to market a new drug product, and ARx, the Patheon pharma services division of Thermo Fisher Scientific Inc., and any other manufacturers that we may use must adhere to the cGMP or similar foreign regulations prescribed by the FDA or foreign regulatory authorities.

As such, these third-party manufacturers will be required to comply with cGMPs, and other applicable laws and regulations. We have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our other product candidates or any products that we may successfully develop, or if it withdraws any such approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates and adversely affect our business.

We, ARx, the Patheon pharma services division of Thermo Fisher Scientific Inc., and/or our other third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our products. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If we, ARx, the Patheon pharma services division of Thermo Fisher Scientific Inc., or our other third-party manufacturers were to

encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any product for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

We, or third-party manufacturers on whom we rely, including ARx, may be unable to successfully scale-up manufacturing of our product and product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing any approved products.

In order to conduct clinical trials of our product candidates and commercialize any approved product candidates, we, or our manufacturers, including ARx, and the Patheon pharma services division of Thermo Fisher Scientific Inc., will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our approved products or product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our approved products or product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our approved products, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our approved products or product candidates successfully.

Our failure to find third-party collaborators to assist or share in the costs of product development could materially harm our business, financial condition, and results of operations.

Our strategy for the development and commercialization of our proprietary products and product candidates may include the formation of collaborative arrangements with third parties. Collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing IGALMI® or product candidates.

If we are not able to establish collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into collaborations could materially harm our business, financial condition and results of operations.

In addition, our dependence on licensing, collaboration and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or commercialize successfully any product candidate to which they have obtained rights from us could materially harm our business, financial condition and results of operations.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, the competent authorities of the European Economic Area ("EEA") countries and comparable foreign regulatory authorities for all of our products in clinical development.

Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If regulatory authorities determine that we or any of our CROs failed to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA 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 by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP and similar foreign regulations. Any failure, whether by us or our CROs, to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

In addition, if any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. For example, investigator misconduct during our TRANQUILITY II trial evaluating BXCL501 in patients with probable Alzheimer's disease could require us to conduct additional clinical trials before we are able to seek or obtain approval for BXCL501 for use in this patient population, as described more fully in the risk factor above entitled: "*Developments relating to our TRANQUILITY II Phase 3 trial may impact the timing of our development plans for, and prospects for seeking or obtaining regulatory approval of, BXCL501 for the acute treatment of agitation (non-daily) associated with dementia in patients with probable Alzheimer's disease*." As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our GCP preclinical studies or our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Our Business and Industry

Unfavorable global political or economic events and conditions could adversely affect our business, financial condition or results of operations.

Our business could be adversely affected by unstable economic and political conditions within the United States and foreign jurisdictions, including as a result of an economic downturn and geopolitical events, such as changes in U.S. federal policy that affect the geopolitical landscape. In addition, the global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. A severe or prolonged economic downturn or recession and a continued increase in inflation rates or interest rates could result in a variety of risks to our business, and our ability to raise additional capital when needed on acceptable terms, if at all. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Increased inflation rates and related increases in interest rates can adversely affect us by increasing our costs, including labor and employee benefit costs. In addition, events such as pandemics, epidemics, or outbreaks of an infectious disease may materially and adversely impact our business if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions. Furthermore, geopolitical conflicts and war, such as the current military conflict between Russia and Ukraine and the war between Israel and Hamas, and other conflicts in the Middle East, could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions have and may in the future be initiated by nations including the U.S., the EU or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with which we conduct business. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our future success may depend on our ability to attract and retain qualified personnel, including consultants.

We are dependent on the principal members of our management and scientific teams. Our success and the execution of our operating strategy, to the extent we continue operations, depend largely on the continued service of our employees. In addition to our employees, we have access to certain of BioXcel LLC's employees and resources through the various agreements we have with BioXcel LLC. We have expanded our management team to include an operational ramp-up of additional technical staff required to achieve our business objectives. We will need to retain such employees, and may need to continue to expand our managerial, commercial, operational, technical, and scientific, financial, and other resources to manage our operations and clinical trials, continue our research and development activities, and any approved product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth.

We may utilize the services of third-party vendors to perform tasks including preclinical and clinical trial management, statistics and analysis, regulatory affairs, medical advisory, market research, formulation development, chemistry, manufacturing and control activities, other drug development functions, legal, auditing, financial advisory, and investor relations. Because we rely on numerous consultants to outsource many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidate or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to recruit and retain qualified personnel, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidate and, accordingly, may not achieve our research, development and commercialization goals.

We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our success depends largely upon the continued services of our key executive officers, including Vimal Mehta, our Chief Executive Officer, President and a member of our Board, as well as the other principal members of our management, scientific, clinical teams and commercial readiness teams. We do not maintain "key person" insurance for any of these executive officers or any of our other key employees. We also rely on our leadership team in the areas of research and development, marketing, services and selling, general and administrative functions. From time to time, there may be changes in our executive management and leadership teams resulting from the hiring or departure of executives or other key employees, which could disrupt our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives.

To continue to execute our business strategy, we also must attract and retain highly skilled personnel. We might not be successful in maintaining our unique culture and continuing to attract and retain qualified personnel. We have, from time to time, had difficulty hiring and retaining highly skilled personnel with appropriate qualifications, including as a result of the Reprioritization and related consequences for our reputation. We may experience such difficulties in the future, and any further restructuring or related reduction in force could exacerbate such difficulties. The pool of qualified personnel with experience working within the biopharmaceutical and biotechnology market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

Furthermore, prior workforce reductions and any future similar cost-saving initiatives may make it difficult for us to maintain valuable aspects of our culture, retain institutional knowledge and expertise, to prevent a negative effect on employee morale or attrition beyond our planned reduction in headcount, and to attract competent personnel who are willing to embrace our culture in the future. Our executive officers and other employees are at-will employees, which means they may terminate their employment relationship with us at any time, and their knowledge of our business and industry would be extremely difficult to replace. We may not be able to retain the services of any members of our senior management or other key employees. If we do not succeed in retaining and motivating existing employees or attracting well-qualified employees in the future, our business, financial condition and results of operations could be materially and adversely affected.

In addition, in making employment decisions, particularly in the biotechnology and high-technology industries, job candidates often consider the value of the stock options or other equity instruments they are to receive in connection with their employment. Volatility in the price of our stock might, therefore, adversely affect our ability to attract or retain highly skilled personnel. Furthermore, the requirement to expense the fair value of stock options and other equity instruments might discourage us from granting the size or type of stock option or equity awards that job candidates require to join our Company. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects could be severely harmed.

We may acquire other companies or technologies, which could divert our management's attention, result in dilution to our stockholders and otherwise disrupt our operations and adversely affect our operating results.

We may in the future seek to acquire or invest in businesses, applications and services or technologies that we believe could complement or expand our services, enhance our technical capabilities or otherwise offer growth opportunities. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated.

In addition, we do not have any experience in acquiring other businesses. If we acquire additional businesses, we may not be able to integrate the acquired personnel, operations and technologies successfully, or effectively manage the combined business following the acquisition. We also may not achieve the anticipated benefits from the acquired business due to a number of factors, including:

- inability to integrate or benefit from acquired technologies or services in a profitable manner;
- unanticipated costs or liabilities associated with the acquisition;

- difficulty integrating the accounting systems, operations and personnel of the acquired business;
- difficulties and additional expenses associated with supporting legacy products and hosting infrastructure of the acquired business;
- difficulty converting the customers of the acquired business onto our platform and contract terms, including disparities in the revenue, licensing, support or professional services model of the acquired company;
- diversion of management's attention from other business concerns;
- adverse effects to our existing business relationships with business partners and customers as a result of the acquisition;
- the potential loss of key employees;
- use of resources that are needed in other parts of our business; and
- use of substantial portions of our available cash to consummate the acquisition.

In addition, a significant portion of the purchase price of companies we acquire may be allocated to acquired goodwill and other intangible assets, which must be assessed for impairment at least annually. In the future, if our acquisitions do not yield expected returns, we may be required to take charges to our operating results based on this impairment assessment process, which could adversely affect our results of operations.

Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, which could adversely affect our operating results. In addition, if an acquired business fails to meet our expectations, our operating results, business and financial position may suffer.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with any regulations applicable to us, to provide accurate information to regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state health care fraud and abuse laws and regulations, or to report financial information or data accurately or disclose unauthorized activities to us. In particular, 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. Employee misconduct could also involve the improper use of information obtained during clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risk.

Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses.

Our operations, and those of our directors, advisors, contractors, consultants, CROs, and collaborators, could be adversely affected by earthquakes, floods, hurricanes, typhoons, extreme weather conditions, fires, water shortages, power failures, business systems failures, medical epidemics, and other natural and man-made disaster or business interruptions. Our phones, electronic devices and computer systems and those of our directors, advisors, contractors, consultants, CROs, and collaborators are vulnerable to damages, theft and accidental loss, negligence, unauthorized access, terrorism, war, electronic and telecommunications failures, and other natural and man- made disasters. Several of our employees conduct business outside of our headquarters and leased or owned facilities. These locations may be subject to additional security and other risk factors due to the limited control of our employees. If such an event as

described above were to occur in the future, it may cause interruptions in our operations, delay research and development programs, clinical trials, regulatory activities, manufacturing and quality assurance activities, sales and marketing activities, hiring, training of employees and persons within associated third parties, and other business activities. 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 data.

Likewise, we will rely on third parties, including ARx, to manufacture IGALMI® and our product candidates and to conduct clinical trials, and similar events as those described in the prior paragraph relating to their business systems, equipment and facilities could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidate could be delayed or altogether terminated.

Data breaches or cyber-attacks could disrupt our business operations and information technology systems or those of third parties on which we rely, adversely impact our financial results, or result in the loss or exposure of confidential or sensitive product candidate, clinical trial, employee, or Company information.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, including our mobile and web-based applications, our e-commerce platform and our enterprise software. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data, and personal information (collectively, "Confidential Information") of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

Our information technology systems and those of third parties on which we rely have been and may in the future be attacked or breached by individuals or organizations intending to obtain our Confidential Information; harm or disrupt our business operations; or otherwise misappropriate information or Company funds. A security compromise of our information technology systems or business operations, or those of third parties on which we rely, could occur through a variety of methods such as from cyber-attacks and cyber-intrusions over the Internet, misconfigurations, "bugs" or other vulnerabilities, malware, computer viruses, email spoofing, attachments to e-mails, persons inside or outside our organization or persons with access to systems inside our organization. The risk of such intrusions, threats to data and information technology systems and breaches has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

While we maintain some of our own critical information technology systems, we also depend on third parties to provide important information technology services relating to several key business functions. Our measures to prevent, detect and mitigate these threats, including password protection, firewalls, backup servers, threat monitoring and periodic penetration testing, may not be successful in preventing a data breach or limiting the effects of a breach. 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 may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

Furthermore, the security measures employed by third-party service providers may prove to be ineffective at preventing breaches of their systems. Any attack that results in disruptions to our operations, or the unauthorized release or loss of Confidential Information, could have a material adverse effect on our business reputation, increase our costs and expose us to material legal claims and liability (such as class actions) and result in regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. If the unauthorized release or loss of Confidential Information were to occur, our operations and financial results and our share price could be adversely affected. Although we maintain insurance for our business, the coverage under our policies may not be adequate to compensate us for all losses that may occur.

Actual or perceived failures to comply with applicable data protection, privacy and security laws, regulations, standards and other requirements could adversely affect our business, results of operations, and financial condition.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal data, such as information that we may collect in connection with clinical trials in the U.S. and abroad.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission, and breach reporting of individually identifiable health information. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. If we are determined to act as a covered entity or business associate under HIPAA and be directly regulated under HIPAA, any person acting on our behalf may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act (collectively, the "CCPA"), requires covered businesses that process the personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information, and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. If we are subject to or affected by HIPAA, the CCPA, or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In Europe, the General Data Protection Regulation ("GDPR") went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the U.S., and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework ("DPF"), rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue. In particular, we expect the DPF Adequacy Decision to be challenged and international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, since January 1, 2021, companies have had to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR (i.e., fines up to the greater of £17.5 million or 4% of global turnover). On October 12, 2023,

the UK Extension to the DPF came into effect (as approved by the UK Government), as a data transfer mechanism from the UK to U.S. entities self-certified under the DPF.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another, and may conflict with one another or other legal obligations with which we must comply. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

Increased scrutiny of and evolving expectations for environmental, social and governance ("ESG") initiatives may impose additional costs or otherwise adversely impact our business.

There has been an increased focus from investors, capital providers, shareholder advocacy groups, other market participants, customers, and other stakeholder groups regarding companies' ESG initiatives. While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) or commitments to improve the ESG profile of our Company and/or offerings, such initiatives or achievements of such commitments may be costly and may not have the desired effect. Additionally, some investors may use third-party or proprietary ESG ratings to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our ESG practices are inadequate. The criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

If our ESG practices do not meet evolving investor or other stakeholder expectations and our standards, reputation, ability to attract or retain employees and desirability as an investment or business partner could be negatively impacted. Similarly, our failure or perceived failure to adequately pursue or fulfill any ESG goals and objectives or to satisfy various reporting standards, if any, could expose us to additional regulatory, social or other scrutiny, the imposition of unexpected costs, or damage to our reputation, which in turn could have a material adverse effect on our business and could cause the market value of our common stock to decline.

Our failure to successfully acquire, develop and market additional product candidates or approved drug products could impair our ability to grow.

As part of our growth strategy, we may evaluate, acquire, license, develop and/or market third-party products or product candidates and technologies. Our internal research capabilities are limited and we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's and technical personnel's time and attention to develop acquired products or technologies;

- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any products that we develop or approved products that we acquire will be manufactured profitably or achieve market acceptance.

Our ability to use our net operating losses and tax credits to offset future taxable income and income tax liabilities may be limited.

At December 31, 2024 the Company had approximately $432.6 million of gross federal and $443.5 million of gross state net operating loss carry-forwards. Tax Cuts and Jobs Act ("TCJA") in 2017 amended the net operating losses carryforward rules. Net operating losses generated after December 31, 2017, may be carried forward indefinitely, subject to certain limitations on their use. Net operating losses generated prior to 2018 may be carried forward for twenty years. If not utilized, these net operating losses will expire by 2037. State net operating losses have varying carryforward and applicable expiration periods. $430.0 million of the federal net operating losses were incurred after December 31, 2017, and will be carried forward indefinitely; the balance of the federal net operating losses are subject to expiration no later than 2037. The utilization of such net operating loss carry-forwards and realization of tax benefits in future years depends predominantly upon having taxable income. The Company has approximately $16.0 million of federal orphan drug credits and research and development credits which will begin to expire in 2037 if not utilized. The Company also has approximately $1.5 million of state research and development credits which will begin to expire in 2040 if not utilized.

In addition, under sections 382 and 383 of the Code, our federal net operating losses and tax credit carryforwards, such as research/development credits and orphan drug credits, may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders (or groups of stockholders) in excess of 50% over a rolling three-year period. Similar state provisions may also exist. These ownership changes may limit the amount of the net operating losses and tax credit carryforwards that can be utilized annually to offset future taxable income and income tax, respectively.

Entities are also required to evaluate, measure, recognize and disclose any uncertain federal or state income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2024, there were no uncertain tax positions. The Company's U.S. federal and state net operating losses have occurred since its inception in 2017 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant tax year to audit by The U.S. Internal Revenue Service ("IRS") and/or state taxing authorities. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the 12 months ended December 31, 2024 and 2023.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining, maintaining enforcing and defending our patents, trademarks, trade secrets and other intellectual property rights and proprietary technology for our current and future approved products and product candidates, the processes used to manufacture them and the methods for using them, as well as successfully defending these patents against third-party challenges. We are the owner of record of certain patents and patent applications pending in the U.S. and in certain foreign jurisdictions. Patents issued from non-provisional applications, which are typically filed from provisional patent applications or from PCT applications that enter the national phase. Neither provisional patent applications nor PCT applications issue directly as patents. We own PCT patent applications relating to our platform technologies covering methods of use and applications of the platform technologies.

We cannot be certain that any future patents will issue with claims that cover our product candidates. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents, trademarks, trade secrets and other intellectual property rights and proprietary technology that cover these activities.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions that have been the subject of much litigation in recent years and for which important legal principles remain unresolved. Therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the U.S. or in foreign jurisdictions outside of the U.S. Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict which of our patent applications will issue, the breadth of claims that may be enforced in the patents that may be issued from the applications we currently, or may in the future, own or license from third parties, whether any of the issued patents will be found to be infringed, invalid or unenforceable or will be threatened or challenged by third parties, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products and services. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third-party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition, reexamination, review, reissue, post grant review or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to independently develop, make and commercialize compounds that are similar to, or are alternatives or duplicates of any of our product candidates, but that are not covered by the claims of our patents or are not infringing, misappropriating, or otherwise violating our other intellectual property rights;

- we might not have been the first to make the inventions covered by our issued patents or pending patent applications that we license or may own in the future;

- we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;

- our pending patent applications or those that we may own in the future may not result in issued patents;
- the claims of our issued patents or patent applications when issued may not cover our products or product candidates;
- any patents that we obtain may not provide us with any competitive advantages;
- 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, manufacture and commercialize competitive products or product candidates for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we may choose not to seek patent protection for some of our proprietary technology or product candidates to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such trade secrets or know-how;
- any granted patents may be held invalid or unenforceable as a result of legal challenges by third parties; and
- the patents of others may have an adverse effect on our business.

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

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and foreign patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. In addition, the USPTO and various foreign governmental patent agencies require compliance with various procedural, document submission, fee payment and other requirements 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, potential competitors might be able to enter the market with similar or identical products or technology. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, it would have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

We may be required to enter into intellectual property license agreements that are important to our business. These license agreements may impose various diligence, payment, and other obligations on us. For example, we may enter into exclusive license agreements with universities, research institutions, or peer industry third parties pursuant to which we may be required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products and may need to satisfy specified milestone and royalty payment obligations. If we fail to comply with any obligations under our agreements with any of these licensors, we may be subject to termination of the license agreement in whole or in part; increased financial obligations to our licensors or loss of exclusivity in a particular field or territory, in which case our ability to develop or commercialize products covered by the license agreement will be impaired.

In addition, disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- if a third-party expresses interest in an area under a license that we are not pursuing, under the terms of certain of our license agreements, we may be required to sublicense rights in that area to a third-party, and that sublicense could harm our business; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected approved products or product candidates.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly.

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

We or our licensors may be subject to claims that third parties have an interest in our patents, trade secrets, or other intellectual property that we regard as our own or our licensor's, based on claims that the relevant agreements with employees or consultants obligating them to assign their intellectual property rights to us or our licensor are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights to another employer, to a former employer, or to another person or entity. We may also be subject to claims that our former employees, contractors or collaborators, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees, consultants and contractors who may be involved in the development of 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, conceives or develops intellectual property rights that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

We are not aware of any threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets, or other intellectual property, and it may be necessary or we may desire to obtain a license to a third party's intellectual property rights to settle any such claim; however, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If we or our licensors fail in defending any such claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates. A court could prohibit us from using technologies, features or other intellectual property rights that are essential to our products or technologies, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of another person or entity, including another or former employers. An inability to incorporate technologies, features or other intellectual property rights that are important or essential to our products or product candidates could have a material adverse effect on our business, financial condition, results of operations, and competitive position, and may prevent us from developing, manufacturing and/or commercializing our

products or technologies. In addition, we may lose valuable intellectual property rights or personnel. 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 litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to develop, manufacture and/or commercialize our products or services, which could materially and adversely affect our business, financial condition and results of operations. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

An NDA submitted under Section 505(b)(2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate.

Our product candidates have been or will be submitted to the FDA for approval under Section 505(b)(2) of the FDCA. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies that were not conducted by, or for, the applicant and on which the applicant has not obtained a right of reference. The 505(b)(2) application would enable us to reference published literature and/or the FDA's previous findings of safety and effectiveness for a branded reference drug with the same active ingredient. For NDAs submitted under Section 505(b)(2) of the FDCA, the patent certification and related provisions of the Hatch-Waxman Act apply. In accordance with the Hatch-Waxman Act, such NDAs may be required to include paragraph IV certifications, that certify that any patents listed in the FDA's Orange Book, with respect to any product referenced in the 505(b)(2) application, are invalid, unenforceable or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505(b)(2) NDA.

Under the Hatch-Waxman Act, the holder of patents that the 505(b)(2) application references may file a patent infringement lawsuit after receiving notice of the paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505(b)(2) applicant within 45 days of the patent owner's receipt of notice triggers a one-time, automatic, 30-month stay of the FDA's ability to approve the 505(b)(2) NDA, unless patent litigation is resolved in the favor of the paragraph IV certification filer, or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505(b)(2) application will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the branded reference drug product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505(b)(2) submissions and require us to file such submissions under Section 505(b)(1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug product for the proposed use and could cause delay and be considerably more expensive and time consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates.

If our intellectual property related to IGALMI® BXCL501, BXCL502, BXCL701, BXCL702 or any future product candidates is not adequate or if we are not able to successfully enforce our intellectual property rights, the commercial value of our products or product candidates may be adversely affected and we may not be able to compete effectively in our market.

Third parties, including our competitors, may currently, or in the future, infringe, misappropriate or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time-consuming and unsuccessful. We regularly monitor for unauthorized use of our intellectual property rights and, from time to time, analyze whether to seek enforce our rights against potential infringement, misappropriation or violation of our intellectual property rights. However, the steps we have taken, and are taking, to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation or violation of our intellectual property rights. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, particularly in certain developing countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual

property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products or technologies. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or technologies. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our products and product candidates.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we choose to commence a proceeding or litigation to prevent another party from infringing our patents, that party could counterclaim that our patents are invalid or should not be enforced against them. In patent litigation in the United States, 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, including 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 relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is a risk that the examiner or court will decide that our patents are invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the related inventions. There is also the risk that, even if the validity of our patents is upheld, the examiner or court may construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that such other party's activities do not infringe our rights to such patents. In addition, the U.S. Supreme Court has recently modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge to any patents we obtain or license. Any proceedings or litigation to enforce our intellectual property rights or defend ourselves against claims of infringement of third-party intellectual property rights could be costly and divert the attention of managerial and scientific personnel, regardless of whether such litigation is ultimately resolved in our favor. We may not have sufficient resources to bring these actions to a successful conclusion. If a defendant were to prevail on its legal assertion of invalidity and/or unenforceability against our intellectual property related to a product or a product candidate, we could lose at least part, and perhaps all, of the patent protection on such product or product candidate. Such a loss of patent protection would have a material adverse impact on our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations. Moreover, if we are unable to successfully defend against claims that we have infringed the intellectual property rights of others, we may be prevented from using certain intellectual property and may be liable for damages, which in turn could materially adversely affect our business, financial condition or results of operations. Even if we are successful in any litigation, we may incur significant expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage as a result of the infringement and the proceedings. Further, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business. Any of the foregoing may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, and/or third party claims seeking to invalidate our patents, which would be costly, time consuming and, if successfully asserted against us, may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our commercial success will depend in part on our ability to develop, manufacture or commercialize our products and product candidates without infringing, misappropriating or otherwise violating the intellectual property rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries, and companies in the industry have used intellectual property litigation to gain a competitive advantage. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our products, or the manufacture or use of our product candidates. In addition to infringement claims against us, third parties may also raise similar claims before administrative bodies in the United States or abroad. Such mechanisms include interference proceedings, post grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions. If third parties prepare and file patent applications in the United States that also claim technology similar or identical to ours, we may have to participate in interference or derivation proceedings in the USPTO to determine which party is entitled to a patent on the disputed invention. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications 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. Such administrative proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our products or product candidates. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our products or technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and prospects.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. The costs of these lawsuits could affect our results of operations and divert the attention of managerial and scientific personnel. Some of these third parties may be better capitalized and have more resources than us. There is a risk that a court would decide that we are infringing the third-party's patents and would order us to stop the activities covered by the patents. In that event, we may not have a viable way around the patent and may need to halt commercialization of the relevant product candidate. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents. We also could be ordered to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents or other intellectual property rights. In addition, we may be obligated to indemnify our licensors and collaborators against certain intellectual property infringement claims brought by third parties, which could require us to expend additional resources. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third party patents are valid and enforceable, and infringed by the use of our products and/or technologies, which could have a negative impact on the commercial success of our current and any future products or technologies.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the U.S., proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur

substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the U.S. may be maintained in secrecy until the patents are issued;
- patent applications in the U.S. are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed U.S. patent applications on inventions similar to ours that claim priority to any applications filed prior to the priority dates of our applications, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the U.S. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar inventions prior to our own inventions, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

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.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our technology.

Finally, a Unitary Patent and Unified Patent Court ("UPC") system was implemented in Europe on June 1, 2023. This new regime may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be harmed.

Our trademarks could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products or technologies, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Further, there can be no assurance that competitors will not infringe on our trademarks or that we will have adequate resources to enforce our trademarks. 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. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. 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. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, operating results and prospects.

We rely on our trademarks, trade names and brand names, such as "IGALMI®" and our logo, to distinguish our company and our products from our competitors and the products of our competitors, and have registered or applied to register many of these trademarks in the United States and certain countries outside the United States, however, we have not yet registered all of our trademarks in all of our current and potential markets. There can be no assurance that our trademark applications will be approved for registration. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties may also oppose our trademark applications and may seek to cancel trademark registrations or otherwise challenge our use of the trademarks. Opposition or cancellation proceedings may be filed against our trademark filings in these agencies, and such filings may not survive such proceedings. While we may be able to continue the use of our trademarks in the event registration is not available, particularly in the United States, where trademark rights are acquired based on use and not registration, third parties may be able to enjoin the continued use of our trademarks if such parties are able to successfully claim infringement in court. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. Our trademarks or trade names may be infringed, circumvented, declared generic or determined to be violating or infringing on other marks.

If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

In addition to patent protection, we also rely on other intellectual property rights, including protection of copyright, trade secrets, know-how and/or other proprietary information to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. However, 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 and we may not enter into such agreements with all employees, consultants and third parties who have been involved in the development of our intellectual property rights. Although we generally require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed. In addition, despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property rights by employees, consultants and other third parties who have access to such intellectual property or other proprietary rights is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors or third parties, despite the existence generally of these confidentiality restrictions. These agreements may not effectively prevent disclosure of

confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. There can be no assurances that such employees, consultants, advisors or third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by third parties, including our competitors. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. The exposure of our trade secrets and other proprietary information would impair our competitive advantages and could have a material adverse effect on our business, financial condition and results of operations. In particular, a failure to protect our proprietary rights may allow competitors to copy our technology, which could adversely affect our pricing and market share.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not, for example, in the case of misappropriation of a trade secret by an employee, consultant or other third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, consultant or other third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products or services that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. While we use commonly accepted security measures, trade secret violations are often a matter of state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our intellectual property rights or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Furthermore, any license agreements we enter into in the future may require us to notify, and in some cases license back to the licensor, certain additional proprietary information or intellectual property that we developed using the rights licensed to us under these agreements. Any such licenses back to the licensor could allow our licensors to use that proprietary information or intellectual property in a manner that could harm our business. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its transparency initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position. Further, it is possible that others will independently develop the same or similar technology, products or services or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology or products similar to ours, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We may be subject to claims that our employees, consultants or independent contractors have misappropriated the intellectual property rights, including know-how or trade secrets of a third party.

We may be subject to claims that our employees or consultants have wrongfully used for our benefit or disclosed to us confidential information of third parties. As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or

engagement. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property rights, proprietary information, know-how, or trade secrets of others in their work for us, and do not perform work for us that is in conflict with their obligations to another employer or any other entity, we may be subject to claims that we or our employees, consultants or independent contractors have, inadvertently or otherwise misappropriated the intellectual property, including know-how, trade secrets or other proprietary information of their former employers or clients. To the extent that our employees, consultants or contractors use intellectual property rights or proprietary information owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we could lose valuable intellectual property rights or personnel, which could adversely impact our business. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial costs and be a distraction to management.

Our intellectual property may not be sufficient to protect our products from competition, which may negatively affect our business as well as limit our partnership or acquisition appeal.

We may be subject to competition despite the existence of intellectual property we license or own. We can give no assurances that our intellectual property claims will be sufficient to prevent third parties from designing around patents we own or license and developing and commercializing competitive products. The existence of competitive products that avoid our intellectual property could materially adversely affect our operating results and financial condition.

Furthermore, limitations, or perceived limitations, in our intellectual property may limit the interest of third parties to partner, collaborate or otherwise transact with us, if third parties perceive a higher than acceptable risk to commercialization of our products or future products.

Our drug re-innovation approach involves the filing of patent applications covering new methods of use and/or new formulations of previously known, studied and/or marketed drugs. Although the protection afforded by our patent and patent applications may be significant with respect to BXCL501, BXCL502, BXCL701 and BXCL702, when looking at our patents' ability to block competition, the protection offered by our patents may be, to some extent, more limited than the protection provided by patents claiming the composition of matter of entirely new chemical structures previously unknown. If a competitor were able to successfully design around any method of use and formulation patents we may have in the future, our business and competitive advantage could be adversely affected.

We may elect to sue a third party, or otherwise make a claim, alleging infringement or other violation of patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights that we either own or license from BioXcel LLC. If we do not prevail in enforcing our intellectual property rights in this type of litigation, we may be subject to:

- paying monetary damages related to the legal expenses of the third party;
- facing additional competition that may have a significant adverse effect on our product pricing, market share, business operations, financial condition, and the commercial viability of our products; and
- restructuring our company or delaying or terminating select business opportunities, including, but not limited to, research and development, clinical trial, and commercialization activities, due to a potential deterioration of our financial condition or market competitiveness.

A third-party may also challenge the validity, enforceability or scope of the intellectual property rights that we license or own; and the result of these challenges may narrow the scope or claims of or invalidate patents that are integral to our product candidates in the future. There can be no assurance that we will be able to successfully defend patents we own in an action against third parties due to the unpredictability of litigation and the high costs associated with intellectual property litigation, amongst other factors.

Intellectual property rights and enforcement may be less extensive in jurisdictions outside of the U.S.; thus, we may not be able to protect our intellectual property and third parties may be able to market competitive products that may use some or all of our intellectual property.

Changes to patent law, including the Leahy-Smith America Invents Act of 2011 and the Patent Reform Act of 2009 and other future article of legislation, may substantially change the regulations and procedures surrounding patent applications, issuance of patents, and prosecution of patents. We can give no assurances that patents we own or license and can be successfully defended or will protect us against future intellectual property challenges, particularly as they pertain to changes in patent law and future patent law interpretations.

In Europe, a new unitary patent system took effect on June 1, 2023, and may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, Applicants can, upon grant of a patent, opt for that patent to become a Unitary Patent which will be subject to the jurisdiction of a new Unitary Patent Court (UPC). Patents granted before the implementation of the new system can be opted out of UPC jurisdiction, remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. Further, because the UPC is a new court system and there is little precedent for the court's laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market. In addition to changes in patent laws, geopolitical dynamics, including Russia's incursion into Ukraine, and the imposition of tariffs and responses to tariffs, may impact our ability to obtain and enforce patents in particular jurisdictions. If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced.

In addition, enforcing and maintaining our intellectual property protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by the USPTO, courts and foreign government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements.

Risks Related to Owning our Common Stock

The price of our common stock may fluctuate substantially.

You should consider an investment in our common stock to be risky, and you should invest in our common stock only if you can withstand a significant loss and wide fluctuations in the market value of your investment. Some factors that may cause the market price of our common stock to fluctuate, in addition to the other risks mentioned in this "Risk Factors" section, are:

- sale of our common stock by our stockholders, executives, and directors;
- volatility and limitations in trading volumes of our shares of common stock;
- speculative trading in and short sales of our stock, as well as trading phenomena such as the "short squeeze" and "short and distort" schemes;
- our ability to obtain financings to conduct and complete research and development activities including, but not limited to, our clinical trials, and other business activities;
- possible delays in the expected recognition of revenue due to lengthy and sometimes unpredictable sales timelines;
- the timing and success of introductions of new applications and services by us or our competitors or any other change in the competitive dynamics of our industry, including consolidation among competitors, customers or strategic partners;
- network outages or security breaches;
- our ability to attract new customers;

- customer renewal rates and the timing and terms of customer renewals;
- our ability to secure resources and the necessary personnel to conduct clinical trials on our desired schedule;
- commencement, enrollment or results of our clinical trials for our product candidates or any future clinical trials we may conduct;
- changes in the development status of our product candidates;
- any delays or adverse developments or perceived adverse developments with respect to the FDA's review of our preclinical and clinical trials;
- any delay in our submission for studies or product approvals or adverse regulatory decisions, including failure to receive regulatory approval for our product candidates;
- unanticipated safety concerns related to the use of our product candidates;
- failures to meet external expectations or management guidance;
- changes in our capital structure or dividend policy, future issuances of securities, sales of large blocks of common stock by our stockholders;
- our cash position;
- announcements and events surrounding financing efforts, including debt and equity securities;
- our inability to enter into new markets or develop new products;
- reputational issues;
- competition from existing technologies and products or new technologies and products that may emerge;
- announcements of acquisitions, partnerships, collaborations, joint ventures, new products, capital commitments, or other events by us or our competitors;
- changes in general economic, political and market conditions in or any of the regions in which we conduct our business;
- changes in industry conditions or perceptions;
- changes in valuations of similar companies or groups of companies;
- analyst research reports, recommendation and changes in recommendations, price targets, and withdrawals of coverage;
- departures and additions of key personnel;
- disputes and litigations related to intellectual properties, proprietary rights, and contractual obligations;
- changes in applicable laws, rules, regulations, or accounting practices and other dynamics; and
- other events or factors, many of which may be out of our control.

In addition, if the market for stocks in our industry or industries related to our industry, or the stock market in general, experiences a loss of investor confidence, the trading price of our common stock could decline for reasons unrelated to our business, financial condition and results of operations. If any of the foregoing occurs, it could cause our

stock price to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

Future sales and issuances of our common stock, including common stock that may be sold following exercise of outstanding warrants, would result in additional dilution of the percentage ownership of our stockholders and could adversely impact the share price of our common stock.

We expect that significant additional capital will be needed in the future to continue our planned operations, including, without limitation, funding our trials and studies, marketing and commercializing our products and funding our operations. Accordingly, we have sold, and in the future 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. To the extent we raise additional capital by issuing additional shares of common stock or securities convertible or exchangeable for our common stock, our stockholders may experience substantial dilution, and new investors could gain rights superior to our existing stockholders.

In March 2024, we issued and sold in a registered direct offering 190,913 shares of our common stock, accompanying warrants to purchase up to 538,728 shares of our common stock and pre-funded warrants to purchase up to 347,814 shares of our common stock. In November 2024, we issued and sold in a registered direct offering 350,000 shares of our common stock, accompanying warrants to purchase up to 912,500 shares of our common stock and pre-funded warrants to purchase up to 562,500 shares of our common stock, (see Note 11, *Common Stock Financing Activities* in this Annual Report on Form 10-K for additional information). In addition, we issued additional warrants to purchase up to 312,506 shares of common stock in connection with the Fifth Amendment of our Credit Agreement (see Note 9, *Debt and Credit Facilities* in this Annual Report on Form 10-K for additional information). In March 2025, we issued and sold in a registered direct offering 188,383 shares of common stock, pre-funded warrants to purchase up to 3,811,617 shares of our common stock, accompanying warrants to purchase up to 4 million shares, and option warrants to purchase an additional 4 million shares and 4 million warrants. The number of shares of common stock underlying our outstanding warrants is significant in relation to our outstanding common stock (145% as of March 21, 2025), which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In the event these warrants are exercised, our stockholders will experience additional dilution. To the extent outstanding stock options or warrants are exercised, there would be further dilution to our existing stockholders, which could impact the price of our common stock.

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

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. Any return to stockholders will therefore be limited to the increase, if any, of our share price.

If we were deemed to be an investment company under the Investment Company Act of 1940, as amended (the "1940 Act"), applicable restrictions could make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

Under Sections 3(a)(1)(A) and (C) of the 1940 Act, a company generally will be deemed to be an "investment company" for purposes of the 1940 Act if (1) it is, or holds itself out as being, engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting or trading in securities or (2) it engages, or proposes to engage, in the business of investing, reinvesting, owning, holding or trading in securities and it owns or proposes to acquire investment securities having a value exceeding 40% of the value of its total assets (exclusive of U.S. government securities and cash items) on an unconsolidated basis. We do not believe that we are an "investment company," as such term is defined in the 1940 Act.

Notwithstanding Sections 3(a)(1)(A) and (C) of the 1940 Act, we are a research and development company and comply with the safe harbor requirements of Rule 3a-8 of the 1940 Act. We intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could

make it impractical for us to continue our business as contemplated and could have a material adverse effect on our business, financial condition and results of operations.

We are a "smaller reporting company" and are able to avail ourselves of reduced disclosure requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company until we determine that either (1) our annual revenues are at least $100 million and our voting and non-voting common stock held by non-affiliates is at least $250 million measured on the last business day of our most recent second fiscal quarter, or (2) our voting and non-voting common stock held by non-affiliates is at least $700 million measured on the last business day of our most recent second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors. In addition, as a non-accelerated filer, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile.

We are and may in the future be subject to legal proceedings, claims and investigations in or outside the ordinary course of business. Such proceedings, claims and investigations could be costly and time-consuming to defend and could result in unfavorable outcomes, which may have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock.

We are, and may in the future become, subject to various legal proceedings, claims and investigations that arise in or outside the ordinary course of business. For example, on July 7, 2023, plaintiff Katelyn Martin filed a class action complaint against the Company and certain executives in the United States District Court for the District of Connecticut, captioned *Martin v. BioXcel Therapeutics, et al.*, 3:23-cv-00915 (D. Conn). The case has since been renamed to *Hills et al v. BioXcel Therapeutics, Inc. et al*. On October 4, 2023, pursuant to the Private Securities Litigation Reform Act, the court appointed two co-Lead Plaintiffs. The co-Lead Plaintiffs filed an amended complaint on December 5, 2023, alleging violations of Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder. On July 11, 2024, the Court dismissed the amended complaint without prejudice and, on August 1, 2024, co-Lead Plaintiffs filed a second amended complaint. The second amended complaint alleges that defendants made false or misleading statements regarding the TRANQUILITY II trial and the development of BXCL501 for an expanded indication related to the treatment of certain Alzheimer's-related agitation. The Company moved to dismiss the second amended complaint on September 6, 2024. On February 24, 2025, while the Company's motion to dismiss remained pending, Plaintiffs moved for leave to further amend their complaint. The Company filed an opposition to the motion on March 17, 2025. Plaintiffs' reply is due April 7, 2025.

On November 28, 2023, Plaintiffs Pratheesan Panancherry and Jeffrey Bastress filed a stockholder derivative complaint in the United States District Court for the District of Connecticut purportedly on behalf of the Company and against Vimal Mehta, Richard I. Steinhart, Peter Mueller, June Bray, Sandeep Laumas, Michael Miller, Michal Votruba, and Krishnan Nandabalan as Defendants, and the Company as Nominal Defendant under the caption *Panancherry et al v. Mehta et al*, 3:23-cv-1554. Following the initial action, Plaintiffs Maria Vomvolakis (3:24-cv-3) and Kelly Fowler (3:24-cv-203) each filed separate stockholder derivative complaints in the District of Connecticut raising similar claims as Panancherry and Bastress, including business torts and violations of the Exchange Act. The cases have been consolidated under the caption *In re BioXcel Therapeutics, Inc. Stockholder Derivative Litigation*, 3:23-cv-1554 (D. Conn.). The consolidated action is currently stayed.

On January 11, 2024, Plaintiff Jeremy Smith filed a stockholder derivative complaint in the United States District Court for the United States District Court for the District of Delaware purportedly on behalf of the Company and against Vimal Mehta, Peter Mueller, June Bray, Sandeep Laumas, Michael Miller, Michal Votruba, Richard I. Steinhart, Robert Risinger, and Krishnan Nandabalan as Defendants, and the Company as Nominal Defendant under the caption *Smith v.*

Mehta et al, 1:24-cv-00041. Following the initial action, Plaintiff Janice Korff filed a stockholder derivative complaint in the District of Delaware raising similar claims as Smith (1:24-cv-130), including business torts and violations of the Exchange Act. The cases have been consolidated under the caption *In re BioXcel Therapeutics, Inc. Derivative Litigation,* 1:24-cv-00041 (D. Del.). The consolidated action is currently stayed.

The Company is also cooperating with a formal investigation of the Company and certain of its officers and directors by the SEC, relating to the Company's public disclosures, including about product sales and the receipt of a Form 483 by an investigator at one of the Company's clinical trial sites in the TRANQUILITY II study, and trading in the securities of the Company. The Company has produced documents, and current and former officers and employees of the Company have testified before the SEC. The above-captioned proceedings, as well as any investigation or proceeding that may be instituted by the SEC may result in substantial costs or liabilities, as well as a diversion of management's attention and resources, which could harm our business, result in a decline in the market price of our common stock and impact our financing efforts.

The potential costs and liabilities associated with legal proceedings, claims and investigations involving us or members of our leadership team is uncertain, and the results of such legal proceedings, claims and investigations cannot be predicted with certainty. Lawsuits and other administrative or legal proceedings that may arise can involve substantial costs, including the costs associated with investigation, litigation and possible settlement, judgment, penalty or fine. In addition, lawsuits and other legal proceedings may be time consuming to defend or prosecute and may require a commitment of management and personnel resources that will be diverted from our normal business operations. Also, our insurance coverage may be insufficient, our assets may be insufficient to cover any amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. Moreover, we may be unable to continue to maintain our existing insurance at a reasonable cost, if at all, or to secure additional coverage, which may result in costs associated with lawsuits and other legal proceedings being uninsured. Any such payments or settlement arrangements in current or future litigation could have a material adverse effect on our business, operating results or financial condition. Even if the plaintiffs' claims are not successful, current or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management's attention and resources, which could have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock. In addition, such lawsuits may make it more difficult to finance our operations.

Biotechnology and pharmaceutical companies with publicly traded stock or who obtain funding through the stock market often experience significant stock price volatility, based on events beyond their control, including outcomes of clinical trials, actions of regulators and product approvals. Such further litigation, may result in substantial costs and a diversion of management's attention and resources, which could harm our business and result in a decline in the market price of our common stock.

Our certificate of incorporation, our bylaws, and Delaware law may have anti-takeover effects that could discourage, delay, or prevent a change in control, which may cause our stock price to decline.

Our amended and restated certificate of incorporation, our amended and restated bylaws and Delaware law could make it more difficult for a third party to acquire us, even if closing such a transaction would be beneficial to our stockholders. We are authorized to issue up to 10 million shares of preferred stock. This preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by our board of directors without further action by stockholders. The terms of any series of preferred stock may include voting rights (including the right to vote as a series on particular matters), preferences as to dividend, liquidation, conversion and redemption rights and sinking fund provisions. No preferred stock is currently outstanding. The issuance of any preferred stock could materially adversely affect the rights of the holders of our common stock, and therefore, reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with, or sell our assets to, a third party and thereby preserve control by the present management.

Provisions of our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law also could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. Such provisions

may also prevent or frustrate attempts by our stockholders to replace or remove our management. In particular, the certificate of incorporation and bylaws and Delaware law, as applicable, among other things:

- provide the board of directors with the ability to alter the bylaws without stockholder approval;
- place limitations on the removal of directors;
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings; and
- provide that vacancies on the board of directors may be filled by a majority of directors in office, although less than a quorum.

Financial reporting obligations of being a public company in the U.S. are expensive and time-consuming, and our management is required to devote substantial time to compliance matters.

As a publicly traded company we have incurred and will continue to incur significant legal, accounting and other expenses. The obligations of being a public company in the U.S. require significant expenditures and place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Exchange Act and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. Moreover, despite reforms made possible by the JOBS Act, the reporting requirements, rules, and regulations will make some activities more time-consuming and costly, particularly as we are no longer an "emerging growth company." In addition, we expect these and similar 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 such insurance. Our continued compliance with applicable requirements and to keep pace with new regulations requires management and other personnel to devote a substantial amount of their time, otherwise we may fall out of compliance and risk becoming subject to litigation or being delisted, among other potential problems.

General Risk Factors

If securities or industry analysts do not publish research or reports, or publish unfavorable research or reports about our business, our stock price and trading volume may decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us, our business, our markets and our competitors. We do not control these analysts. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. Furthermore, if one or more of the analysts who do cover us downgrade our stock or if those analysts issue other unfavorable commentary about us or our business, which has occurred in the past, our stock price would likely decline. If one or more of these analysts cease coverage of us or fails to regularly publish reports on us, we could lose visibility in the market and interest in our stock could decrease, which in turn could cause our stock price or trading volume to decline and may also impair our ability to expand our business with existing customers and attract new customers.

If we fail to comply with the rules under the Sarbanes-Oxley Act related to accounting controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

Section 404 of the Sarbanes-Oxley Act requires annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to comply with the rules under the Sarbanes-Oxley Act related to disclosure controls and procedures in the future, or, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock price could decline significantly and raising capital could be more difficult.

We have discovered material weaknesses in the past. If future material weaknesses or significant deficiencies are discovered or if we otherwise fail to achieve and maintain the adequacy of our internal control, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly.

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our business, results of operations, financial condition and cash flows.

The tax regimes we are subject to or operate under, including income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our business, financial condition, results of operations, and prospects. For example, the TCJA, the Coronavirus Aid, Relief and Economic Security Act, and the Inflation Reduction Act (the "IRA") made many significant changes to the U.S. tax laws. Beginning in 2022, the TCJA requires taxpayers to capitalize and amortize certain research and development expenditures over five years if incurred in the U.S. and 15 years if incurred in foreign jurisdictions, rather than deducting them currently. Although there have been legislative proposals to repeal or defer the research and development expenditure capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. As another example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a minimum tax on the book income of certain large corporations and a 1% excise tax on the value of certain corporate stock repurchases by publicly traded companies that would be imposed on the company repurchasing such stock. Regulatory or accounting guidance with respect to existing or future tax laws could materially affect our tax obligations and effective tax rate. It is uncertain if, and to what extent, various states will conform to current federal law or any newly enacted federal tax legislation.

Additional indirect taxes in various jurisdictions could materially adversely affect our business, financial condition, results of operations, and prospects.

We currently collect and remit applicable indirect taxes in jurisdictions where we, through our employees or economic activity, have a presence and where we have determined, based on applicable legal precedents, that our activities are taxable. We do not currently collect and remit indirect taxes, including state and local excise, utility user, and ad valorem taxes, fees, and surcharges in jurisdictions where we believe we do not have sufficient "nexus." Tax authorities may challenge our position that we do not have sufficient nexus in a taxing jurisdiction or that our activities are not taxable in such jurisdiction and may decide to audit our business and operations with respect to indirect taxes, which could result in significant tax liabilities (including related penalties and interest) for us or our customers, which could materially adversely affect our business, financial condition, results of operations, and prospects.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity risk management program includes a cybersecurity incident response plan.

We designed and assessed our program based on the National Institute of Standards and Technology Cybersecurity Framework. This does not imply that we meet any particular technical standards, specifications, or requirements, only

that we used the National Institute of Standards and Technology Cybersecurity Framework as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity risk management program is integrated into our overall enterprise risk management program, and shares common methodologies, reporting channels and governance processes that apply across the enterprise risk management program to other legal, compliance, strategic, operational, and financial risk areas.

Our cybersecurity risk management program includes:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, products, services, and our broader enterprise information technology environment;
- a management team responsible for managing (1) our cybersecurity risk assessment processes, (2) our security controls, and (3) our response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of our security controls;
- cybersecurity awareness training of our employees, incident response personnel, and senior management;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for service providers, suppliers, and vendors.

There can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and information.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section titled "Risk Factors—Business interruptions could adversely affect future operations, revenues, and financial conditions, and may increase our costs and expenses."

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee (the "Committee") oversight of cybersecurity and other information technology risks. The Committee oversees management's implementation of our cybersecurity risk management program.

The Committee receives periodic reports from management on our cybersecurity risks. In addition, management updates the Committee, as necessary, regarding any material cybersecurity incidents, as well as any incidents with lesser impact potential.

The Committee reports to the full Board regarding its activities, including those related to cybersecurity. The full Board also receives briefings from management on our cyber risk management program. Board members receive presentations on cybersecurity topics from the internal Security Incident Management Team or external experts as part of the Board's continuing education on topics that impact public companies.

Our Security Incident Management Team, which includes our Chief Financial Officer, the Executive Director of Information Technology, Chief Legal Officer and the Quality Assurance Director, has approximately 30 combined years of risk management experience and is responsible for assessing and managing our material risks from cybersecurity threats. The team has primary responsibility for our overall cybersecurity risk management program and supervises both our internal cybersecurity personnel and our retained external cybersecurity consultants. Our Security Incident Management Team's experience includes prior work experience in cybersecurity; financial management and controls, data quality assurance and liability and risk management.

Our management team supervises efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us; and alerts and reports produced by security tools deployed in the information technology environment.

Item 2. Properties

Our corporate headquarters are located at 555 Long Wharf Drive in New Haven, Connecticut. The Company occupies 18,285 square feet of space. The leases for this space expire in February 2026 and we have a renewal option for one additional five-year term. We believe that our existing facilities are suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. For information about our legal proceedings, see Note 18 to our audited financial statements included elsewhere in this Annual Report on Form 10-K which information is incorporated herein by reference.

In addition, in February 2024, we became aware that the SEC had initiated a formal investigation involving the Company and certain of its directors and officers. This formal investigation relates to the Company's public disclosures, including about product sales and the receipt of a Form 483 by an investigator at one of the Company's clinical trial sites in the TRANQUILITY II study, and trading in the securities of the Company. We are cooperating fully with the investigation including producing documents, and current and former officers and employees of the Company have testified before the SEC. We cannot predict or determine whether any proceeding may be instituted by the SEC in connection with its investigation or the outcome of any proceeding that may be instituted, or the effects any such proceeding could have on the Company's business or financing efforts.

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

Our common stock is traded on The Nasdaq Capital Market® under the symbol "BTAI."

Stockholders

As of March 21, 2025, there were 13 stockholders of record of our common stock. The actual number of holders of our common stock 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 or held by other nominees.

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations,

financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors that our board of directors deems relevant.

Equity Compensation Plans

The information required by Item 5 of Form 10-K regarding equity compensation plans is incorporated herein by reference to Item 11. of Part III of this Annual Report on Form 10-K.

Unregistered Sales of Securities

There were no unregistered sales of equity securities by the Company during the three months ended December 31, 2024, that was not previously disclosed on a Current Report on Form 8-K or Quarterly Report on Form 10-Q.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. All dollar amounts in the below Management's Discussion and Analysis of Financial Condition and Results of Operations are presented in U.S. dollars, and all dollar and share amounts are presented in thousands, unless otherwise noted or the context otherwise provides.

Overview

BioXcel Therapeutics, Inc. ("BTI" or the "Company") is a biopharmaceutical company utilizing artificial intelligence ("AI") to develop transformative medicines in neuroscience and, through the Company's wholly owned subsidiary, OnkosXcel Therapeutics LLC ("OnkosXcel"), immuno-oncology. We are focused on utilizing cutting-edge technology and innovative research to develop high-value therapeutics aimed at transforming patients' lives. We employ various AI platforms to reduce therapeutic development costs and potentially accelerate development timelines. Our approach leverages existing approved drugs and/or clinically evaluated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indications. We believe this differentiated approach has the potential to reduce the expense and time associated with drug development in diseases with substantial unmet medical needs.

Our most advanced neuroscience candidate is BXCL501. In indications other than those approved by the United States ("U.S.") Food and Drug Administration ("FDA") as IGALMI®, BXCL501 is an investigational, proprietary, orally dissolving film formulation of dexmedetomidine (or "Dex") in development for the treatment of agitation associated with psychiatric and neurological disorders. Our most advanced immuno-oncology asset, BXCL701, is an investigational oral innate immune activator being developed by OnkosXcel Therapeutics as a potential therapy for the treatment of aggressive forms of prostate cancer, pancreatic cancer, and other solid and liquid tumors.

On April 6, 2022, we announced that the FDA approved IGALMI® (dexmedetomidine) sublingual film for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. IGALMI® is approved to be self-administrated by patients under the supervision of a health care provider. On July 6, 2022, we announced that IGALMI® was commercially available in doses of 120 and 180 micrograms.

We are continuing to develop BXCL501 for the acute treatment of agitation associated with bipolar disorders or schizophrenia in the at-home setting and for the acute treatment of agitation (non-daily) associated with dementia due to probable Alzheimer's disease in the at-home setting and in care facilities. As described further below, we have recently deprioritized the development of BXCL501 for certain indications, including development of BXCL501 as a potential adjunctive treatment for major depressive disorder ("MDD"), as well as our BXCL701 program except as noted in Part, Item 1, "Business" under the heading "Immuno-Oncology."

In our SERENITY program, we are evaluating BXCL501 for use in the at-home setting for agitation associated with bipolar disorders or schizophrenia. We completed Part 1 of the SERENITY III trial and announced topline results on May 25, 2023.

We reviewed our SERENITY III program with the FDA in Type C meetings on November 8, 2023 and March 6, 2024. Based on the feedback received from the FDA to date, we are moving forward to evaluate at-home use of the 120 mcg dose of BXCL501, with safety as the primary objective and efficacy measures as exploratory endpoints to support continued efficacy in the at-home setting as recommended by the FDA in the November 8, 2023 meeting, for the acute treatment of agitation in bipolar disorders or schizophrenia. We also plan to initiate a clinical study designed to enroll approximately 30 patient-informant dyads to evaluate the correlation between patient-and informant-reported efficacy measurement and the PEC scale, conducted by trained clinician raters as previously recommended by the FDA.

On September 5, 2024, we announced the initiation of patient enrollment in our SERENITY At-Home trial. The pivotal Phase 3 trial is designed to evaluate the safety of BXCL501 in the at home setting. On March 27, 2025, we announced that 24 clinical trial sites had been opened and 127 patients had been enrolled, representing 63% of the total required enrollment. Topline data results, which are expected in the second half of 2025, are intended to support a supplemental new drug application (sNDA) submission to potentially expand the label of IGALMI® (dexmedetomidine) sublingual film. See further discussion in *"Our Neuroscience Clinical Programs"*.

For our TRANQUILITY program, we have conducted clinical studies evaluating BXCL501 for the acute treatment of agitation associated with mild to moderate dementia in patients with probable Alzheimer's disease, who reside in assisted living facilities ("ALFs") and residential care settings and who required minimal assistance with activities of daily living. On June 29, 2023, we announced positive topline data from our TRANQUILITY II trial, as well as information regarding certain investigator misconduct and noncompliance at a clinical trial site. Since that time, we have taken steps to further investigate and evaluate the conduct of the TRANQUILITY II trial at this clinical site. Based on these steps to date, we believe that there have been no further instances of misconduct or fraud or other findings that adversely impact the data integrity or reliability of the eligibility, safety, and efficacy data obtained at the clinical trial site in question.

On March 3, 2025 we announced that the U.S. Food and Drug Administration (FDA) concluded that the inspection of a single site in its TRANQUILITY II Phase 3 trial was closed under 21 C.F.R.20.64(d)(3) and released the Establishment Inspection Report. The FDA designated "Voluntary Action Indicated" for the site.

We had previously been conducting the TRANQUILITY III clinical trial, which was designed to evaluate the potential for BXCL501 to treat acute agitation in patients with moderate to severe dementia associated with probable Alzheimer's disease living in nursing homes and who require moderate to full assistance with activities of daily living. We paused enrollment in TRANQUILITY III due to the much higher-than-expected background frequency of episodes of agitation experienced by the first several patients enrolled in the study.

We held Type B/Breakthrough Therapy Designation meetings with the FDA on October 11, 2023 and on February 20, 2024 to obtain additional feedback on our plans for further development of BXCL501 for the treatment of agitation associated with dementia in patients with probable Alzheimer's disease. We are currently planning to generate additional Phase 3 efficacy and safety data, in a variety of relevant care-facility settings and across severity of dementia using the Positive and Negative Syndrome Scale-Excitatory Component ("PEC") as the primary efficacy measure. In addition, we plan to discuss the details of the requirement for long-term safety data at a future meeting with the FDA.

On September 5, 2024, we submitted to the FDA the proposed protocol for our TRANQUILITY In-Care Phase 3 trial designed to evaluate the efficacy and safety of a 60 mcg dose of BXCL501 for agitation associated with Alzheimer's dementia. On November 12, 2024, we announced that we had received feedback from the FDA on the proposed protocol. See further discussion in *"Our Neuroscience Clinical Programs"*.

On October 15, 2024, we announced a U.S. Department of Defense grant to the University of North Carolina to fund a study of BXCL501 (Sublingual Dexmedetomidine) for treating Acute Stress Disorder (ASD). See further discussion in *"Additional Neuroscience Opportunities"*.

IGALMI® Commercialization Strategy

We continue to support IGALMI® in the hospital setting with minimal commercial support. On August 14, 2023, the Company announced it had implemented a shift in commercial strategy for IGALMI® in the institutional setting, a reduction of in-hospital commercialization expenses, a suspension of programs no longer deemed core to the Company's business, and a shift to focus on the development of BXCL501 for use in the at-home and care facilities in the treatment of acute agitation in schizophrenia and bipolar disorders, and in the treatment of acute agitation (non-daily) associated with dementia due to probable Alzheimer's disease (collectively, the "Reprioritization").

Following the Reprioritization, a small Corporate Account Director ("CAD") team supported current customers and targeted Integrated Delivery Networks ("IDNs") with educational support and contracting opportunities, while our trade operation supported customers with drug supply. The goal of this approach was to help maintain current business and potentially broaden IGALMI® utilization through volume contracting.

As part of the Clinical Prioritization in September 2024, further workforce reductions were made, including 9 additional marketing and sales employees. The Clinical Prioritization staff reductions may have future impacts on net revenue. Despite our reduction in commercial resources, net revenues from IGALMI® product sales of $2,266 for the year ended December 31, 2024 were up 64% over net revenues from IGALMI® product sales of $1,380 for the year ended December 31, 2023. We believe this positive growth reflects increasing market acceptance and interest in our product.

We are currently seeking potential commercial partners. Our continued commercialization efforts for IGALMI® are designed to build the foundation to launch additional potential follow-on indications, if any. If IGALMI® would be approved outside the U.S., we would consider launching the product through collaborations with third parties.

Recent Developments

Nasdaq Delisting Notice

As previously reported, on September 20, 2024, we received a letter from Nasdaq Staff notifying us that for the 30 consecutive business days prior to the date of the letter, the Company's market value of listed securities closed below the minimum $35 million requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(C), the Company was granted a period of 180 calendar days, or until March 19, 2025, to regain compliance.

As anticipated, on March 20, 2025, the Company received another letter from the Staff stating that, as a result of the Company's continued non-compliance with the MVLS Requirement, its securities would be delisted from Nasdaq unless the Company appeals the Staff's delisting determination by requesting a hearing before the Nasdaq Panel. The Company made timely request for a hearing before the Panel to appeal the Staff's determination. The Company's common stock will remain listed and eligible for trading on Nasdaq at least pending the ultimate conclusion of the hearing process; however, there can be no assurance that the Company will ultimately regain compliance and remain listed on Nasdaq.

Credit Agreement Amendments

Fifth Amendment to Credit Agreement

On November 21, 2024, we entered into the Fifth Amendment to our Credit Agreement (the "Fifth Amendment"), pursuant to which the Lenders agreed to, among other things, (i) waive the Credit Agreement's covenant that the report and opinion the Company will receive from its independent registered public accounting firm with respect to the financial statements for the year ending December 31, 2024 will not contain a "going concern" or similar qualification, (ii) permanently waive the Credit Agreement's minimum revenue covenant, and (iii) waive the Fourth Amendment's requirement that the Company raise, after the effective date of the Fourth Amendment and on or before November 30, 2024, at least $50,000 in gross cash proceeds from the issuance of its common stock, warrants, and/or pre-funded warrants, and/or in cash and/or non-cash consideration from newly entered-into partnering transactions.

The Fifth Amendment included a new capital raising covenant requiring that the Company receive (A) after the effective date of the Fifth Amendment and on or prior to November 27, 2024, at least $7,000 in gross cash proceeds from the issuance of the Company's common stock, warrants and/or pre-funded warrants("Raise 1"), (B) after the effective date of the Fifth Amendment and on or before March 15, 2025 (provided that the Company will use its commercially reasonable efforts to satisfy the requirement by February 15, 2025), at least $18,000 in net cash proceeds (including the proceeds of Raise 1) from (i) the issuance of the Company's common stock, warrants and/or pre-funded warrants, (ii) non-refundable cash consideration from partnering transactions entered into after the effective date of the Fifth Amendment (so long as such partnering transactions would not require the Company or any of its subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made), (iii) the issuance of the Company's

subordinated debt (subject to terms set forth in the Fifth Amendment), and/or (iv) asset sales permitted pursuant to the Credit Agreement or consented to by the Lenders (such capital raise, "Raise 2"), and (C) after the effective date of the Fifth Amendment and on or prior to the earlier of (x) August 15, 2025 and (y) the date that is 30 days after the final data readout of the SERENITY At-Home Phase 3 trial, at least $29,000 in net cash proceeds (including the proceeds from Raise 1 and Raise 2) from the same permitted capital raising activities listed in the preceding clause (B). The Company met the requirements of Raise 1, discussed in Note 11, *Common Stock Financing Activities*. The Company met the requirements of Raise 2, discussed in Note 20, *Subsequent Events*.

In connection with the Fifth Amendment and the required capital raises described in the preceding paragraph, the Lenders agreed to modify the Credit Agreement's minimum liquidity covenant to require minimum cash liquidity of $7,500 (instead of $25,000) from and after the closing of Raise 1 until March 30, 2025. On March 31, 2025, the minimum liquidity amount will increase to $10,000, and on September 30, 2025, the minimum liquidity amount will further increase to $15,000.

In connection with the Fifth Amendment, the Company paid a one-time amortization payment of $2,500 principal amount, together with accrued and unpaid interest and a portion of the prepayment fee and other fees payable in December 2024.

The Fifth Amendment also modified the interest rate of the loans provided under the Credit Agreement from a floating rate of Term SOFR plus 7.50% per annum, to a fixed rate of 13% per annum, retroactive to and effective as of September 30, 2024. For the quarterly payment dates ending December 31, 2024, March 31, 2025, and June 30, 2025, the Company has the ability to make interest payments of up to 10% per annum "in-kind" by capitalizing and adding such interest to the outstanding principal amount of the loans under the Credit Agreement. In addition, pursuant to the Fifth Amendment, the Company will be required to make quarterly amortization payments equal to 5.0% of the principal amount of funded loans, together with applicable prepayment fees, beginning on March 31, 2026.

On the effective date of the Fifth Amendment and as a condition to effectiveness thereof, the Company's wholly owned subsidiaries OnkosXcel Therapeutics, LLC and OnkosXcel Employee Holdings, LLC (collectively, "OnkosXcel"), which previously provided unsecured guarantees of the Company's obligations under the Credit Agreement, granted security interests in substantially all of their assets to support such obligations.

The Fifth Amendment amended the negative covenants under the Credit Agreement to remove flexibility the Company and its subsidiaries previously had thereunder to undertake various transactions, including, without limitation, with respect to potential dispositions of OnkosXcel or out-licenses by OnkosXcel of its intellectual property.

Pursuant to the Fifth Amendment, the Company committed to appoint a new independent board director (subject to customary background checks, applicable law, confirmation of independence and Nasdaq rules), and to provide the independent director with various privileges and committee memberships on the board of directors of the Company (including the appointment of such director on committee to be formed to focus on capital raising and evaluate strategic options). The Company also agreed to engage an investment banker reasonably acceptable to OFA and the Lenders to assist the Company and its board of directors with evaluating and exploring strategic options.

The Company also agreed to covenants requiring that the Company's cash expenditures be monitored by the Lenders according to a board-approved budget provided to the Lenders prior to the signing of the Fifth Amendment, which cash budget will be updated on a bi-weekly basis going forward. The Company will not be permitted to make disbursements for any two-week period in excess of 115% of the aggregate budgeted amount of disbursements for the applicable period. Finally, pursuant to the Fifth Amendment, the Company is restricted from paying cash bonuses to its employees or executives during the fiscal years 2024 and 2025 without OFA's consent or increasing the cash compensation for fiscal year 2025 for certain senior officers of the Company from their compensation for fiscal year 2024.

Company Warrants and Registration Rights Agreement

In connection with the closing of the Fifth Amendment, the Company agreed to, substantially concurrently with the closing of Raise 1, grant new warrants to the Lenders to purchase an aggregate of 313 shares of common stock on the

closing date of the Fifth Amendment, at an exercise price of $0.16 per share (the "New Warrants"). The New Warrants will expire on the seventh anniversary of their issuance.

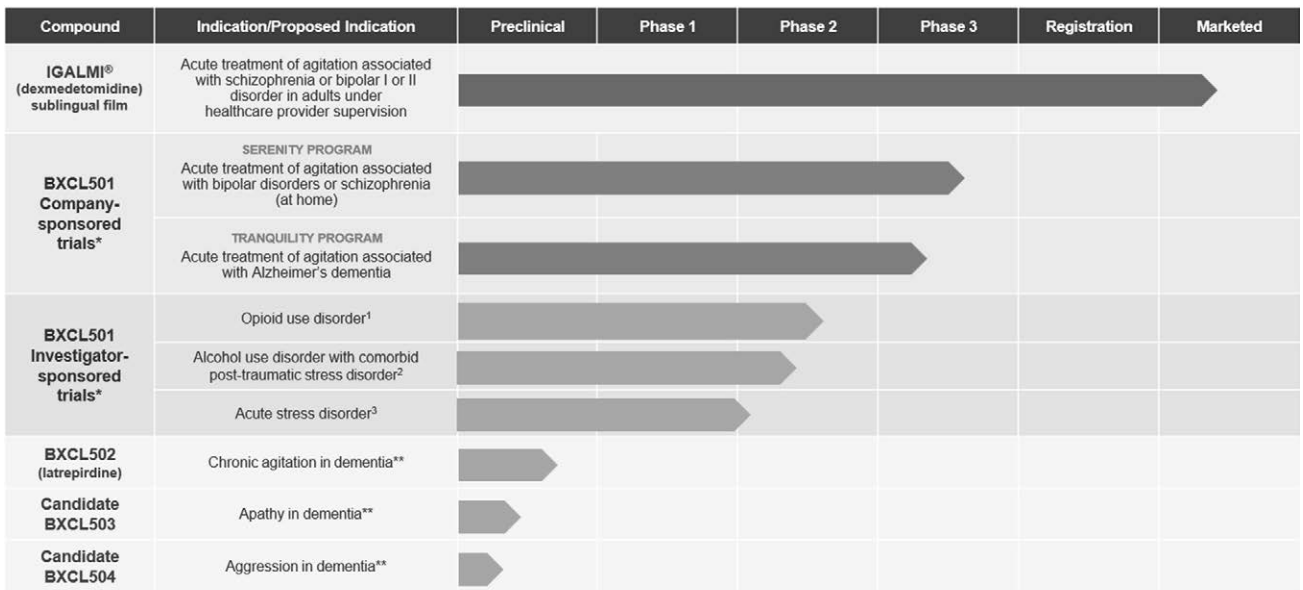
In addition, the Company agreed to, substantially concurrently with the closing of Raise 1, amend and restate all warrants to purchase stock of the Company issued to the Lenders prior to the effective date of the Fifth Amendment, to revise the exercise price thereunder to an exercise price equal to the lower of (i) the price per share of the common stock of the Company issued in Raise 1 and (ii) arithmetic average of the volume-weighted average price of the Company's common stock on the Nasdaq Capital Market during the 30 trading days preceding Raise 1 (such existing warrants, as amended and restated, the "Original Warrants"). The Original Warrants provide the Lenders with the right to purchase a total of 28 shares of common stock of the Company.

Sixth Amendment to Credit Agreement

On March 4, 2025, we entered into the Sixth Amendment to our Credit Agreement (the "Sixth Amendment"), pursuant to which the Lenders agreed to, among other things, delay the date on which we are required to engage an investment banker (which date has been subsequently extended to April 30, 2025).

Our Neuroscience Clinical Programs

The following is a summary of the status of our major clinical development programs as of the date of this Annual Report on Form 10-K:



1 Collaborator: Columbia University; 2 Collaborator: Yale University Medical School; 3 Collaborator: University of North Carolina at Chapel Hill

*The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established
**Development paused due to Strategic Reprioritization announced on Aug. 14, 2023

For additional information regarding our pipeline candidates, see Part I, Item 1, "Business" in this Annual Report on Form 10-K.

Basis of Presentation

The Company's consolidated financial statements are prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP").

Components of Our Results of Operations

Product Revenue, Net

Revenue relates to sales of IGALMI® and reflect limited market access since commercial launch in July 2022. The revenues are net of rebates, chargebacks, discounts, and other adjustments. During the fourth quarter of 2022, we began contracting directly with intermediaries such as GPOs.

Operating Costs and Expenses

Cost of Goods Sold

Cost of goods sold primarily relates to the costs of producing, packaging, and delivering our product to customers as well as costs related to excess or obsolete inventory.

Research and Development

Our research and development expenses reflect costs associated with the identification of our preclinical and clinical product candidates. Expenditures primarily consist of salary, benefits and non-cash stock-based compensation for our research and development personnel, costs incurred under agreements with contract research organizations and sites that conduct our non-clinical studies and clinical trials, costs of outside consultants engaged in research and development activities, travel expenses, the cost of acquiring, developing and manufacturing preclinical and clinical trial materials and lab supplies, and depreciation and other expenses. Payments to BioXcel LLC are also included in research and development expenses. Costs associated with third parties that provide non-clinical services such as toxicology, pharmacology, research and discovery, biomarker studies and similar services are included in the professional fees category of research and development expenses.

We expense research and development costs as incurred.

Our research and development costs by program for the years ended December 31, 2024 and 2023 were as follows:

	Year ended December 31,	
	2024	2023
Direct external costs		
BXCL501	$ 13,397	$ 46,661
BXCL701	2,058	7,050
Other research and development programs	771	4,142
Total direct external costs	$ 16,226	$ 57,853
Internal personnel costs	12,047	22,675
Sub-total direct costs	$ 28,273	$ 80,528
Indirect costs and overhead	2,162	3,798
Total research and development expenses	$ 30,435	$ 84,326

Selling, General and Administrative

Selling, general and administrative expenses primarily consist of salaries, benefits and non-cash stock-based compensation for our sales, executive and administrative personnel. Selling, general and administrative expenses also include legal expenses to pursue patent protection of our intellectual property and other corporate matters, professional fees for audit and tax services and insurance charges. We may also incur increased costs to comply with corporate governance, internal controls, investor relations and disclosures and similar requirements applicable to public companies.

As a result of our restructuring activities completed during 2024, we expect that our selling, general and administrative expenses will decline due to IGALMI®'s restructured commercialization plan and reduced personnel costs. However, we may also experience increased selling, general and administrative expenses due to higher fees for outside consultants, attorneys, and accountants.

Restructuring Costs

2023 Strategic Reprioritization

On August 8, 2023, our Board of Directors approved a broad-based strategic reprioritization (the "Reprioritization"). We determined to take actions to reduce certain operational and workforce expenses no longer deemed core to ongoing operations to extend its cash runway and drive innovation and growth in high-potential clinical development and value-creating opportunities. These actions included a shift in commercial strategy for IGALMI® in the institutional setting as described, a reduction of in-hospital commercialization expenses, a de-prioritization of programs no longer determined to be core to ongoing operations, and a prioritization on at-home treatment setting opportunities for BXCL501, all as described in Part I, Item 1, "Business". As part of this strategy, our Board of Directors approved a reduction of approximately 60% of our workforce. Annualized operating expenses were expected to be reduced by approximately $80,000. The Reprioritization was substantially completed by the end of 2023.

As a result of the Reprioritization, the Company recorded restructuring costs of $4,163 in the year ended December 31, 2023. These costs consisted of severance and benefit costs of $4,063 and contract termination costs of $100. The Company paid $3,998 of severance and benefit costs and $100 of contract termination costs during the year ended December 31, 2023. Remaining costs were paid during the first quarter of 2024.

2024 Clinical Prioritization

As discussed in Note 4, *Restructuring*, on May 8, 2024 the Company took additional actions as part of its continued efforts to preserve cash and prioritize investment in its core clinical programs. As part of these actions, the Company initiated a further reduction of approximately 15% of the Company's then current workforce. The Company notified impacted employees on May 8, 2024 and recorded total restructuring costs of $856 for the three months ended June 30, 2024. These costs consisted of severance and benefit costs, all of which were paid during the three month period ended June 30, 2024.

On September 17, 2024, the Company approved a plan for an additional reduction in its workforce by 15 employees (including all but one marketing and sales employee), or approximately 28% of the Company's headcount (the "Clinical Prioritization"), in order to extend its cash runway and prioritize investment on the clinical development of its lead neuroscience asset, BXCL501. The Company incurred aggregate charges in connection with the Clinical Prioritization of $1,586 which relate primarily to severance and benefits costs. Accordingly, the Company recorded a restructuring charge of $1,553 in the third quarter 2024, and $33 in the fourth quarter. The Company completed the Clinical Prioritization in October 2024, and paid $983 of the related costs during the fourth quarter of 2024. The remaining costs of approximately $603, is included in Accrued Expenses on the Consolidated Balance at December 31, 2024, and is expected to be paid in the first quarter of 2025. As a result of these actions, operating costs of $69,511 for the year ended December 31, 2024 decreased by approximately $103,651 compared to operating costs of $173,162 for the year ended December 31, 2023. Net cash used in operating activities of $72,027 for the year ended December 31, 2024 decreased by approximately $82,979, compared to Net cash used in operating activities of $155,006 for the year ended December 31, 2023. These achievements demonstrate the Company's operational capability and commitment to be focused on limited objectives in the near term.

Other (Income) Expense

Other (income) expense primarily consists of interest costs associated with the Credit Agreement the Company entered into in April 2022, changes in fair value of derivative financial instruments, and interest income earned on cash and cash equivalents that were comprised primarily of money market funds. Interest expense may increase in the future if we meet required milestones, and we are able to draw down additional funds under the Credit Agreement.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements is set forth in Note 3, Summary of Significant Accounting Policies to the consolidated financial statements included in this Annual Report on Form 10-K.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

Product Revenue, Net

Commercial sales of IGALMI® launched in July 2022. Product revenue, net for the years ended December 31, 2024 and 2023 was $2,266 and $1,380, respectively, comprised of sales of IGALMI® reflecting an increase of 64%. As part of the Company's Reprioritization in August 2023, the IGALMI® commercial team shifted focus to a hospital/contracting strategy with a corporate account director team to work with large Integrated Delivery Networks and drive sales utilizing a top-down approach. As part of the Clinical Prioritization in September 2024, further workforce reductions were made. We are currently seeking potential commercial partners. Our continued commercialization efforts for IGALMI® are designed to build the foundation to launch additional potential follow-on indications, if any.

Cost of Goods Sold

Cost of goods sold for the years ended December 31, 2024 and 2023 were $2,143 and $1,260, respectively, which primarily related to the costs to produce, package and deliver IGALMI® to customers, as well as costs related to excess or obsolete inventory. We entered into a commercial supply agreement with ARx, LLC ("ARx") pursuant to which ARx has agreed to exclusively manufacture and supply us with all of our worldwide demand of film formulation of Dex to be used for the commercial supply of IGALMI® and for ongoing clinical trials of our product candidate BXCL501, subject to certain alternative supply provisions. The increase in Cost of goods sold for the year ended December 31, 2024 is primarily the result of increased sales and a $474 increase in the reserve for excess and obsolete inventory, compared to the prior year.

Research and Development Expense

Research and development expenses for the years ended December 31, 2024 and 2023 were as follows:

	Year ended December 31,			
	2024	2023	Change	% Change
Personnel and related costs	$ 9,796	$ 16,351	$ (6,555)	(40)%
Non-cash stock-based compensation	2,251	6,324	(4,073)	(64)%
Professional fees	5,067	14,590	(9,523)	(65)%
Clinical trials expense	9,384	35,094	(25,710)	(73)%
Chemical, manufacturing and controls cost	1,927	8,687	(6,760)	(78)%
Other expenses	2,010	3,280	(1,270)	(39)%
Total research and development expenses	$ 30,435	$ 84,326	$ (53,891)	(64)%

The decrease of $53,891 for the year ended December 31, 2024, compared to the year ended December 31, 2023 is primarily attributable to the following:

- A decrease in clinical trials expense was a result of reduced costs associated with the wind down of the SERENITY III study to evaluate BXCL501 for at home use for the acute treatment of agitation related to schizophrenia and bipolar disorders. In addition, the TRANQUILITY II study of BXCL501 for the potential treatment of agitation in patients with Alzheimer's disease was completed in 2023, and the reduction of these costs were partially offset by the September 2024 launch of SERENITY-At Home trial.

- A decrease in personnel and related costs related to the Clinical Prioritization.

- A decrease in Chemical, manufacturing and controls ("CMC") costs due to lower CMC costs related to decreased clinical trial activities.

- A decrease in non-cash stock-based compensation due to higher award forfeitures in 2024.

Following IGALMI®'s approval by the FDA, we capitalize costs related to commercial production of IGALMI® as inventory and expense those CMC costs related to clinical trials.

Selling, General and Administrative Expense

Selling, general and administrative expenses for the years ended December 31, 2024 and 2023 were as follows:

	Year ended December 31,			
	2024	2023	Change	% Change
Personnel and related costs	$ 7,856	$ 27,171	$ (19,315)	(71)%
Non-cash stock-based compensation	3,904	12,290	(8,386)	(68)%
Professional fees	16,137	22,310	(6,173)	(28)%
Commercial and marketing	1,389	12,485	(11,096)	(89)%
Insurance	1,671	1,743	(72)	(4)%
Other expenses	3,535	7,414	(3,879)	(52)%
Total selling, general and administrative expenses	$ 34,492	$ 83,413	$ (48,921)	(59)%

The decrease of $48,921 for the year ended December 31, 2024, relative to the year ended December 31, 2023 is primarily attributable to:

- A decrease in personnel costs due to the Clinical Prioritization, reducing 9 full-time employees.
- Decreased professional fees, primarily related to lower legal costs in 2024 compared to 2023 for the investigation of our TRANQUILITY II study, and reductions in consulting and recruiting fees in 2024.
- Decreased other expenses as a result of lower headcount.
- Decreased non-cash stock-based compensation costs due to increased award forfeitures in 2024 and lower headcount.
- Decreased commercial and marketing research costs.

Restructuring Costs

Restructuring costs were $2,441 and $4,163 for the years ended December 31, 2024 and 2023, respectively. See "Components of Our Results of Operations - Restructuring Costs" above for a discussion of the Company's Reprioritization and restructuring activities.

Other (Income) Expense

Interest expense increased to $15,129 for the year ended December 31, 2024 compared to $13,314 for the year ended December 31, 2023, due to an increase in interest rates compared to the prior year and higher average debt balances during the year due to borrowings under the Credit Agreement. The expense was partially offset by interest income earned on cash and cash equivalents that were held primarily in short-term money market funds. Interest income decreased to $2,602 for the year ended December 31, 2024 compared to $5,649 for the year ended December 31, 2023, due to lower average cash balances during the year. Other (income) expense, net is primarily associated with changes in fair value of derivative financial instruments for the period, which relate to instruments associated with the Credit Agreement.

Inflation

Inflation generally affects us by increasing our labor costs and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the periods presented. For a discussion of inflationary risks to our future revenues under the Inflation Reduction Act, see "*Health care reform measures could hinder or prevent our product candidates*' commercial success." in Part I, Item 1A., "Risk Factors" elsewhere in this Annual Report on Form 10-K.

Reverse Stock Split

On February 10, 2025, the Company effected a 1-for-16 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each 16 shares of common stock issued and outstanding immediately prior to February 10, 2025 were automatically converted into 1 share of common stock. The Reverse Stock Split did not change the par value of the common stock or the authorized number of shares of common stock. All outstanding convertible notes, stock options and RSUs entitling their holders to purchase or obtain or convert into shares of our common stock were adjusted, as required by the terms of these securities. All applicable common share and per share amounts have been retrospectively restated to show the effect of the reverse stock split.

Liquidity and Capital Resources

As of December 31, 2024, we had cash and cash equivalents of $29,854, working capital of $15,161 and stockholders' deficit of $93,101. Net cash used in operating activities was $72,027 and $155,006 for the years ended December 31, 2024 and 2023, respectively. We incurred losses of approximately $59,599 and $179,053 for the years ended December 31, 2024 and 2023, respectively. We will need to generate significant product revenues to achieve profitability. Our history of significant losses, negative cash flows from operations, potential near-term increased covenant-driven amortization payments or full repayment obligations under our Credit Agreement, the regulatory event of default triggers under the Credit Agreement, other funding requirement covenants under the Credit Agreement, limited liquidity resources currently on hand, and dependence on our ability to obtain additional financing to fund our operations after the current resources are exhausted, about which there can be no certainty, have resulted in management's assessment that there is substantial doubt about our ability to continue as a going concern for a period of at least 12 months from the issuance date of the financial statements included in this Annual Report on Form 10-K.

Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent upon future events, including obtaining adequate financing to support the Company's cost structure and operating plan. Management's plans to improve the Company's liquidity and reduce its operating expenses and capital requirements include, among other things, pursuing one or more of the following steps to raise additional capital, none of which can be guaranteed or are entirely within the Company's control:

- raise funding through the sale of the Company's equity securities;
- raise funding through third-party investments in or other strategic options for OnkosXcel;
- raise funding through debt financing and/or restructuring of its existing Credit Agreement;
- establish collaborations with potential partners to advance the Company's product pipeline;
- establish collaborations with potential marketing partners;
- reduce overhead and headcount to focus on core priorities, and/or
- any combination of the foregoing.

To date, we have continued research and development activities while managing our cash position. However, we require additional funding to continue as a going concern. There are no assurances that we will be successful in obtaining an adequate level of financing as and when needed to finance our operations on terms acceptable to us or at all, particularly when there is market uncertainty or an economic downturn or if other events make investment in our securities less appealing. If we are unable to secure adequate additional funding as and when needed on acceptable or commercially reasonable terms, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more product candidates. In addition, there are various macro-economic trends affecting the financing markets whose impact on our liquidity and future funding requirements are uncertain as of the filing date of this Annual Report on Form 10-K. We will need substantial additional funding, and if we are unable to raise capital when needed, we could be compelled to pursue alternative options, including, without limitation, implementing further workforce reductions, reducing or ceasing product development programs and advancement of our clinical trials and product candidates, selling our assets or seeking other strategic alternatives. See "Risks Related to Financial Position and

Need for Additional Capital — *We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts or otherwise seek strategic alternatives.*" in Part I. Item 1A., "Risk Factors" elsewhere in this Annual Report on Form 10-K.

Sources of Liquidity

We have primarily focused our efforts on raising capital and building the products in our pipeline, and, although we generate revenue from sales of IGALMI®, we do not expect to generate positive cash flows from operations in the near term. Since our inception, our operations have been financed primarily from proceeds from the sale of equity securities, including our initial public offering, private placements of our common stock, registered offerings of our common stock, an Open Market Sale Agreement (as amended, supplemented and/or restated from time to time, the "Sale Agreement") with Jefferies LLC ("Jefferies"), and borrowings under our Credit Agreement (as described below). We have not yet established an ongoing source of revenue sufficient to cover our operating costs and will need to do so in future periods.

Financing Agreements

On April 19, 2022, we entered into two financing agreements: the Credit Agreement and the RIFA. Pursuant to the Credit Agreement, the Lenders originally agreed to provide up to $135,000 in senior secured term loans to us. On April 28, 2022, we borrowed the first $70,000 tranche of loans under the Credit Agreement. Pursuant to the RIFA, the Purchasers agreed to provide us with up to $120,000 in financing for our near-term commercial activities of IGALMI®, development and commercialization of BXCL501 and other general corporate purposes. On July 8, 2022, we drew down the first tranche of $30,000 under the RIFA. In connection with the Credit Agreement, we granted to the Lenders (i) warrants to purchase up to 17 shares of our common stock (the "Closing Date Warrants"), (ii) rights to purchase up to $5,000 of our common stock and (iii) warrants to purchase up to 175 individual ownership units (i.e., not in thousands) in OnkosXcel (the "OnkosXcel Warrants").

On November 13, 2023, we, the Lenders and OFA entered into a Waiver and First Amendment to Credit Agreement and Guaranty (the "First Amendment") that provided for, among other things, a waiver and a modification to the covenant in the Credit Agreement regarding investments in OnkosXcel, pursuant to which we were permitted to invest up to a maximum of $30,000 at any time outstanding in OnkosXcel, increased from the $25,000 at any time outstanding. The First Amendment waived any defaults or events of default arising under the Credit Agreement due to a breach prior to the date of the First Amendment of the OnkosXcel investment covenant, or a breach of our obligation to notify OFA of such default, including our investment in an amount in excess of what was previously permitted under the OnkosXcel investment covenant. In connection with the First Amendment, we paid to the Lenders a fee of $180 (representing 0.25% of the loans outstanding under the Credit Agreement on the date of the First Amendment) and agreed to pay to the Lenders an exit fee equal to 0.25% of the loans under the Credit Agreement repaid upon maturity or prepayment of the loans.

On December 5, 2023, we entered into the Second Amendment to Credit Agreement and Guaranty and Termination of Revenue Interest Financing Agreement (the "Second Amendment") with the Lenders and OFA, as administrative agent. The Second Amendment terminated the RIFA and converted the financing previously provided to us thereunder to term loans under the Credit Agreement. In addition, the Second Amendment replaced the Credit Agreement's existing "Tranche B" and "Tranche C" term loan opportunities with three new tranches aggregating up to $100,000 in potential funding:

- A $20,000 "Tranche B" term loan available upon satisfaction of the following conditions on or before December 31, 2024: (i) us raising an aggregate of at least $40,000 after the date of the First Amendment from (a) equity proceeds or (b) a bona fide contract with a governmental authority to use BXCL501 for opioid withdrawal, (ii) initiation of a new clinical trial in the TRANQUILITY program based on our meeting with the FDA held on October 11, 2023, and (iii) the total pro forma indebtedness outstanding under the Credit Agreement as a percentage of our trailing 30-day market capitalization being less than 30%;

- A $30,000 "Tranche C" term loan available upon satisfaction of the following conditions on or before December 31, 2025: (i) either (a) receipt of approval from the FDA of an sNDA in respect of the use of BXCL501 for the acute treatment of agitation associated with dementia or (b) the receipt of approval from the FDA of an sNDA in respect of the use of BXCL501 for (x) the acute treatment of agitation associated with schizophrenia in adults and (y) the acute treatment of agitation associated with bipolar I or II disorder in adults, in each case, in the community/at home setting without the requirement for administration under the supervision of a healthcare provider, and (ii) the total pro forma indebtedness outstanding under the Credit Agreement as a percentage of our trailing 30-day market capitalization being less than 30%; and

- A $50,000 "Tranche D" term loan available upon satisfaction of the following conditions on or before December 31, 2025: (i) the conditions precedent to the borrowing of Tranche C (as described in the preceding bullet point) have been satisfied, and (ii) our total net revenue attributable to sales of BXCL501 (for the avoidance of doubt, including any revenues attributable to use of BXCL501 for opioid withdrawal) for the trailing twelve consecutive month period exceeding a specified amount.

The Second Amendment also modified the interest rate of the loans provided under the Credit Agreement to be a floating rate per annum equal to the secured overnight financing rate ("SOFR") (subject to a SOFR floor of 2.5% and a cap of 5.5%) plus 7.5%.

Following the Second Amendment, we were required to comply with certain covenants under the Credit Agreement, including a financial covenant that requires we maintain a minimum cash liquidity amount of $15,000 (or higher upon certain events) and a modified minimum revenue requirement measured on a quarterly basis based on the revenue attributable to BXCL501 for the six consecutive month period ending on the last day of the relevant quarter (the "Revenue Covenant"), subject to cure payments of not less than $1,000 if we failed to meet the minimum revenue requirement.

In connection with the closing of the Second Amendment, we amended and restated the Closing Date Warrants granted to the Lenders on April 19, 2022 to purchase up to 17 shares of the Company's common stock at an exercise price of $320.64 per share. Pursuant to the amendment and restatement of the Closing Date Warrants, dated December 5, 2023 (the "Amended and Restated Closing Date Warrants"), the exercise price of the Closing Date Warrants was reduced to $58.3232 per share, which represented the arithmetic average of the volume-weighted average price of the Company's common stock on the Nasdaq Capital Market during the 30 trading days preceding the Second Amendment Effective Date. In addition, the Company granted new warrants to the Lenders to purchase up to 4 shares of the Company's common stock (the "2023 Warrant Shares") at an exercise price of $58.3232 per share (the "2023 Warrants"). The Amended and Restated Closing Date Warrants and the 2023 Warrants will expire on April 19, 2029 and may be net exercised at the holder's election.

On February 12, 2024 (the "Third Amendment Effective Date"), we entered into the Third Amendment to Credit Agreement and Guaranty (the "Third Amendment"), pursuant to which the Lenders agreed to waive the covenant that we shall not receive a report and opinion from our independent auditors that contains a "going concern" or like qualification or exception or emphasis of matter of going concern footnote with respect to our financial statements for the fiscal year ended December 31, 2023 and, as a result, such event shall not be an event of default. As a condition to the effectiveness of the Third Amendment, among other things, we shall have received at least $40,000 in gross proceeds from a registered public sale of the Company's common stock, warrants and/or pre-funded warrants on or before February 20, 2024. We did not meet this condition and therefore the Third Amendment did not become effective.

On March 20, 2024, we entered into the Fourth Amendment to the Credit Agreement ("the Fourth Amendment"), pursuant to which the Lenders waived the Credit Agreement's covenant that the report and opinion the Company received from its independent registered public accounting firm with respect to the financial statements for the year ending December 31, 2023 not contain a "going concern" or similar qualification.

The Fourth Amendment included covenants that we receive, (i) after the effective date of the Fourth Amendment and on or before April 15, 2024, at least $25,000 in gross proceeds from the issuance of our common stock, warrants and/or pre-funded warrants, and/or in non-refundable cash consideration from partnering transactions entered into after the effective date of the Fourth Amendment (so long as such partnering transactions would not require us or any of our

subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made), and (ii) after the effective date of the Fourth Amendment and on or before November 30, 2024, at least $50,000 (for the avoidance of doubt, inclusive of amounts previously counted toward the preceding clause (i)) in gross proceeds from the issuance of our common stock, warrants and/or pre-funded warrants, and/or in cash and/or non-cash consideration (measured at fair market value, as determined by the Administrative Agent (as defined in the Credit Agreement) in its sole discretion) from partnering transactions entered into after the effective date of the Fourth Amendment. Failure to perform this covenant would constitute (A) a default under the Credit Agreement and (B) an event of default under the Credit Agreement, subject to a cure period, in the case of clause (i) of the preceding sentence, until May 15, 2024 (for the avoidance of doubt, failure to perform clause (ii) would constitute an immediate event of default under the Credit Agreement without any cure or grace period).

In addition, the Fourth Amendment provided that if we had not, after the Effective Date and on or before September 30, 2024, received at least $40,000 in gross proceeds from the issuance of our common stock, warrants and/or pre-funded warrants, and/or cash and/or non-cash consideration (measured at fair market value, as determined by the Administrative Agent in its sole discretion) from partnering transactions entered into after the effective date of the Fourth Amendment, the "Minimum Liquidity Amount" (as defined in the Credit Agreement) that we are required to maintain at all times will increase to $25,000 from $15,000, unless and until we had received, after the effective date of the Fourth Amendment and on or before November 30, 2024, at least $50,000 in gross proceeds from the issuance of our common stock, warrants and/or pre-funded warrants, and/or in cash and/or non-cash consideration (measured at fair market value, as determined by the Administrative Agent in its sole discretion) from partnering transactions entered into after the effective date of the Fourth Amendment.

In connection with the Fourth Amendment, on the effective date of the Fourth Amendment, we granted new warrants to the Lenders to purchase up to 6 shares of our common stock (the "2024 Warrant Shares") at an exercise price of $49.1568 per share (the "2024 Warrants"), which represents a 10% premium over the arithmetic average of the volume-weighted average price of our common stock on the Nasdaq Capital Market during the 30 trading days preceding the Effective Date. The 2024 Warrants will expire on April 19, 2029 and may be net exercised at the holder's election.

On November 21, 2024, the Company entered into the Fifth Amendment to Credit Agreement and Guaranty and First Amendment to Fourth Amendment to Credit Agreement and Guaranty (the "Fifth Amendment").

Pursuant to the Fifth Amendment, the Lenders agreed to, among other things, (i) waive the Credit Agreement's covenant that the report and opinion the Company will receive from its independent registered public accounting firm with respect to the financial statements for the year ending December 31, 2024 will not contain a "going concern" or similar qualification, (ii) permanently waive the Credit Agreement's minimum revenue covenant, and (iii) waive the Fourth Amendment's requirement that the Company raise, after the effective date of the Fourth Amendment and on or before November 30, 2024, at least $50,000 in gross cash proceeds from the issuance of its common stock, warrants, and/or pre-funded warrants, and/or in cash and/or non-cash consideration from newly entered-into partnering transactions.

The Fifth Amendment included a new capital raising covenant requiring that the Company receive (A) after the effective date of the Fifth Amendment and on or prior to November 27,2024, at least $7,000 in gross cash proceeds from the issuance of the Company's common stock, warrants and/or pre-funded warrants("Raise 1"), (B) after the effective date of the Fifth Amendment and on or before March 15, 2025 (provided that the Company was required to use its commercially reasonable efforts to satisfy the requirement by February 15, 2025), at least $18,000 in net cash proceeds (including the proceeds of Raise 1) from (i) the issuance of the Company's common stock, warrants and/or pre-funded warrants, (ii) non-refundable cash consideration from partnering transactions entered into after the effective date of the Fifth Amendment (so long as such partnering transactions would not require the Company or any of its subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made), (iii) the issuance of the Company's subordinated debt (subject to terms set forth in the Fifth Amendment), and/or (iv) asset sales permitted pursuant to the Credit Agreement or consented to by the Lenders (such capital raise, "Raise 2"), and (C) after the effective date of the Fifth Amendment and on or prior to the earlier of (x) August 15, 2025 and (y) the date that is 30 days after the final data readout of the SERENITY At-Home Phase 3 trial, at least $29,000 in net cash proceeds (including the proceeds from Raise 1 and Raise 2) from the same permitted capital raising activities listed in the preceding clause (B).

In connection with the Fifth Amendment and the required capital raises described in the preceding paragraph, the Lenders agreed to modify the Credit Agreement's minimum liquidity covenant to require minimum cash liquidity of $7,500 (instead of $25,000) from and after the closing of Raise 1 until March 30, 2025. On March 31, 2025, the minimum liquidity amount will increase to $10,000 and on September 30, 2025, the minimum liquidity amount will further increase to $15,000.

In connection with the Fifth Amendment, the Company made the required one-time amortization payment of $2,500 principal amount, together with accrued and unpaid interest and a portion of the prepayment fee and other fees payable by December 31, 2024.

The Fifth Amendment also modified the interest rate of the loans provided under the Credit Agreement from a floating rate of Term SOFR plus 7.50% per annum, to a fixed rate of 13% per annum, retroactive to and effective as of September 30, 2024. For the quarterly payment dates ending December 31, 2024, March 31, 2025, and June 30, 2025, the Company will have the ability to make interest payments of up to 10% per annum "in-kind" by capitalizing and adding such interest to the outstanding principal amount of the loans under the Credit Agreement. In addition, pursuant to the Fifth Amendment, the Company will be required to make quarterly amortization payments equal to 5.0% of the principal amount of funded loans, together with applicable prepayment fees, beginning on March 31, 2026.

On the effective date of the Fifth Amendment and as a condition to effectiveness thereof, the Company's wholly owned subsidiaries OnkosXcel Therapeutics, LLC and OnkosXcel Employee Holdings, LLC (collectively, "OnkosXcel"), which previously provided unsecured guarantees of the Company's obligations under the Credit Agreement, granted security interests in substantially all of their assets to support such obligations.

The Fifth Amendment amended the negative covenants under the Credit Agreement to remove flexibility the Company and its subsidiaries previously had thereunder to undertake various transactions, including, without limitation, with respect to potential dispositions of OnkosXcel or out-licenses by OnkosXcel of its intellectual property.

Pursuant to the Fifth Amendment, the Company committed to appoint a new independent board director (subject to customary background checks, applicable law, confirmation of independence and Nasdaq rules), and to provide the independent director with various privileges and committee memberships on the board of directors of the Company (including the appointment of such director on committee to be formed to focus on capital raising and evaluate strategic options). The Company also agreed to engage an investment banker reasonably acceptable to OFA and the Lenders to assist the Company and its board of directors with evaluating and exploring strategic options.

The Company also agreed to covenants requiring that the Company's cash expenditures be monitored by the Lenders according to a board-approved budget provided to the Lenders prior to the signing of the Fifth Amendment, which cash budget will be updated on a bi-weekly basis going forward. The Company will not be permitted to make disbursements for any two-week period in excess of 115% of the aggregate budgeted amount of disbursements for the applicable period. Finally, pursuant to the Fifth Amendment, the Company is restricted from paying cash bonuses its employees or executives during the fiscal years 2024 and 2025 without OFA's consent or increasing the cash compensation for fiscal year 2025for certain senior officers of the Company from their compensation for fiscal year 2024.

As of December 31, 2024, we had aggregate principal indebtedness of $106,722 outstanding under the Credit Agreement.

Company Warrants and Registration Rights Agreement

Prior to the Fifth Amendment, pursuant to the Credit Agreement, the Lenders had the right to purchase shares of our common stock, so long as borrowings under the Credit Agreement are outstanding, for a purchase price of $5,000 at a price per share equal to a 10% premium to the volume-weighted average price of the common stock over the 30 trading days prior to the Lenders' election to proceed with such equity investment (the "Equity Investment Right"). The Equity Investment Right was terminated as part of the Fifth Amendment. Also, in connection with the closing of the Fifth Amendment, the Company agreed to, substantially concurrently with the closing of Raise 1, grant new warrants to the

Lenders to purchase an aggregate of 313 shares of common stock, at an exercise price of $0.16 per share (the "New Warrants"). The New Warrants will expire on the seventh anniversary of their issuance.

In addition, the Company agreed to, substantially concurrently with the closing of Raise 1, amend and restate all warrants to purchase stock of the Company issued to the Lenders prior to the effective date of the Fifth Amendment, to revise the exercise price thereunder to an exercise price equal to the lower of (i) the price per share of the common stock of the Company issued in Raise 1 and (ii) arithmetic average of the volume-weighted average price of the Company's common stock on the Nasdaq Capital Market during the 30 trading days preceding Raise 1 (such existing warrants, as amended and restated, the "Original Warrants"). The Original Warrants provide the Lenders with the right to purchase a total of 28 shares of common stock of the Company.

We entered into a registration rights agreement with the Lenders in connection with the original closing of the Credit Agreement, which has been amended and restated since in connection with each issuance of additional warrants to the Lenders, including most recently, in connection with the Fifth Amendment (as so amended and restated the "Amended and Restated Registration Rights Agreement"). Pursuant to the Amended and Restated Registration Rights Agreement, we have filed registration statements on Form S-3 to register the shares issuable upon exercise of the Original Warrants and the New Warrants for resale. The maximum shares of our common stock issuable under the Original Warrants and the New Warrants is 366.

As part of entering into the Credit Agreement, OnkosXcel, a wholly owned subsidiary of BTI, granted the OnkosXcel Warrants to the Lenders to purchase 175 individual limited liability company units. The strike price of the OnkosXcel Warrants is formulaic based on the value of OnkosXcel at the time of exercise and can only be exercised upon occurrence of an equity related liquidity event for OnkosXcel of at least $20,000. The exercise price per unit of the OnkosXcel Warrants will be set upon the earlier of the closing of the next sale (or series of related sales) by OnkosXcel of equity securities of OnkosXcel with aggregate proceeds of not less than $20,000 to unrelated third parties (the "Next Equity Financing") at an exercise price per unit equal to a 10% premium over the price per unit of the equity securities sold by OnkosXcel in such Next Equity Financing or, in the event of a sale of OnkosXcel prior to the Next Equity Financing or an initial public offering constituting the Next Equity Financing, the lesser of (x) 75% of the fair value of the consideration to be paid for a unit upon the consummation of such transaction and (y) 150% of the valuation applicable to the initial profits units issued by OnkosXcel after the closing of the Credit Agreement. The OnkosXcel Warrants are transferable with approval from BTI, which cannot be unreasonably withheld, expire on April 19, 2029, and may be net exercised at the holder's election.

See Note 9, *Debt and Credit Facilities* and Note 20, *Subsequent Events* in the notes to consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information relating to the Credit Agreement and RIFA, including applicable interest rates, payment obligations and certain restrictive and financial covenants thereunder. As of December 31, 2024, we were in compliance with all restrictive and financial covenants under the Credit Agreement.

ATM Program

In May 2021, we entered into the Sale Agreement with Jefferies pursuant to which we could offer and sell shares of our common stock, having an aggregate offering price of up to $100,000, from time to time, through an "at the market offering" program under which Jefferies will act as sale agent. On November 1, 2023, we entered into an amendment to the Sale Agreement with Jefferies to increase the size of the "at the market offering" program; pursuant to the Sale Agreement, as amended, we can offer and sell shares of our common stock having an aggregate offering price of up to $150,000 (excluding any shares of common stock already sold in the "at the market offering" program prior to the date of the amendment), from time to time, through an "at the market offering" program under which Jefferies will act as sale agent. During the year ended December 31, 2024, we sold 240 shares under the Sale Agreement for net proceeds of $7,451. During the year ended December 31, 2023, we sold 88 shares under the Sale Agreement for net proceeds of $26,221. We terminated the Sales Agreement with Jefferies on March 26, 2025.

Cash Flows

	Year ended December 31,	
	2024	2023
Cash (used in) provided by:		
Operating activities	$ (72,027)	$ (155,006)
Investing activities	$ —	$ (20)
Financing activities	$ 36,660	$ 26,522

Operating Activities

Net cash used in operating activities for the year ended December 31, 2024 was $72,027 and was primarily attributable to our net loss of $59,599, a $20,180 increase in the change in fair value of our derivative liability, a $4,327 decrease in accounts payable, accrued expenses, due to related parties, and other current liabilities, and a $1,872 increase in prepaid expenses, other current assets and other assets, offset by $6,543 in payable in kind interest on our credit agreement and $6,156 in non-cash stock-based compensation.

Net cash used in operating activities for the year ended December 31, 2023 was $155,006 and was primarily attributable to our net loss of $179,053 and a $3,219 decrease in accounts payable, accrued expenses, due to related parties, and other current liabilities, partially offset by a $2,888 decrease in prepaid expenses, other current assets and other assets, $18,614 in non-cash stock-based compensation, and a $4,369 increase in accrued and payable in kind interest.

Investing Activities

Net cash used in investing activities for the years ended December 31, 2024 and 2023, respectively was $0 and $20 and was primarily attributable to leasehold improvements in 2023.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024, was $36,660 and was primarily attributable to net proceeds of $39,214 from the sale of common stock under public offerings and the Sale Agreement with Jefferies, less a debt principal payment of $2,500.

Net cash provided by financing activities for the year ended December 31, 2023, was $26,522 and was primarily attributable to net proceeds of $26,221 from the sale of common stock under the Sale Agreement with Jefferies and net proceeds of $508 from the exercise of stock options.

Operating Capital and Capital Expenditure Requirements

We expect to continue to incur significant and increasing operating losses at least for the next several years as we commercialize IGALMI® and as we expand our clinical trials of and seek marketing approval focused on BXCL501 while pursuing development of additional product candidates for BXCL502, BXCL701 and BXCL702. We expect to continue to incur net losses in the near term. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our planned clinical trials and our expenditures on other research and development activities.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development, and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. We anticipate that our expenses will increase substantially as we:

- continue our clinical development of our product candidates;
- conduct additional research and development with our product candidates;

- seek to identify, acquire, license, develop and commercialize product candidates;
- integrate acquired technologies into a comprehensive regulatory and product development strategy;
- maintain, expand and protect our intellectual property portfolio;
- hire scientific, clinical, quality control and administrative personnel and utilize professional services, including consultants, lawyers, and accountants;
- add operational, financial and management information systems and personnel, including personnel to support our drug development and commercial efforts;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- fully develop a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize IGALMI® and any product candidates for which we may obtain regulatory approval; and
- continue to operate as a public company.

We believe that our existing cash and cash equivalents as of December 31, 2024 will not be sufficient to enable us to fund operating expenses and capital expenditure requirements for at least the next 12 months from the date of the issuance of the consolidated financial statements included in this Annual Report on Form 10-K, including funding our ongoing research and development and commercialization efforts. In particular, we believe that our cash and cash equivalents of $29,854 as of December 31, 2024 plus the approximately of $14,000 gross proceeds from our financing in March 2025 will allow us to fund our operations and meet our liquidity requirements into the third quarter of 2025, assuming we are able to comply with the covenants under our Credit Agreement. We expect that we will need to obtain substantial additional funding to fund our ongoing operations. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interests of our existing stockholders may be materially diluted, and the terms of these securities could include liquidation or other preferences that could adversely affect the rights of our existing stockholders. In addition, debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, which could adversely impact our ability to conduct our business. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed or on attractive terms, we could be forced to significantly delay, scale back or discontinue the development or commercialization of our product candidates, seek collaborators at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available, and relinquish or license, potentially on unfavorable terms, our rights to our product candidates that we otherwise would seek to develop or commercialize ourselves. To date, we have continued research and development activities while managing our cash position. However, we can provide no assurance that will be successful in obtaining additional necessary resources and, if we are unable to fund our operations, including our clinical trials, we may need to focus on advancing fewer of our product candidates or otherwise consider strategic alternatives.

Contractual Obligations and Commitments

In July 2024, the Company signed an amendment to its commercial supply agreement that requires minimum annual payments for the first five years of the agreement ending in 2026 that in aggregate total $10,000. The Company has met the minimum requirements for the first 3 years ending in 2024. The remaining minimum commitments for years 4 and 5 (2025 and 2026) is $2,000 each year.

In February 2022, we signed a distribution agreement with a third party to distribute product related to BXCL501 in the U.S. The distributor will be paid defined fees for its services under the agreement, which can be terminated by either party for cause. The distribution agreement can also be terminated by us without cause, subject to payment of agreed termination fees.

BTI leases office space for its corporate headquarters at 555 Long Wharf Drive, New Haven, Connecticut (the "HQ Lease"). The HQ Lease expires in February 2026. The Company has an option to renew the HQ Lease for one additional five-year term. Payments under the HQ Lease are fixed. The Company has approximately $456 of payments remaining under the HQ Lease. For additional details, see Note 13, *Leases* in the notes to consolidated financial statements included in this Annual Report on Form 10-K for additional information relating to the Company's leases.

In addition, we are obligated to make quarterly interest payments under our Credit Agreement. For additional details, see Note 9, *Debt and Credit Facilities* in the notes to consolidated financial statements included in this Annual Report on Form 10-K for additional information relating to the Company's debt payment obligations.

Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with U.S. GAAP requires management to exercise its judgment. We exercise considerable judgment with respect to establishing sound accounting policies and in making estimates and assumptions that affect the reported amounts of our assets and liabilities, our recognition of revenues and expenses, and disclosure of commitments and contingencies at the date of the consolidated financial statements.

On an ongoing basis, we evaluate our estimates and judgments. We base our estimates and judgments on a variety of factors including our historical experience, knowledge of our business and industry, current and expected economic conditions, the attributes of our products and the regulatory environment. We periodically re-evaluate our estimates and assumptions with respect to these judgments and modify our approach when circumstances indicate that modifications are necessary.

While we believe that the factors we evaluate provide us with a meaningful basis for establishing and applying sound accounting policies, we cannot guarantee that the results will always be accurate. Since the determination of these estimates requires the exercise of judgment, actual results could differ from such estimates.

We define critical accounting policies as those that are reflective of significant judgments and uncertainty and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies are noted below.

Stock Compensation

The Company has granted stock options, restricted stock units and profit units to employees, directors, and consultants, as well as warrants to other third parties. For employee, director and consultant awards, the value of each grant is estimated on the date of grant using a Black-Scholes option-pricing model. The Black-Scholes pricing model incorporates the volatility of the price of BTI's stock, the risk-free interest rate, the estimated life of the award, the closing market price of the Company's stock and the exercise price of the award. Management bases the Company's estimates of stock price volatility on the historical volatility of the Company's common stock, as well as a peer group of comparable companies. However, these estimates are neither predictive nor indicative of the future performance of the Company's stock. For purposes of the calculation, management assumed that no dividends would be paid during the life of the stock awards. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment.

Research and Development Expenses

As part of the process of preparing the Company's consolidated financial statements, BTI's management is required to estimate prepaid and accrued expenses, including research and development expenses. This process involves reviewing open contracts, communicating with personnel to identify services that have been performed on behalf of the Company and estimating the level of service performed and the associated cost incurred for the service when BTI has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice

BTI monthly for services performed or when contractual milestones are met. BTI management makes estimates of prepaid and/or accrued expenses, including research and development expenses, as of each reporting date in the Company's consolidated financial statements based on facts and circumstances known to management at that time. BTI periodically confirms the accuracy of its estimates with the service providers and makes adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to contract research organizations ("CROs") in connection with clinical studies, amounts paid to contract manufacturing organizations, and fees paid to sites in connection with clinical trials.

The Company bases its expenses related to clinical studies on management's estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trial studies on our behalf. The financial terms of these agreements are subject to an initial negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing certain service fees, BTI management estimates the time period over which services will be performed, enrollment of patients, number of sites activated and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from management's estimate, management will adjust the accrual or prepaid accordingly. Although the Company does not expect management's estimates to be materially different from amounts actually incurred, management's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in BTI reporting amounts that are too high or too low in any particular period.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Foreign Exchange Risk

As of December 31, 2024, we had $29,854 of cash and cash equivalents. Our cash and cash equivalents are primarily held in U.S. Government money market funds. We do not participate in any foreign currency hedging activities and have limited exposure to other derivative financial instruments, primarily resulting from the terms and conditions of the Credit Agreement. We did not recognize any significant exchange rate losses during the years ended December 31, 2024 and 2023, respectively.

We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents do not contain material market risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash at one or more financial institutions that exceed federally insured limits. In the event of a failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

Interest Rate Risk

The loans under the Credit Agreement bear interest at a fixed rate of 13% payable quarterly. Consequently, we have material interest rate exposure due to our indebtedness if market rates drop in the future.

Capital Market Risk

We currently do not have substantial product revenues and depend on funds raised through other sources. One source of funding includes future debt or equity offerings. Our ability to raise funds in this manner depends upon, among other things, capital market forces affecting our stock price, and on the state of the capital markets generally.

Item 8. Financial Statements and Supplementary Data

The financial statements required pursuant to this item and the related report of our independent auditor are included in Item 15 of this report beginning on page F-1 and are incorporated under this Item by reference. Our independent auditor for the years ended December 31, 2024 and 2023 was Ernst & Young LLP (PCAOB ID: 42), located in Stamford, Connecticut, USA.

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, with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Controls Over Financial Reporting

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control-Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2024, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting as we are a "smaller reporting company" and "non-accelerated filer" as defined under SEC rules.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Insider Trading Arrangements

(a) On December 14, 2024, Vimal Mehta, Chief Executive Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 2,184 shares of the Company's common stock to cover taxes due in connection with the vesting of restricted stock units until December 31, 2025.

(b) On December 14, 2024, Richard Steinhart, Chief Executive Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 1,563 shares of the Company's common stock to cover taxes due in connection with the vesting of restricted stock units until December 31, 2025.

(c) On December 14, 2024, Javier Rodriguez, Senior Vice President, Chief Legal Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 1,563 shares of the Company's common stock to cover taxes due in connection with the vesting of restricted stock units until December 31, 2025.

(d) On December 14, 2024, Frank Yocca, Chief Scientific Officer, adopted a Rule 10b5-1 trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 1,563 shares of the Company's common stock to cover taxes due in connection with the vesting of restricted stock units until December 31, 2025.

Each of these plans were terminated effective March 17, 2025.

Open Market Sales Agreement Termination

On March 26, 2025, we and Jefferies terminated that certain Open Market Sales Agreement, dated May 10, 2021, as amended on November 1, 2023.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

INFORMATION ABOUT OUR DIRECTORS & EXECUTIVE OFFICERS

The following information with respect to our Board of Directors (the "Board") and executive officers is presented as of March 28, 2025:

Name	Age	Position at BioXcel
Vimal Mehta, Ph.D.	64	Chief Executive Officer and President, and Director
Richard Steinhart	67	Senior Vice President and Chief Financial Officer
Frank Yocca, Ph.D.	69	Senior Vice President and Chief Scientific Officer
Javier Rodriguez	53	Senior Vice President, Chief Legal Officer and Corporate Secretary
Peter Mueller, Ph.D.	68	Chairman of the Board
June Bray	71	Director
Sandeep Laumas, M.D.	56	Director
Michael Miller	67	Director
Michael Votruba, M.D.	59	Director
David Mack	54	Director
Rajiv Patni, M.D.	59	Director

Business Experience and Background of Directors and Executive Officers

Vimal Mehta, Ph.D. co-founded the Company and has served as a member of our Board since April 2017 and as our Chief Executive Officer and President since May 2017. Dr. Mehta also served as our Corporate Secretary from May 2017 to February 2021. He is also the co-founder of BioXcel Corporation (now BioXcel LLC) and, following its inception in 2005 until March 2023, served as its Chairman of the Board and Chief Executive Officer. Dr. Mehta holds a Ph.D. in Chemistry from the University of Delhi, India and completed a Post-Doctoral Fellowship in Chemistry at the University of Montpellier, France. During the length of his career, Dr. Mehta has garnered a deep understanding of the biopharma and healthcare ecosystem and has been actively involved in diverse global value generating initiatives encompassing corporate strategy and planning, global business development, and corporate fundraising. As our co-founder, he has helped shape our strategic and business trajectory which the Board believes qualifies him to serve as a director of our Company.

Richard I. Steinhart has served as our Senior Vice President and Chief Financial Officer since March 2018. From October 2017 to March 2018, Mr. Steinhart served as our Vice President and Chief Financial Officer. From October 2015 to June 2017, he was Vice President and CFO at Remedy Pharmaceuticals, Inc. From January 2014 to September 2015 Mr. Steinhart worked as a financial and strategic consultant to the biotechnology and medical device industries. From April 2006 through December 2013, Mr. Steinhart was employed by MELA Sciences, Inc., as their Vice President, Finance and Chief Financial Officer, Treasurer and Secretary from April 2006 to April 2012 and as Sr. Vice President, Finance and Chief Financial Officer from April 2012 to December 2013. From May 1992 until joining MELA Sciences, Mr. Steinhart was a Managing Director of Forest Street Capital/SAE Ventures, a boutique investment banking, venture capital, and management consulting firm focused on healthcare and technology companies. Prior to Forest Street Capital/SAE Ventures, he was Vice President and Chief Financial Officer of Emisphere Technologies, Inc. Mr. Steinhart's other experience includes seven years at CW Group, Inc., a venture capital firm focused on medical technology and biopharmaceutical companies, where he was a General Partner and Chief Financial Officer. Mr. Steinhart is a member of the Board of Directors of Actinium Pharmaceuticals, Inc., a position he assumed in November 2013, and Atossa Genetics, Inc., where he began his service in March 2014. Mr. Steinhart serves as the Chairman of the Audit Committee at Actinium Pharmaceuticals, where he also sits on the Corporate Governance Committees. Mr. Steinhart serves as the Chairman of Atossa Genetics Audit Committee and is a member of its Audit Committee and Compensation Committee. He holds B.B.A. and M.B.A. degrees from Pace University and is a Certified Public Accountant (inactive).

Frank D. Yocca, Ph.D. has served as our Executive Vice President and Chief Scientific Officer since December 2023. From March 2018 to December 2023, he served as our Senior Vice President and Chief Medical Officer. From June 2017 to March 2018, Dr. Yocca served as our Vice President and Chief Scientific Officer. From April 2015 to April 2017, he was Senior Vice President, CNS R&D of BioXcel. From 2005 to 2015, Dr. Yocca held multiple leadership roles at AstraZeneca plc, including Vice President, Strategy and Externalization, Neuroscience Virtual Innovative Medicine Unit (iMed) (2011-2015), Vice President and Head, Strategy Unit, CNS and Pain Innovative Medicine Unit (iMed) (2010 to 2011) and Vice President and Head, CNS Pain Discovery (2005 to 2010). Prior to this, he was Executive Director at the Bristol Myers Squibb Pharmaceutical Research Institute from 1984 to 2004 where he served concurrent leadership responsibilities within the Neuroscience Clinical Group for Early and Late Clinical Development Studies. Prior to this, Dr. Yocca served as Executive Director, Neuroscience Discovery from 1997 to 2003, where he was a collaborator in the development and implementation of corporate strategic plans and leader for the Neuroscience Biology Department in the discovery of psychiatry and Alzheimer's clinical candidates. He was a core member of the Abilify Product Development and Commercialization Team from 1999 to 2002 and a core member of the Early and Late Discovery and Development Teams from 1984 to 2001. Dr. Yocca holds a B.S. in biochemistry from Manhattan College and an M.S. in pharmacology and a Ph.D. in neuropharmacology from St. John's University.

Javier Rodriguez has served as our Senior Vice President and Chief Legal Officer and Corporate Secretary since January 2021. Mr. Rodriguez has over 20 years of extensive strategic and legal experience within the biopharmaceutical industry and has broad leadership experience managing legal, compliance, corporate governance, intellectual property, data privacy, and government affairs professionals. Prior to joining BioXcel Therapeutics, he was Chief Legal Officer at Indivior PLC (LSE: INDV), a global pharmaceuticals company with operations in over 40 countries, from December 2014 to December 2020, where he oversaw all legal affairs, data privacy compliance, and corporate governance matters. Before taking on his role at Indivior, Mr. Rodriguez was General Counsel at Reckitt Benckiser Pharmaceuticals Inc. where he played a key leadership role in negotiating and successfully effectuating the demerger and spin-off of the organization in 2014, which included closing a $750 million secured term loan and $50 million revolving credit facility to fund on-going operations of the demerged entity. Earlier in his career, Mr. Rodriguez held roles of increasing responsibility at Reckitt Benckiser LLC, Bayer Healthcare Pharmaceuticals, Inc. and Berlex, Inc. He began his legal career in 2000 as a litigation associate at Thelen Reid & Priest, LLP in New York City. He holds a B.S. in Civil Engineering from Rutgers University, a M.S.E. in Structural Engineering from the University of Michigan and a J.D. from the University of Pennsylvania.

Peter Mueller, Ph.D. has served as a director of our Company since April 2017 and Chairman of the Board since August 2017. With over 30 years of global pharma and biotech experience, Dr. Mueller is currently the President of the Mueller Health Foundation, a private foundation tackling globally lethal infectious diseases such as tuberculosis by addressing latency and the ever-growing challenges of antimicrobial resistance. From 2014 to 2016, he was President of R&D and Chief Scientific Officer of Axcella Health, a biotechnology company. From 2003 to 2014, Dr. Mueller served as Executive Vice President Global Research and Development & Chief Scientific Officer for Vertex Pharmaceuticals, Incorporated, a biotechnology company. He was involved in the development of Incivek (2011), Kalydeco (2012), and Orkambi (2014). Prior to his tenure at Vertex, he served as Senior Vice President, Research and Development, for Boehringer Ingelheim Pharmaceuticals, Inc. overseeing global research programs (immunology, inflammation, cardiovascular diseases and gene therapy) and the development of all drug candidates of the company's worldwide portfolio in North and South America, Canada and Japan, beginning in 1997. He was involved in the development of Spiriva, Combivent, Atrovent and Viramune. Dr. Mueller received both an undergraduate degree and a Ph.D. in Chemistry at the Albert Einstein University of Ulm, Germany, where he also holds a Professorship in Theoretical Organic Chemistry. He completed fellowships in Quantum Pharmacology at Oxford University and in Biophysics at Rochester University. He is a member of various scientific and political societies and currently serves on the Board of the US-India Chamber of Commerce Biotech. He also serves as chairman of the Scientific Advisory Board of BioXcel LLC and is an advisor to the University of Iowa Center for Bioanalysis and Bioprocessing. We believe that Dr. Mueller's extensive experience in the life sciences industry as a scientist and executive qualifies him to serve as a director of our Company.

June Bray has served as a director of our Company since March 2021. She previously served as Senior Vice President, Global Regulatory Affairs and Medical Writing of Allergan, Inc., a pharmaceutical company, from 2008 to 2020, where she was in charge of global regulatory strategies for development projects and lifecycle management for all therapeutic areas. From 2006 to 2008, Ms. Bray was Vice President, Regulatory Affairs at Organon & Co. (prior to its

merger with Merck & Co.), where she led departments responsible for regulatory activities for development and marketed products and, from 1980 to 2006, Ms. Bray served in various capacities at Berlex Laboratories, Inc., most recently as Vice President, Global Regulatory Affairs for Specialized Therapeutics/Oncology, a position she held from 2003 to 2006. Ms. Bray has served on the Board of Quince Therapeutics, Inc. since June 2022. Ms. Bray holds an M.B.A. from Fairleigh Dickinson University and a B.S. from the University of Rhode Island. We believe that Ms. Bray's extensive experience in developing global regulatory strategies for product candidates qualifies her to serve as a director of our Company.

Sandeep Laumas, M.D. has served as a director of our Company since September 2017. Since June 2020, Dr. Laumas has served as Chief Business Officer and Chief Financial Officer of Instil Bio Inc. He served as a Director of BioXcel Corporation from May 2013 to August 2017. Dr. Laumas served as a director of 9 Meters BioPharma, Inc. (formerly Innovate Biopharmaceuticals Inc.), a biopharma company, from January 2014 to June 2021, including serving as the Executive Chairman from 2014 to April 2020, and as its Chief Executive Officer from February 2019 to April 2020. Dr. Laumas has served as a director of Unicycive Therapeutics Inc. since January 2018. He began his career at Goldman Sachs & Co. in New York in the Investment Banking Division. Dr. Laumas then joined Balyasny Asset Management in New York and later moved to North Sound Capital as a Managing Director responsible for global healthcare investments. He has been investing in healthcare via investment vehicles, Bearing Circle Capital. Dr. Laumas has served as a director of Parkway Holdings Ltd. (IHH Healthcare) and SRL Ltd. Dr. Laumas received his A.B. in Chemistry from Cornell University in 1990, M.D. from Albany Medical College in 1995 with a research gap year at the Dana-Farber Cancer Institute and completed his medical internship in 1996 from the Yale University School of Medicine. Dr. Laumas has a novel industry perspective, particularly in both public and private investments and financial transactions in the healthcare arena, which we believe qualifies him to serve as a director of our Company.

Michael Miller has served as a director of our Company since June 2022. He has served as an advisor to several biopharmaceutical companies, including Concarlo Therapeutics since June 2022 and Rigel Pharmaceuticals, Inc. since January 2022. Prior to that, he served as Executive Vice President, Commercial of Jazz Pharmaceuticals plc from March 2014 to August 2020. Since May 2018, Mr. Miller has served on the Board of Puma Biotechnology Inc., where he also serves on the Compensation Committee. Mr. Miller received his B.S. from the University of San Francisco and his M.B.A. from San Francisco State University. The Board believes that Mr. Miller's extensive experience at commercial pharmaceutical and public companies will provide valuable contributions to the Board.

Michal Votruba, M.D., has served as a director of our Company since March 2019. Since 2013, Dr. Votruba has been a Director of the Gradus/RSJ Life Sciences Fund, the largest dedicated fund in Central Europe with a portfolio of companies in Europe and the United States. Dr. Votruba served as a director of Mynd Analytics, Inc., a telebehavioral health services company, from July 2015 to 2019, and served as a director of Telemynd, Inc., successor to Mynd Analytics, since 2019. Since 2010, he has served as a member of the board of PrimeCell Therapeutics as the Director of Global Business Development overseeing the expansion of the largest regenerative medicine company operating in Central Europe. In 2009, the Czech Academy of Sciences solicited Dr. Votruba's expertise for the first successful privatization project of the Institute of Experimental Medicine in Prague: the newly created protocol established a precedent for future privatization projects in the Czech Republic. Dr. Votruba earned his M.D. from the Medical Faculty of Charles University in Prague in 1989. Shortly thereafter, he emigrated from Czechoslovakia and developed his professional career in Canada and the USA. Since 2005, Dr. Votruba combined his theoretical and clinical experience in the field of Competitive Intelligence serving the global pharmaceutical industry for eight years as an industry analyst advising senior leaders of companies including Amgen, Novartis, Eli Lilly, Allergan, EMD, Serono and Sanofi. Dr. Votruba brings valuable expertise to the Board as a clinical psychiatrist and broad experience in the international marketing of innovative medical technologies.

David Mack has more than 25 years of experience as a lawyer, director, and investor. He served as a director of of our Company since November 2024. He has extensive experience in leading transactions as well as deep knowledge of complex restructuring and litigation. He has previously served (or serves) on the boards of TerraForm Global, Inc. (NSDQ: GLBL), Speedcast International Limited (ASX: SDA) and Intelsat S.A., among others. He started his career in Sydney as a lawyer with Mallesons Stephen Jaques and then worked for Linklaters LLP in London. In 2000, he moved to the US, where he worked at Simpson Thacher & Bartlett, LLP followed by Perry Capital LLC. He has a BA and an LLB (Hons) from the University of Sydney. In connection with his appointment, Mr. Mack was also appointed to the Compensation Committee, effective with his commencement of service, as well as the newly formed Capital Raising

Committee. We believe that Mr. Mack is qualified to serve as a director of our Company because of his extensive experience working on strategic transactions.

Dr. Rajiv Patni Since September 2024, Dr. Patni has served as the Chief Executive Officer of Judo Bio, a biopharmaceutical development company focused on pioneering oligonucleotide medicines delivered to the kidney. He previously served as Chief Research and Development Officer at Reata Pharmaceuticals, a commercial-stage company acquired by Biogen and he is currently serving as a board member of Quince Therapeutics, Inc. (Nasdaq: QNCX). Previously, Dr. Patni also served as Chief Medical Officer at several public, commercial-stage biopharmaceutical companies - Global Blood Therapeutics, Portola Pharmaceuticals, and Adamas Pharmaceuticals, until their acquisitions by larger companies. Earlier in his career, Dr. Patni held roles of increasing responsibility at Pfizer, Roche, and Actelion. Dr. Patni received his M.D. from the Icahn School of Medicine at Mount Sinai in New York City as part of an accelerated B.S./M.D. program. He completed an internal medicine residency and adult cardiology fellowship at the Albert Einstein College of Medicine, also in New York City, where he continued as an attending physician-scientist before joining the biopharmaceutical industry. We believe that Dr. Patni's extensive experience in biopharmaceutical product development will provide valuable contributions to the Board.

Board and Committee Information

During fiscal 2024, our Board of Directors met 12 times, the audit committee met four times, the capital raise committee met four times, and the pricing committee met two times. In 2024, each of our incumbent directors attended at least 75% of the meetings of the Board and committees on which he or she then served as a member.

Executive sessions, which are meetings of the non-management members of the Board, are regularly scheduled throughout the year. In addition, at least twice per year, the independent directors meet in a private session that excludes management and any non-independent directors. The Chair of the Board presides at each of these meetings and, in his absence, the non-management and independent directors in attendance, as applicable, determine which member will preside at such session.

Board Leadership Structure

Our Corporate Governance Guidelines provide our Board with flexibility to combine or separate the positions of Chairperson of the Board and Chief Executive Officer in accordance with its determination that utilizing one or the other structure would be in the best interests of the Company and its stockholders. If the Chairperson of the Board is a member of management or does not otherwise qualify as independent, our Corporate Governance Guidelines provide for the appointment by the independent directors of a lead independent director (the "Lead Director"). The Lead Director's responsibilities include, but are not limited to: presiding over all meetings of the Board at which the Chairperson of the Board is not present, including any executive sessions of the independent directors; approving Board meeting schedules and agendas; and acting as the liaison between the independent directors and the Chief Executive Officer and Chairperson of the Board. Our Corporate Governance Guidelines provide that, at such times as the Chairperson of the Board qualifies as independent, the Chairperson of the Board will serve as Lead Director.

The positions of our Chair of the Board and our Chief Executive Officer are currently served by two separate persons. Dr. Mueller serves as Chairman of the Board, and Dr. Mehta serves as our Chief Executive Officer. In his capacity as the independent Board Chair, Dr. Mueller performs the functions of the Lead Director.

The Board believes that our current leadership structure of Chief Executive Officer and Chair of the Board being held by two separate individuals is in the best interests of the Company and its stockholders and strikes the appropriate balance between the Chief Executive Officer and President's responsibility for the strategic direction, day-to day-leadership and performance of our Company and the Chair of the Board's responsibility to guide overall strategic direction of our Company and provide oversight of our corporate governance and guidance to our Chief Executive Officer and President and to set the agenda for and preside over Board meetings. We recognize that different leadership structures may be appropriate for companies in different situations and believe that no one structure is suitable for all companies. Accordingly, the Board will continue to periodically review our leadership structure and make such changes in the future as it deems appropriate and in the best interests of the Company and its stockholders.

Board Committees

Our Board has three standing committees: an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and the responsibilities described below. In addition, from time to time, special committees may be established under the direction of our Board when necessary to address specific issues. Each of the audit committee, the compensation committee and the nominating and corporate governance committee operates under a written charter which are available in the "Governance - Governance Documents" section of the "Investors" page of our website located at *www.bioxceltherapeutics.com*.

	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee
June Bray	—	—	X
Sandeep Laumas, M.D.	Chair	X	X
Peter Mueller, Ph.D.	X	Chair	Chair
Michael Miller	X	—	—
Michal Votruba, M.D.	X	—	—
David Mack	—	X	—
Rajiv Patni	—	—	—

Audit Committee

Our audit committee is responsible for, among other things:

- appointing, approving the compensation of, and assessing the independence of, our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing our annual and quarterly financial statements and related disclosures with management and our independent registered public accounting firm;
- considering whether to recommend to the Board that the Company's audited financial statements be included in the Company's Annual Report on Form 10-K;
- coordinating our Board's oversight of our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- discussing our risk assessment and risk management policies, and overseeing management of our financial risks, cybersecurity risks, information security risks, and, as necessary or advisable, such other material risks facing the Company;
- meeting independently with our internal auditors, if any, independent registered public accounting firm and management;
- reviewing on a periodic basis our investment policy;
- reviewing and approving or ratifying any related person transactions;
- pre-approving all audit and non-audit services provided to us by our independent auditor (other than those provided pursuant to appropriate preapproval policies established by the committee or exempt from such requirement under SEC rules);

- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, and for the confidential and anonymous submission by our employees of concerns regarding questionable accounting or auditing matters; and

- preparing the audit committee report required by SEC rules.

The current members of our audit committee are Peter Mueller, Sandeep Laumas, Michael Miller and Michal Votruba, with Dr. Laumas serving as chair. All members of our audit committee meet the requirements for financial literacy under the applicable Nasdaq rules and regulations. Our Board has affirmatively determined that each member of our audit committee qualifies as "independent" under Nasdaq's additional standards applicable to audit committee members and Rule 10A-3 of the Exchange Act applicable to audit committee members. In addition, our Board has determined that each of Dr. Laumas, Mr. Miller, Dr. Mueller, and Dr. Votruba qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K.

Compensation Committee

Our compensation committee is responsible for, among other things:

- reviewing and approving, or recommending for approval by the board of directors, the compensation of our Chief Executive Officer and our other executive officers;

- reviewing and approving or make recommendations to the Board regarding the Company's incentive compensation plans and equity-based plans and arrangements;

- overseeing and administering our incentive compensation and equity-based plans and arrangement;

- periodically reviewing and making recommendations to our board of directors with respect to director compensation;

- reviewing and discussing annually with management our "Compensation Discussion and Analysis," to the extent required;

- preparing the annual compensation committee report required by SEC rules, to the extent required;

- reviewing and discussing the results of the most recent stockholder advisory vote on executive compensation, and reviewing and recommending to our board of directors for approval the frequency with which we should conduct such votes, to the extent required; and

- overseeing the Company's programs and policies as may be applicable, regarding talent management (including retention, development and training) and diversity and inclusion.

The current members of our compensation committee are Peter Mueller, Ph.D., David Mack and Sandeep Laumas, M.D., with Dr. Mueller serving as chair. Our Board has determined that each member of our compensation committee qualifies as "independent" under Nasdaq's additional standards applicable to compensation committee members and is a "non-employee director" as defined in Section 16b-3 of the Exchange Act.

The compensation committee generally considers the Chief Executive Officer's recommendations when making decisions regarding the compensation of non-employee directors and executive officers (other than the Chief Executive Officer). Pursuant to the compensation committee's charter, the compensation committee has the authority to retain or obtain the advice of compensation consultants, legal counsel and other advisors to assist in carrying out its responsibilities. Before selecting any such consultant, counsel or advisor, the compensation committee reviews and considers the independence of such consultant, counsel or advisor in accordance with applicable Nasdaq rules. We must provide appropriate funding for payment of reasonable compensation to any advisor retained by the compensation committee.

Compensation Consultants

The compensation committee has the authority under its charter to retain outside consultants or advisors, as it deems necessary or advisable. In accordance with this authority, the compensation committee.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee is responsible for, among other things:

- identifying individuals qualified to become members of our Board;
- recommending to our Board the persons to be nominated for election as directors and to each committee of the Board;
- developing and recommending to our Board corporate governance guidelines, and reviewing and recommending to our board of directors proposed changes to our corporate governance guidelines from time to time;
- reviewing and making recommendations to the Board in connection with a director's notification of a change in employment or other circumstances; and
- overseeing a periodic evaluation of our Board.

The current members of our nominating and corporate governance committee are June Bray, Sandeep Laumas and Peter Mueller, with Peter Mueller serving as chair. Our Board has determined that each of Ms. Bray and Drs. Laumas and Mueller qualifies as "independent" under applicable Nasdaq rules applicable to nominating and corporate governance committee members.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics (the "Code of Conduct") that applies to all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. A copy of our Code of Business Conduct and Ethics is available under the "Governance - Governance Documents" section of the Investors page of our website located at *www.bioxceltherapeutics.com*, or by writing to our Corporate Secretary at our offices at 555 Long Wharf Drive, New Haven, CT 06511. We intend to make any required disclosures regarding amendments to, or waivers of, provisions of our Code of Conduct on our website rather than by filing a Current Report on Form 8-K.

Insider Trading Policy

We maintain an Insider Trading Compliance Policy governing the purchase, sale, and other disposition of Company securities that is applicable to all of our directors, officers and employees. We believe our Insider Trading Compliance Policy and procedures are reasonably designed to promote compliance with insider trading laws. A copy of our Insider Trading Compliance Policy is filed hereto as Exhibit 19.1.

The policy additionally prohibits our directors, officers and employees from purchasing financial instruments, such as prepaid variable forward contracts, equity swaps, collars, and exchange funds, or otherwise engaging in transactions that hedge or offset, or are designed to hedge or offset, any decrease in the market value of our equity securities. All such transactions involving our equity securities, whether such securities were granted as compensation or are otherwise held, directly or indirectly, are prohibited.

Compensation Recovery Policy (Clawback Policy)

In 2023, we adopted a compensation recovery, or "clawback," policy (the "Clawback Policy") in accordance with the Nasdaq listing standards and Exchange Act Rule 10D-1. The Clawback Policy provides for the mandatory recovery (subject to limited exceptions) from current and former officers of incentive-based compensation that was erroneously

received during the three years preceding the date that the Company is required to prepare an accounting restatement. The Clawback Policy is overseen and administered by the Compensation Committee. The full text of the Clawback Policy was included as Exhibit 97 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on March 22, 2024.

Interested Persons' Communications with the Board

To help foster input and insight from the Company's stockholders and other interested parties (collectively, "Interested Parties"), Interested Parties may communicate with, or otherwise make his or her concerns known directly to, the Chairperson of the Board, the lead director, if any, any chairperson of a Board committee, or the non-management or independent members of the Board, by addressing such communications to the intended recipient by name or position in care of: BioXcel Therapeutics, Inc., Attn: Chief Legal Officer, 555 Long Wharf Drive, New Haven, Connecticut 06511. The Chief Legal Officer will forward such communications to the appropriate party.

Item 11. Executive Compensation

The following is a discussion of the compensation arrangements of our named executive officers ("NEOs"). As a smaller reporting company, we are not required to include a Compensation Discussion and Analysis section and have elected to comply with the scaled disclosure requirements applicable to smaller reporting companies.

Our NEOs include our principal executive officer and our two most highly compensated executive officers, other than our principal executive officer, for the fiscal year ended December 31, 2024. These NEOs and their positions are:

- Vimal Mehta, Ph.D., our Chief Executive Officer and President;
- Javier Rodriquez, our Senior Vice President, Chief Legal Officer and Secretary; and
- Richard Steinhart, our Senior Vice President and Chief Financial Officer.

Summary Compensation Table

The following table shows information regarding the compensation of our NEOs for the years presented.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)(1)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)(2)	Total ($)
Vimal Mehta, Ph.D.	2024	1,001,570	—	101,250	—	16,425	1,119,245
Chief Executive Officer	2023	1,001,569	1,097,600	2,615,928	—	16,050	4,731,147
Javier Rodriguez	2024	423,833	181,755	398,530	—	8,625	1,012,552
Senior VP and Chief Legal Officer	2023	423,833	191,588	498,272	—	8,250	1,121,943
Richard Steinhart	2024	409,872	181,755	398,339	—	4,128	998,216
SVP and Chief Commercial Officer							

(1) The amounts reported represent the grant date fair value of performance-based units, restricted stock units and stock options granted to our NEOs as computed in accordance with Accounting Standards Codification 718, Compensation - Stock Compensation (ASC 718). For all performance-based units, the amounts were calculated based on the probable outcome of the performance condition as of the grant date. The following are the values of the performance-based units as of the grant date assuming attainment of the maximum level of performance: Dr. Mehta ($300,000), Mr. Rodriguez ($84,000) and Mr. Steinhart ($84,000). Note that the amounts reported in these columns reflect the accounting cost for these awards and do not correspond to the actual economic value that may be received by our NEOs from the awards. We provided information regarding the assumptions used to calculate the value of the restricted stock units and stock options in Note 12 to our financial statements included herein.

(2) The amounts reported for 2024 represent reimbursement for healthcare benefits ($7,800) and ($4,128) for Dr. Mehta and Mr. Steinhart, respectively, and 401(k) matching contributions of ($8,625) for each named executive officer other than Mr. Steinhart. No bonus was paid for the year 2024.

Narrative to Summary Compensation Table

2024 Salaries

Our NEOs receive a base salary to compensate them for services rendered to the Company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. The base salaries of our NEOs are reviewed from time to time and adjusted when our Board or compensation committee determines an adjustment is appropriate. The compensation committee determined not to increase the salaries of the NEOs in 2024.

2024 Equity Awards

During 2024, we awarded stock options, time-based restricted stock units and performance-based restricted stock units ("PSUs") to our NEOs as the long-term incentive component of our executive compensation program. We typically grant equity awards at such times as our Board determines appropriate. The following table sets forth the equity awards we granted to our NEOs during 2024:

	2024 Equity Awards Granted (#)		
Name	**Options**	**RSUs**	**PSUs**
Vimal Mehta, Ph.D.	6,250		15,625
Javier Rodriguez	1,875	625	4,375
Richard Steinhart	1,875	625	4,375

The options were granted with exercise prices equal to the fair market value of our common stock on the date of grant. The stock options generally vest and becomes exercisable as to 50% of the total number of shares underlying the option on each of the first and second anniversaries of the date of grant and the remaining become fully vested on the second anniversary of the date of the grant, subject, in each case, to the holder's continued service through the applicable vesting date. The time-based restricted stock units generally vest fully on the first anniversary of the date of the grant, subject, in each case, to the holder's continued service through the applicable vesting date.

The PSUs granted to Dr. Mehta, Mr. Rodriquez and Mr. Steinhart are eligible to vest within thirty days of the first anniversary of the grant date the participants continued employment with the Company and based on the attainment of the following performance metrics, as determined by the Board: (i) a satisfactory completion of securing at least $25 million of additional funding for the Company (50% of the PSUs); (ii) successfully initiates trials for its Serenity and Tranquility programs and progress towards data readouts for such program trials (25% of the PSUs); (iii) significant progress towards achieving $5 million in IGALMI revenues (15% of the PSUs); and (iv) making progress towards securing a partnership deal (10% of the PSUs). The Board decided to grant PSUs during 2024 in order to further align the interests of Dr. Mehta, Mr. Rodriquez and Mr. Steinhart with the strategic clinical and operational objectives of the Company.

Refer to the "Outstanding Equity Awards at Year End" table below for additional information regarding the equity awards granted to our NEOs during 2024.

2024 Annual Bonuses

We offer our NEOs the opportunity to earn discretionary annual cash bonuses to compensate them for attaining company and individual performance goals. Each NEO's target bonus opportunity is expressed as a percentage of annual base salary. Pursuant to the Fifth Amendment to the Credit Agreement, we are restricted from paying cash bonuses to our employees or executives during the fiscal years 2024 and 2025 without OFA's consent or increasing the cash compensation for fiscal year 2025 for certain senior officers of the Company from their compensation for fiscal year 2024.

The performance goals for annual bonuses are reviewed and approved annually by the compensation committee. For 2024, the annual bonus metrics established by the compensation committee were based on the achievement of certain company performance goals, as well as an assessment of individual performance. In early 2025 the Board determined that it would use its discretion to not award annual bonuses for 2024 performance to the NEOs.

Other Elements of Compensation

Our NEOs are eligible to participate in our employee benefit plans and programs, which generally include medical, dental and vision benefits, and life, short-term, and long-term disability insurance to the same extent as our other full-time employees generally, subject to the terms and eligibility requirements of those plans. During 2024, we reimbursed Dr. Mehta for his healthcare premium payments.

We maintain a 401(k) defined contribution plan (the "401(k) Plan"), for the benefit of our employees who satisfy certain eligibility requirements. Our NEOs are eligible to participate in the 401(k) Plan on the same terms as other full-time employees. In 2024, we matched employee contributions to the 401(k) Plan up to 50% of the first 5% of eligible compensation.

The amounts paid pursuant to these arrangements are set forth in the Summary Compensation Table in the column entitled "All Other Compensation."

In response to Item 402(x)(1) of Regulation S-K, the Company does not currently grant new awards of stock options, stock appreciation rights, or similar option-like instruments within four business days before or one business day after the release of a Form 10-Q, 10-K, or 8-K that discloses material nonpublic information (MNPI). Accordingly, the Company has no specific policy or practice on the timing of awards of such options in relation to the disclosure of MNPI by the Company.

Outstanding Equity Awards at Year End

The following table sets forth all outstanding equity awards held by each of the NEOs as of December 31, 2024.

Name	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units or Stock That Have Not Vested ($)(1)	Equity Incentive Plan Awards: Number of Unearned Shares, Units of Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)(1)
Vimal Mehta, Ph.D.	08/23/2017	18,376	—	6.56	08/23/2027	—	—	—	—
	05/23/2019	11,732	—	160.64	05/23/2029	—	—	—	—
	05/26/2020 (2)	15,625	—	735.84	05/26/2030	—	—	—	—
	03/25/2021 (2)	14,647	978	658.72	03/25/2031	—	—	—	—
	03/14/2022 (2)	7,170	3,268	244.96	03/14/2032	—	—	—	—
	03/14/2022 (4)	—	—	—	—	816	$ 4,882	—	—
	03/15/2023 (3)	4,588	5,913	313.60	03/14/2033	—	—	—	—
	03/15/2023 (5)	—	—	—	—	1,969	$ 11,779	—	—
	07/22/2024 (7)	—	6,250	19.20	07/22/2034	—	—	—	—
	07/22/2024 (6)	—	—	—	—	—	—	15,625	$ 93,475
Javier Rodriquez	02/22/2021 (2)	1,917	84	878.40	02/22/2031	—	—	—	—
	08/16/2021 (2)	523	103	381.44	08/16/2031	—	—	—	—
	03/14/2022 (2)	1,427	659	244.96	03/14/2032	—	—	—	—
	03/14/2022 (4)	—	—	—	—	163	$ 975	—	—
	03/15/2023 (3)	869	1,132	313.60	03/15/2033	—	—	—	—
	03/15/2023 (5)	—	—	—	—	317	$ 1,896	—	—
	07/22/2024 (7)	—	1,875	19.20	07/22/2034	—	—	—	—
	07/22/2024 (8)	—	—	—	—	625	$ 3,739	—	—
	07/22/2024 (6)	—	—	—	—	—	—	4,375	$ 26,173
Richard Steinhart	10/02/2017 (2)	5,010	—	88.80	10/02/2027	—	—	—	—
	03/12/2018 (2)	2,016	—	176.00	03/12/2028	—	—	—	—
	05/26/2020 (2)	3,438	—	735.84	05/25/2030	—	—	—	—
	03/25/2021 (2)	1,172	79	658.72	03/25/2031	—	—	—	—
	03/14/2022 (3)	1,430	655	244.96	03/14/2032	—	—	—	—
	03/14/2022 (4)	—	—	—	—	163	$ 975	—	—
	03/15/2023 (3)	869	1,132	313.60	03/15/2033	—	—	—	—
	03/15/2023 (5)	—	—	—	—	317	$ 1,896	—	—
	07/22/2024 (7)	—	1,875	19.20	07/22/2034	—	—	—	—
	07/22/2024 (8)	—	—	—	—	625	$ 3,739	—	—
	07/22/2024 (6)	—	—	—	—	—	—	4,375	$ 26,173

(1) The amounts shown are based on the closing price of our common stock on December 31, 2024 of $5.9840 per share. For the restricted stock units in Employee Holdings, the amount shown is based on the fair market value of such awards as of December 31, 2024.

(2) The unvested portion of the option vests in substantially equal monthly installments until the fourth anniversary of the vesting commencement date.

(3) The option vests as to 25% of the shares on the first anniversary of the vesting commencement date and in substantially equal monthly installments thereafter until the fourth anniversary of the vesting commencement date.

(4) The RSUs vest in substantially equal quarterly installments until the fourth anniversary of the vesting commencement date

(5) The RSUs vest as to 25% of the shares on the first anniversary of the vesting commencement date and in substantially equal quarterly installments thereafter until the fourth anniversary of the vesting commencement date.

(6) The PSUs are eligible to vest on the first anniversary of the vesting commencement date based on the Board's determination that certain Company performance metrics have been attained. See "*Equity Compensation*" above for a description of these metrics.

(7) The option vests as to 50% of the shares on each of the first and second anniversaries of the grant date.

(8) The RSUs vest on the first anniversary of the grant date.

Employment Arrangements - 2024

We have entered into employment agreements with each of our NEOs that set forth the terms and conditions of each executive's employment with us. All descriptions of the employment agreements herein describe the agreements in effect as of December 31, 2024, and do not reflect subsequent amendments.

Each employment agreement establishes an annual base salary and target bonus opportunity for each NEO. The amounts in effect during 2024 are described above under the headings "2024 Salaries" and "2024 Annual Bonuses." The NEOs are eligible to participate in our employee benefit plans and programs for which the NEO is eligible, subject to the terms and conditions of such plans and programs.

During 2024, in the event that an NEO was terminated by us without cause, or by the executive for good reason, subject to the NEO's timely execution and non-revocation of a release of claims in our favor, the executive would have been eligible to receive (i) a pro-rated portion of the executive's annual bonus for the year of termination; (ii) base salary continuation for 24 months for Dr. Mehta, 6 months for Mr. Rodriguez and Mr. Steinhart; and (iii) reimbursement for COBRA premium payments for the applicable severance period. In addition, Dr. Mehta would be entitled to vesting of 50% of any unvested equity awards held by him immediately prior to his termination. The Company must provide an NEO 30 days' notice in the event we terminate such NEO without cause.

The employment agreements also provide that, in the event an NEO's employment is terminated by us without cause or by the NEO for good reason, in either case, within 6 months prior to or 12 months after a change in control, then, subject to the NEO's timely execution and non-revocation of a release of claims in our favor, the NEO will be entitled to a lump sum payment equal to 6 months of base salary (or 24 months of base salary for Dr. Mehta), which payment is in addition to the severance payments and benefits described above.

The employment agreements generally define "cause" as, subject to certain notice and cure rights, the NEO's (i) material breach or material default of the employment agreement or any other agreement between us and the NEO, or repeated failure to follow the direction of the Company or our Board, as applicable; (ii) gross negligence, willful misfeasance or breach of fiduciary duty to us or our affiliates; (iii) commission of an act or omission involving fraud, embezzlement, misappropriation or dishonesty in connection with NEO's duties to us or our affiliates, or, for Mr. Rodriguez or Mr. Steinhart, that is otherwise likely to be materially injurious to the business or reputation of the Company or our affiliates; or (iv) conviction of, indictment for, or pleading guilty or nolo contendere to, any felony or other crime involving fraud or moral turpitude.

The employment agreements generally define "good reason" as, subject to certain notice and cure rights, the occurrence of any of the following (without the NEO's express written consent): (i) a significant reduction of the NEO's duties, position or responsibilities, or the removal of the NEO from such position, duties or responsibilities; (ii) for Dr. Mehta and Mr. Rodriguez only, the relocation of the NEO by more than 25 miles; or (iii) any action or inaction that constitutes a material breach by us or any of our successors of its obligations to the NEO under the employment agreement (or for Dr. Mehta, any other agreement between us and Dr. Mehta).

The employment agreements also contain covenants prohibiting the NEOs from competing with us or soliciting our suppliers, employees or customers during employment and for a period of one year following termination.

Non-Employee Director Compensation

The non-employee members of our Board are eligible to receive compensation for their service on our Board. Under our director compensation program, during 2024 each non-employee director was eligible to receive an option to purchase 1,875 shares of common stock upon such director's initial election or appointment to the Board. Additionally, each non-employee director who has been serving as a non-employee director for at least six months as of the date of any annual meeting of stockholders and will continue to serve as a non-employee director immediately following such meeting, was eligible to receive an option to purchase 1,062 shares of common stock on the date of such annual meeting. The options granted to our non-employee directors have an exercise price equal to the fair market value of our common stock on the date of grant and expire not later than ten years after the date of grant. The stock options granted upon a director's initial election or appointment vest in three substantially equal annual installments following the date of grant. The stock options granted annually to directors vest in a single installment on the earlier of the day before the next annual meeting or the first anniversary of the date of grant. In addition, all unvested stock options vest in full upon the occurrence of a change in control. For the appointment of David Mack in 2024, we provided a separate grant of RSUs and a separate cash arrangement in lieu of the stock option award and cash payments typically granted to new directors, as described below in the "Director Compensation Table".

In addition, our non-employee directors were eligible to receive cash retainers for service on our Board and committees of our Board during 2024 as set forth in the table below.

Position	Amount
Base Board Fee	$ 60,000
Chair of Board or Lead Independent Director	$ 35,000
Chair of Audit Committee	$ 20,000
Chair of Compensation Committee	$ 15,000
Chair of Nominating and Corporate Governance Committee	$ 10,000
Member of Audit Committee (non-Chair)	$ 10,000
Member of Compensation Committee (non-Chair)	$ 7,500
Member of Nominating and Corporate Governance Committee (non-Chair)	$ 5,000

Director fees under the program are payable in arrears in four equal quarterly installments not later than the fifteenth day following the final day of each calendar quarter, *provided* that the amount of each payment will be prorated for any portion of a quarter that a director is not serving on our board.

We also reimburse all of our non-employee directors for all reasonable and customary business expenses in accordance with company policy.

Director Compensation Table

The following table sets forth information for the year ended December 31, 2024 regarding the compensation awarded to, earned by or paid to our non-employee directors:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	Stock Awards ($)	Total ($)
Peter Mueller, Ph.D.[2]	$ 130,000	$ 20,410 [2]	$ —	$ 150,410
Sandeep Laumas, M.D.[3]	$ 92,500	$ 20,410 [3]	$ —	$ 112,910
Michal Votruba, M.D.[4]	$ 70,000	$ 20,410 [4]	$ —	$ 90,410
June Bray[5]	$ 65,000	$ 20,410 [5]	$ —	$ 85,410
Michael Miller[6]	$ 70,000	$ 20,410 [6]	$ —	$ 90,410
David Mack[7]	$ 30,000 [8]	$ — [7]	$ 185,619	$ 215,619

(1) The amounts reported represent the grant date fair value of stock options granted to our non-employee directors as computed in accordance with ASC 718. Note that the amounts reported in this column reflect the accounting cost for these stock options and do not correspond to the actual economic value that may be received by the recipients from the options. We provide information regarding the assumptions used to calculate the value of the option awards in Note 12 to our financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2024.

(2) As of December 31, 2024, Dr. Mueller held options to purchase an aggregate of 16,667 shares of our common stock, of which 15,604 shares of common stock were exercisable.

(3) As of December 31, 2024, Dr. Laumas held options to purchase an aggregate of 14,028 shares of our common stock, of which 12,965 shares of common stock were exercisable.

(4) As of December 31, 2024, Dr. Votruba held options to purchase an aggregate of 6,265 shares of our common stock, of which 5,202 shares of common stock were exercisable.

(5) As of December 31, 2024, Ms. Bray held options to purchase an aggregate of 5,013 shares of our common stock, of which 3,950 shares of common stock were exercisable.

(6) As of December 31, 2024, Mr. Miller held options to purchase an aggregate of 4,001 shares of our common stock, of which 2,938 shares of common stock were exercisable.

(7) As of December 31, 2024, Mr. Mack held 16,932 unvested restricted stock units.

(8) As of December 31, 2024, Mr. Mack earned $30,000 in board fees for services provided since joining the Board in November 2024.

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

The following table sets forth information relating to the beneficial ownership of our common stock as of March 21, 2025 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our directors;
- each of our named executive officers for 2024; and
- all of our current directors and executive officers as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, a person is deemed to be a "beneficial" owner of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. Except as indicated in the footnotes below, we believe, based on the information furnished to us, that the individuals and entities named in the table below have sole voting and investment power with respect to all shares of common stock beneficially owned by them, subject to any applicable community property laws.

The percentage of shares beneficially owned is computed on the basis of 5,468,038 shares of our common stock outstanding as of March 21, 2025. Shares of our common stock that a person has the right to acquire within 60 days of March 21, 2025 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o 555 Long Wharf Drive, New Haven, CT 06511.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Holders of more than 5%:		
BioXcel LLC[1]	480,343	8.78 %
Armistice Capital Master Fund Ltd.[2]	1,385,083	9.99 %
Named executive officers and directors:		
Vimal Mehta, Ph.D.[1][3]	573,619	10.3 %
Javier Rodriguez[4]	6,903	*
Richard Steinhart[5]	21,437	*
June Bray[6]	3,950	*
Sandeep Laumas, M.D.[7]	12,965	*
Michael Miller[8]	2,312	*
Peter Mueller, Ph.D.[9]	23,091	*
Michal Votruba, M.D.[10]	16,725	*
David Mack[11]	10,158	*
Rajiv Patni[12]	938	*
All executive officers and directors as a group (11 individuals)[13]	692,185	12.3 %

* Represents less than 1%.

(1) Based solely on a Schedule 13D filed with the SEC on June 6, 2024. BioXcel LLC and BioXcel Holdings, Inc. have shared voting power and shared dispositive power over 480,343 shares of our common stock. Dr. Mehta and affiliated trusts are significant stockholders of BioXcel Holdings, Inc. BioXcel LLC is majority owned and controlled by BioXcel Holdings, Inc. BioXcel LLC is a subsidiary of BioXcel Holdings, Inc. Mr. Mehta is an executive officer and the sole member of the board of directors of BioXcel Holdings, Inc. and an executive officer and one of two managers on the board of managers of BioXcel LLC and BioXcel Holdings, Inc. As such, each of Mr. Mehta and BioXcel Holdings, Inc. may be deemed to beneficially own the Common Stock held of record by BioXcel LLC. The address of BioXcel LLC and BioXcel Holdings, Inc. is 2614 Boston Post Road Suite 33B, Guilford, CT 06437.

(2) Based on information known to us, Armistice Capital Master Fund Ltd. owns warrants to purchase 1,385,083 shares of our common stock that are exercisable within 60 days of March 21, 2025. The warrants to purchase shares of common stock are directly held by Armistice Capital Master Fund Ltd., a Cayman Islands exempted company ("Master Fund"), and may be deemed to be beneficially owned by: (i) Armistice Capital, LLC ("Armistice Capital"), as the investment manager of Master Fund; and (ii) Steven Boyd, as the Managing Member of Armistice Capital. Armistice Capital has sole voting and dispositive control of the shares reported herein. The address for the stockholder is 510 Madison Avenue, 7th Floor, New York, New York 10022. Warrants held by Armistice Capital are subject to a beneficial ownership limitation of 4.99% or 9.99%, which such limitation restricts the stockholder from exercising that portion of the warrants, as applicable, that would result in the stockholder and its affiliates owning, after exercise, a number of shares of common stock in excess of the beneficial ownership limitation.

(3) Represents for Dr. Mehta: (i) 4,236 shares of common stock (of which 125 shares are owned jointly with Dr. Mehta's spouse); (ii) options to purchase 89,050 shares of our common stock that can be exercised within 60 days of March 21, 2025; and (iii) 480,343 shares of common stock held by BioXcel LLC as to which Dr. Mehta may be deemed to have beneficial ownership as described under footnote (1) above.

(4) Represents for Mr. Steinhart: (i) 1,373 shares of common stock and (ii) options to purchase 20,064 shares of our common stock that can be exercised within 60 days of March 21, 2025.

(5) Represents for Mr. Rodriguez: (i) 1,591 shares of common stock and (ii) options to purchase 5,312 shares of our common stock that can be exercised within 60 days of March 21, 2025.

(6) Represents for Ms. Bray: options to purchase 3,950 shares of our common stock that can be exercised within 60 days of March 21, 2025.

(7) Represents for Dr. Laumas: options to purchase 12,965 shares of our common stock that can be exercised within 60 days of March 21, 2025.

(8) Represents for Mr. Miller: options to purchase 2,312 shares of our common stock that can be exercised within 60 days of March 21, 2025.

(9) Represents for Dr. Mueller: (i) 7,487 shares of common stock held by Dr. Mueller (including shares of our common stock held by the Peter Mueller 2018 Irrevocable Family Trust, as to which Dr. Mueller serves as trustee); and (iii) options to purchase 15,604 shares of our common stock that can be exercised within 60 days of March 21, 2025.

(10) Represents for Dr. Votruba: 11,523 shares of our common stock held by RSJ Investments SICAV a.s. ("RSJ/Gradus") and over which Dr. Votruba, an asset manager at RSJ/Gradus, has voting and/or dispositive power. Also includes options to purchase 5,202 shares of our common stock that can be exercised within 60 days of March 21, 2025, which options Dr. Votruba was granted in respect of his service on our Board but as to which he assigned to RSJ/Gradus pursuant to the policies of RSJ/Gradus regarding stock ownership by employees.

(11) Represents for Mr. Mack: 3,386 restricted stock units that vest within 60 days of March 21, 2025.

(12) Represents for Mr. Patni: options to purchase 938 shares of our common stock that vest within 60 days of March 21, 2025.

(13) Includes options to purchase 173,611 shares of our common stock that can be exercised within 60 days of March 21, 2025 and 3,386 RSUs that vest within 60 days of March 21, 2025.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information with respect to the Company's equity compensation plans in effect as of December 31, 2024:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))[4] (c)
Equity compensation plans approved by security holders[1]	407,477 [2]	$ 265.36 [3]	117,044
Equity compensation plans not approved by security holders	—	—	—
Total	407,477	$ 265.36	117,044

(1) Consists of the BioXcel Therapeutics, Inc. 2017 Incentive Award Plan (the "2017 Plan"), the BioXcel Therapeutics, Inc. 2020 Incentive Award Plan (the "2020 Plan") and the BioXcel Therapeutics, Inc. 2020 Employee Stock Purchase Plan (the "2020 ESPP").

(2) Includes 119,781 outstanding options to purchase shares under the 2017 Plan, 69,506 performance-based units, 26,898 restricted stock units and 191,292 outstanding options to purchase shares under the 2020 Plan.

(3) As of December 31, 2024, the weighted-average exercise price of outstanding options under the 2017 Plan was $59.74 and the weighted-average exercise price of outstanding options under the 2020 Plan was $394.11. The weighted average exercise price of outstanding awards does not take into account the shares issuable upon vesting of outstanding performance-based units and restricted stock units which have no exercise price.

(4) Includes 41,748 shares available for future issuance under the 2020 Plan and 75,296 shares available for issuance under the 2020 ESPP. Following the effective date of the 2020 Plan, we ceased making grants under the 2017 Plan. To the extent outstanding awards under the 2017 Plan are forfeited or lapse unexercised, the shares of common stock subject to such awards will be available for issuance under the 2020 Plan. The 2020 Plan provides for an annual increase to the number of shares available for issuance thereunder on the first day of each calendar year beginning on January 1, 2021 and ending on and including January 1, 2030, by an amount equal to the lesser of (i) 4% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as determined by our board of directors (but no more than 625,000 shares may be issued upon the exercise of incentive stock options). The 2020 ESPP provides for an annual increase to the number of shares available for issuance thereunder on the first day of each calendar year beginning on January 1, 2021 and ending on and including January 1, 2030, by an amount equal to the lesser of (i) 1% of the aggregate number of shares of common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of common stock as is determined by our board of directors, provided that no more than 31,250 shares of our common stock may be issued under the component of the 2020 ESPP that is intended to qualified under Section 423 of the Code. As of the date of this proxy statement, we have not commenced offering periods under the 2020 ESPP.

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

Certain Relationships and Related Transactions

March 2024 Registered Direct Offering

On March 27, 2024, we completed a registered direct offering, which resulted in the issuance and sale of (i) 190,913 shares of our common stock, (ii) pre-funded warrants to purchase up to 347,814 shares of our common stock at an exercise price of $0.016 per share and (iii) accompanying warrants to purchase up to 538,728 shares of our common stock at an exercise price of $51.20 per share. The combined offering price of the common stock and accompanying warrants was $46.416 per share and share underlying each accompanying warrant, and the combined offering price of the Armistice pre-funded warrants and accompanying warrants was $46.40 per share underlying each pre-funded warrant and accompanying warrant. The Armistice pre-funded warrants and the accompanying warrants are exercisable at any time after the date of issuance, however, the accompanying warrants will expire on the fifth anniversary of the date of issuance. A holder of Armistice pre-funded warrants will not be entitled to exercise any portion of such Armistice pre-funded warrants which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our

securities beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Armistice Pre-Funded Warrants. A holder of Accompanying Warrants will not be entitled to exercise any portion of such Accompanying Warrants which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Accompanying Warrants. In each case, such percentages may be increased by a holder of Armistice Warrants to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to us. We received net proceeds of approximately $24.9 million from this offering, after deducting offering expenses. The following table sets forth the aggregate number of shares of our common stock and shares of common stock underlying the Armistice Warrants acquired in the offering by holders of more than 5% of our common stock, including entities that became holders of more than 5% of our common stock as a result of the registered direct offering. On November 21, 2024, the exercise price of warrants to purchase 538,728 shares of common stock issued in March 2024 Registered Direct Offering described here was reduced to $9.136 per share.

Participants	Shares of Common Stock	Shares Underlying Pre-Funded Warrants	Shares Underlying Accompanying Warrants	Aggregate Value
Holders of More than 5 %[1]				
Armistice Capital Master Fund Ltd..	190,913	347,814	538,728	$ 24,999,999.01

(1) Additional details regarding certain of these stockholders and their equity holdings are provided in this Proxy Statement under the caption "Stock Ownership - Security Ownership of Certain Beneficial Owners and Management."

November 2024 Offering

On November 25, 2024, we completed an offering, which resulted in the issuance and sale to Armistice of (i) 283,854 shares of our common stock, (ii) pre-funded warrants to purchase up to 562,500 shares of our common stock at an exercise price of $0.016 per share and (iii) accompanying warrants to purchase up to 846,355 shares of our common stock at an exercise price of $7.68 per share. The combined offering price of the common stock and accompanying warrants was $7.68 per share and share underlying each accompanying warrant, and the combined offering price of the Armistice pre-funded warrants and accompanying warrants was $7.664 per share underlying each pre-funded warrant and accompanying warrant. The Armistice pre-funded warrants and the accompanying warrants are exercisable at any time after the date of issuance, however, the accompanying warrants will expire on the fifth anniversary of the date of issuance. A holder of Armistice pre-funded warrants will not be entitled to exercise any portion of such Armistice pre-funded warrants which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 9.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Armistice pre-funded warrants. A holder of accompanying warrants will not be entitled to exercise any portion of such accompanying warrants which, upon giving effect to such exercise, would cause (i) the aggregate number of shares of our common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, or (ii) the combined voting power of our securities beneficially owned by the holder (together with its affiliates) to exceed 4.99% of the combined voting power of all of our securities then outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the accompanying warrants. In each case, such percentages may be increased by a holder of Armistice Warrants to any other percentage not in excess of 19.99% upon at least 61 days' prior notice from the holder to us.

BioXcel LLC

BioXcel LLC owned approximately 8.8% of the shares of our outstanding common stock as of March 21, 2025. BioXcel LLC is the successor in interest to BioXcel Corporation, our former parent. BioXcel LLC is a subsidiary of, and majority owned and controlled by BioXcel Holdings, Inc. Vimal Mehta and affiliated trusts are significant stockholders of BioXcel Holdings, Inc. Dr. Mehta is also an executive officer and the sole member of the board of managers of BioXcel Holdings, Inc. and an executive officer and one of two managers of BioXcel LLC and BioXcel Holdings, Inc.

Amended and Restated Asset Contribution Agreement with BioXcel LLC

We entered into an asset contribution agreement, effective June 30, 2017, with BioXcel LLC (formerly BioXcel Corporation), as amended and restated on November 7, 2017, pursuant to which BioXcel LLC contributed to us, and we acquired from BioXcel LLC, all of BioXcel LLC's rights, title and interest in and to BXCL501, BXCL701, BXCL502 and BXCL702 (collectively, the "Candidates") and all of the assets and liabilities associated with the Candidates, in consideration for (i) 592,500 shares of our common stock, (ii) $1 million upon completion of our initial public offering ("IPO"), (iii) $500,000 upon the later of the 12 month anniversary of our IPO and the first dosing of a patient in the bridging bioavailability/bioequivalence study for the BXCL501 program, (iv) $500,000 upon the later of the 12 month anniversary of our IPO and the first dosing of a patient in the Phase 2 Proof of Concept open label monotherapy or combination trial with Keytruda for the BXCL701 program and (v) a one-time payment of $5 million within 60 days after the achievement of $50 million in cumulative net sales of any product or combination of products resulting from the development and commercialization of any one of the Candidates or a product derived therefrom. There were no such payments during the years ended December 31, 2023 or 2024 pursuant to such provisions in the Contribution Agreement.

In addition, pursuant to the Contribution Agreement, BioXcel LLC granted us a first right to negotiate exclusive rights to any additional product candidates in the fields of neuroscience and immuno-oncology (the "Option Field") that BioXcel LLC may identify on its own, excluding the Candidates, and not in connection with BioXcel LLC's provision of services to us under the Services Agreement as defined and described below. This first right to negotiate an exclusivity period expired on March 12, 2023.

Amended and Restated Separation and Shared Services Agreement

We entered into a separation and shared services agreement, dated June 30, 2017, or the Effective Date, with BioXcel LLC (formerly BioXcel Corporation), as amended and restated thereafter, pursuant to which services provided by BioXcel LLC through its subsidiaries in India and the United States will continue indefinitely, as agreed upon by the parties. These services are primarily for drug discovery, chemical, manufacturing and controls cost and general and administrative support. Service charges recorded under this agreement were $1.3 million for each of the years ended December 31, 2024 and 2023.

Under the Services Agreement, the Company has an option, exercisable through December 31, 2024, to enter into a collaborative services agreement with BioXcel LLC pursuant to which BioXcel LLC shall perform product identification and related services for us utilizing EvolverAI. The Company agreed to pay BioXcel LLC $18,000 per month, prorated for any partial month, as applicable, for the period beginning March 13, 2023 and ending December 31, 2024 as consideration for the option. The parties are obligated to negotiate the collaborative services agreement in good faith and to incorporate reasonable market-based terms, including consideration for BioXcel LLC reflecting a low, single-digit royalty on net sales and reasonable development and commercialization milestone payments, *provided* that (i) development milestones shall not exceed $10 million in the aggregate and not be payable prior to proof of concept in humans and (ii) commercialization milestones shall be based on reaching annual net sales levels, be limited to 3% of the applicable net sales level, and not exceed $30 million in the aggregate.

InveniAI

On September 19, 2023, we, Krishnan Nandabalan, Ph.D., a former member of our Board, InveniAI and Invea Therapeutics, Inc., a wholly-owned subsidiary of BioXcel LLC ("Invea") and the other parties thereto entered into a non-compete agreement pursuant to which Dr. Nandabalan, InveniAI and Invea agreed not to compete with us and our controlled affiliates in the fields of neuroscience and immuno-oncology for a period of five years from September 19, 2023 and not to solicit employees of the Company or its controlled affiliates for a period of two years from September 19, 2023.

Director and Officer Indemnification and Insurance

We have agreed to indemnify each of our directors and executive officers against certain liabilities, costs and expenses, and have purchased directors' and officers' liability insurance.

Director Independence

Under our Corporate Governance Guidelines and Nasdaq rules, a director is independent if he or she does not have a material or other disqualifying relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities as a director. In addition, the director must meet the bright-line tests for independence set forth by the Nasdaq rules.

Our Board has undertaken a review of its composition, the composition of its committees and the independence of our directors and considered whether any director has a material relationship with us that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our Board of Directors has determined that none of Ms. Bray, Mr. Miller, Mr. Mack or Drs. Laumas, Mueller, Patni or Votruba, representing seven of our eight current directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors qualifies as "independent" as that term is defined under the Nasdaq rules. In making these determinations, our Board considered the relationships that each non-employee director has with us and all other facts and circumstances our Board deemed relevant in determining their independence, including the director's beneficial ownership of our common stock and the relationships of our non-employee directors with certain of our significant stockholders.

Item 14. Principal Accounting Fees and Services

The Audit Committee retained Ernst & Young LLP to audit the Company's consolidated financial statements for the years ended December 31, 2024 and December 31, 2023.

The table below sets forth the aggregate fees billed to us for services related to the fiscal year ended December 31, 2024 and 2023 by Ernst & Young LLP.

	Year Ended December 31,	
	2024	2023
Audit Fees[1]	$ 946,270	$ 903,500
Audit-Related Fees[2]	—	16,000
Tax Fees	—	—
All Other Fees	—	—
Total	$ 946,270	$ 919,500

(1) Audit fees consisted of audit services performed in connection with the audit of the Company's consolidated financial statements, the reviews of the Company's interim condensed consolidated financial statements, and related services that are normally provided in connection with registration statements. Included in the 2024 and 2023 audit fees are $155,000 and $105,000, respectively, billed in connection with our follow-on offerings. 2024 and 2023 audit fees also include fees related to the audit and review of the registration statements of the Company's subsidiary, OnkosXcel Therapeutics LLC, of $0 and $65,000, respectively.

(2) Audit-related fees consisted of out-of-pocket costs for the annual audit.

Pre-Approval Policies and Procedures

Consistent with SEC policies and guidelines regarding audit independence, the audit committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our independent registered public accounting firm on a case-by-case basis. Our audit committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. No non-audit services were performed by our independent registered public accounting firm during the years ended December 31, 2024 and 2023. Our audit committee pre-approves these services by category and service. Our audit committee has pre-approved all of the above-described services.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements:

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Amended and Restated Certificate of Incorporation	10-Q	001-38410	3.1	08/10/2021	
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-38410	3.1	06/12/2024	
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	8-K	001-38410	3.1	02/06/2025	
3.4	Amended and Restated Bylaws	8-K	001-38410	3.2	03/13/2018	
4.1	Description of the Registrant's Securities Registered Under Section 12 of the Exchange Act					*
4.2	Specimen Stock Certificate evidencing the shares of common stock	S-1/A	333-222990	4.2	02/26/2018	
4.3	Form of Amended and Restated Warrant Agreement, dated December 5, 2023	8-K	001-38410	4.1	12/06/2023	
4.4	Form of Warrant Agreement, dated December 5, 2023	8-K	001-38410	4.2	12/06/2023	
4.5	Form of Amended and Restated Warrant Agreement, dated November 25, 2024					*
4.6	Form of Pre-Funded Warrant, dated March 25, 2024	8-K	001-38410	4.1	03/25/2024	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
4.7	Form of Accompanying Warrant, dated March 25, 2024	8-K	001-38410	4.2	03/25/2024	
4.8	Form of Fifth Amendment Warrant, dated November 21, 2024	8-K	001-38410	4.1	11/21/2024	
4.9	Form of Pre-Funded Warrant, dated November 21, 2024	8-K	001-38410	4.1	11/25/2024	
4.10	Form of Warrant, dated November 21, 2024	8-K	001-38410	4.2	11/25/2024	
4.11	Form of Amended and Restated Fourth Amendment Warrant, dated November 25, 2024	S-3	333-284224	4.3	01/10/2025	
4.12	Second Amended and Restated Registration Rights Agreement, between the Company and the parties thereto, dated March 20, 2024.	10-K	001-38410	4.6	03/22/2024	
4.13	Form of Third Amended and Restated Registration Rights Agreement, between the Company and the parties thereto, dated November 25, 2024	8-K	001-38410	4.2	11/21/2024	
10.1+	Second Amended and Restated Separation and Shared Services Agreement, dated March 6, 2020, by and between BioXcel Corporation and BioXcel Therapeutics, Inc.	10-K	001-38410	10.2	03/09/2020	
10.2#	First Amendment to Second Amended and Restated Separation and Shared Services Agreement, dated March 3, 2021, by and between BioXcel LLC and BioXcel Therapeutics Inc.	10-K	001-38410	10.3	03/12/2021	
10.3	Second Amendment to Second Amended and Restated Separation and Shared Services Agreement, dated March 3, 2021, by and between BioXcel LLC and BioXcel Therapeutics Inc.	10-Q	001-38410	10.2	05/09/2022	
10.4#	Amended and Restated Asset Contribution Agreement, effective November 7, 2017, by and between BioXcel LLC and BioXcel Therapeutics, Inc.	S-1/A	333-222990	10.2	02/12/2018	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.5	Lease Agreement, dated as of August 20, 2018, by and between Fusco Harbour Associates, LLC, as Landlord, and BioXcel Therapeutics, Inc., as Tenant	8-K	001-38410	10.1	08/23/2018	
10.6	First Amendment, dated August 19, 2020, to Lease Agreement, dated as of August 20, 2018, by and between Fusco Harbour Associates, LLC, as Landlord, and BioXcel Therapeutics, Inc., as Tenant	10-Q	001-38410	10.1	11/12/2020	
10.7@	2017 Equity Incentive Plan	S-1/A	333-222990	10.3	02/12/2018	
10.8@	Form of Incentive Stock Option Agreement under the 2017 Equity Incentive Plan	S-1/A	333-222990	10.4	02/12/2018	
10.9@	Form of Non-Statutory Stock Option Agreement under the 2017 Equity Incentive Plan	S-1/A	333-222990	10.5	02/12/2018	
10.10@	BioXcel Therapeutics, Inc. 2020 Incentive Award Plan and forms of award agreements thereunder	10-Q	001-38410	10.1	08/14/2020	
10.11@	BioXcel Therapeutics, Inc. 2020 Employee Stock Purchase Plan	10-Q	001-38410	10.2	08/14/2020	
10.12@	Form of Indemnification Agreement with directors and executive officers	S-1/A	333-222990	10.6	02/12/2018	
10.13@	Employment Agreement, dated March 7, 2018 by and between BioXcel Therapeutics, Inc. and Vimal Mehta	8-K	001-38410	10.1	03/13/2018	
10.13.1@	Amendment to Employment Agreement, dated January 7, 2025 by and between BioXcel Therapeutics, Inc. and Vimal Mehta	8-K	001-38410	10.1	01/08/2025	
10.14@	Employment Agreement, dated February 12, 2018, by and between BioXcel Therapeutics, Inc. and Frank Yocca	S-1/A	333-222990	10.11	02/12/2018	
10.14.1@	Amendment to Employment Agreement, dated January 7, 2025 by and between BioXcel Therapeutics, Inc. and Frank Yocca	8-K	001-38410	10.3	01/08/2025	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.15@	Employment Agreement, effective October 2, 2017, by and between BioXcel Therapeutics, Inc. and Richard Steinhart	S-1/A	333-222990	10.12	02/12/2018	
10.15.1@	Amendment to Employment Agreement, dated January 7, 2025 by and between BioXcel Therapeutics, Inc. and Richard Steinhart	8-K	001-38410	10.2	01/08/2025	
10.16@	Employment Agreement, dated June 1, 2018, by and between BioXcel Therapeutics, Inc. and Dr. Vincent O'Neill, M.D.	8-K	001-38410	10.1	06/07/2018	
10.17@	Employment Agreement between Javier Rodriguez and BioXcel Therapeutics, Inc., dated February 15, 2021.	10-K	001-38410	10.19	03/12/2021	
10.18@	Separation Agreement between Matthew Wiley and BioXcel Therapeutics, Inc., dated October 3, 2024.	8-K	001-38410	10.1	10/09/2024	
10.18.1@	Consulting Agreement between Matthew Wiley and BioXcel Therapeutics, Inc. dated October 8, 2024	10-Q	001-38410	10.2	10/09/2024	
10.19@	Employment Agreement BioXcel Therapeutics, Inc. and Vincent O'Neill, M.D. dated July 1, 2022	10-Q	001-38410	10.2	05/08/2023	
10.20@	Non-Employee Director Compensation Program	10-Q	001-38410	10.4	08/11/2022	
10.21	BioXcel Trademark License Agreement, between the Company and BioXcel LLC	10-Q	001-38410	10.1	05/09/2022	
10.22+&	Credit Agreement and Guaranty, by and among BioXcel Therapeutic, Inc., Oaktree Fund Administration, LLC, the Subsidiary Guarantors from time to time party thereto and the Lenders from time to time party thereto, dated April 19, 2022	10-Q	001-38410	10.1	08/11/2022	
10.22.1+&	Waiver and First Amendment to Credit Agreement and Guaranty, by and between the Company, the lenders party thereto and Oaktree Fund Administration LLC dated November 13, 2023.	10-Q	001-38410	10.2	11/14/2023	
10.22.2&	Second Amendment to Credit Agreement and Guaranty and Termination of Revenue Interest Financing Agreement dated	8-K	001-38410	10.1	02/08/2024	

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
	December 5, 2023, to the Credit Agreement and Guaranty, dated April 19, 2022, by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto, and Oaktree Fund Administration LLC, as administrative agent (as amended)					
10.22.3&	Third Amendment to Credit Agreement and Guaranty dated February 12, 2024, to the Credit Agreement and Guaranty, dated April 19, 2022, by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto, and Oaktree Fund Administration LLC, as administrative agent (as amended)	8-K	001-38410	10.1	02/12/2024	
10.22.4	Fourth Amendment to Credit Agreement and Guaranty, dated March 20, 2024, to the Credit Agreement and Guaranty, dated April 19, 2022, by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto, and Oaktree Fund Administration LLC, as administrative agent (as amended)	10-K	001-38410	10.22.4	03/22/2024	
10.22.5+&	Fifth Amendment to Credit Agreement and Guaranty, dated November 21, 2024, to the Credit Agreement and Guaranty, dated April 19, 2022, by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto, and Oaktree Fund Administration LLC, as administrative agent (as amended)	8-K	001-38410	10.1	11/21/2024	
10.22.6	Sixth Amendment to Credit Agreement and Guaranty, dated March 4, 2025, to the Credit Agreement and Guaranty, dated April 19, 2022, by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto, and Oaktree Fund Administration LLC, as administrative agent (as amended)					*

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.23+&	Commercial Supply Agreement, between ARx, LLC and BioXcel Therapeutics, Inc., dated April 1, 2022	10-Q	001-38410	10.3	08/11/2022	
10.23.1+&	Amendment No. 1 to Commercial Supply Agreement, between Arx, LLC and BioXcel Therapeutics, Inc. dated July 11, 2024	10-Q	001-38410	10.1	08/06/2024	
10.24@	OnkosXcel Therapeutics, LLC and OnkosXcel Employee Holdings, LLC Management Incentive Plan	8-K	001-38410	10.1	08/19/2022	
10.25@	Form of Profits Interest Award Agreement under the Management Incentive Plan	8-K	001-38410	10.2	08/19/2022	
10.26@	Form of RSU Agreement pursuant to the OnkosXcel Therapeutics, LLC and OnkosXcel Employee Holdings, LLC Management Incentive Plan.	10-Q	001-38410	10.3	05/08/2023	
10.27+	Non-Compete Agreement, by and among the Company, Dr. Krishnan Nandabalan, InveniAI LLC, Invea Therapeutics, Inc. and the other parties thereto, dated September 19, 2023.	8-K	001-38410	10.1	09/25/2023	
19.1	Insider Trading Policy					*
21.1	Subsidiaries of BioXcel Therapeutics, Inc.					*
23.1	Consent of Ernst & Young LLP					*
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.					*
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.					*
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.					**

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
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.					**
97.1	Policy for Recovery of Erroneously Awarded Compensation	10-K	001-38410	97.1	03/22/2024	
101.INS	Inline eXtensible Business Reporting Language (XBRL) Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

@ Indicates a management contract or any compensatory plan, contract or arrangement.
+ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.
# Confidential treatment has been granted for portions omitted from this exhibit and those portions have been separately filed with the Securities and Exchange Commission.
& Annexes, schedules, and certain exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted annex, schedule or exhibit to the SEC upon request.
* Filed herewith.
** Furnished herewith.

Item 16. Form 10-K Summary

None

SIGNATURES

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

BioXcel Therapeutics, Inc.

Dated: March 28, 2025

By:
/s/ Vimal Mehta
Vimal Mehta, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Dated: March 28, 2025

By:
/s/ Richard Steinhart
Richard Steinhart
Chief Financial Officer
(Principal Financial Officer)

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

Signature	Title	Date
/s/ Vimal Mehta Vimal Mehta, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 28, 2025
/s/ Richard Steinhart Richard Steinhart	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 28, 2025
/s/ Peter Mueller Peter Mueller, Ph.D.	Chairman of the Board of Directors	March 28, 2025
/s/ June Bray June Bray	Director	March 28, 2025
/s/ Sandeep Laumas Sandeep Laumas, M.D.	Director	March 28, 2025
/s/ Michael Miller Michael Miller	Director	March 28, 2025
/s/ Michal Votruba Michal Votruba	Director	March 28, 2025
/s/ David Mack David Mack	Director	March 28, 2025
/s/ Rajiv Patni Rajiv Patni	Director	March 28, 2025

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of BioXcel Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BioXcel Therapeutics, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, changes in stockholders' (deficit) equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations, has used significant cash in operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the Audit Committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgment. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosure to which it relates.

Clinical trial expense and related accrued clinical trial expenses

Description of the Matter

As discussed in Note 3 to the consolidated financial statements, at the end of the reporting period, the Company estimates the progress toward completion of the research or development objectives, and depending on the amount and timing of payments to the service providers may record net prepaid or accrued expense for associated research and development costs. As of December 31, 2024, research and development expenses and accrued research and development expenses includes clinical trial expenses and related accrued clinical trial expenses.

Auditing the Company's clinical trial expenses and related accrued clinical trial expenses was complex because the evidence is accumulated from multiple third-party service providers and in certain circumstances, the nature and amount of services that have been rendered during the reporting period does not correspond to the timing and pattern of vendor invoicing.

How We Addressed the Matter in Our Audit

To test the clinical trial expenses and accrued clinical trial expenses, our audit procedures included, among others, evaluating the significant assumptions used by management to estimate the clinical trial expenses and testing the accuracy and completeness of the underlying data. To test the significant assumptions, we inspected the Company's contracts with third-party service providers, corroborated the progress of clinical trials and other research and development projects with the Company's internal personnel that oversee these activities, and obtained information directly from third-party service providers which included the third parties' estimates of clinical trial costs incurred to date. We also examined invoices received from vendors and cash disbursements made to third-party service providers subsequent to December 31, 2024 to assess the completeness of the recorded accruals.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

Stamford, Connecticut
March 28, 2025

BIOXCEL THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(amounts in thousands, except per share amounts)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 29,854	$ 65,221
Accounts receivable, net	131	71
Inventory	679	1,991
Prepaid expenses	5,290	2,782
Other current assets	1,440	2,078
Total current assets	37,394	72,143
Property and equipment, net	475	784
Operating lease right-of-use assets	382	688
Other assets	87	87
Total assets	$ 38,338	$ 73,702
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities		
Accounts payable	$ 15,990	$ 13,654
Accrued expenses	5,762	12,424
Due to related parties	107	107
Accrued interest	—	736
Other current liabilities	374	346
Total current liabilities	22,233	27,267
Long-term portion of operating lease liabilities	65	440
Derivative liabilities	6,633	1,905
Long-term debt	102,508	100,598
Total liabilities	131,439	130,210
Commitments and contingencies (Note 18)		
Stockholders' (deficit) equity		
Preferred stock, $0.001 par value, 10,000 shares authorized; no shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000 and 100,000 shares authorized as of December 31, 2024 and December 31, 2023, respectively; 3,102 and 1,871 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	49	30
Additional paid-in-capital	557,047	534,060
Accumulated deficit	(650,197)	(590,598)
Total stockholders' (deficit) equity	(93,101)	(56,508)
Total liabilities and stockholders' (deficit) equity	$ 38,338	$ 73,702

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

BIOXCEL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(amounts in thousands, except per share amounts)

	Year ended December 31,	
	2024	**2023**
Revenues		
Product revenue, net	$ 2,266	$ 1,380
Operating expenses		
Cost of goods sold	2,143	1,260
Research and development	30,435	84,326
Selling, general and administrative	34,492	83,413
Restructuring costs	2,441	4,163
Total operating expenses	69,511	173,162
Loss from operations	(67,245)	(171,782)
Other (income) expense		
Interest expense	15,129	13,314
Interest income	(2,602)	(5,649)
Other (income) expense, net	(20,173)	(394)
Net loss	$ (59,599)	$ (179,053)
Basic and diluted net loss per share attributable to common stockholders	$ (23.51)	$ (98.33)
Weighted average shares outstanding - basic and diluted	2,535	1,821

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

BIOXCEL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' (DEFICIT) EQUITY

(amounts in thousands)

	Common Stock		Additional Paid in	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance as of January 1, 2023	**1,759**	**$ 28**	**$ 488,292**	**$ (411,545)**	**$ 76,775**
Issuance of common stock, net of offering costs	88	2	26,219	—	26,221
Stock-based compensation	—	—	18,614	—	18,614
Exercise of stock options	20	—	508	—	508
Repricing of stock purchase warrants	—	—	254	—	254
Issuance of stock purchase warrants	—	—	200	—	200
Vesting of restricted stock units, net of employee tax obligations	4	—	(27)	—	(27)
Net loss	—	—	—	(179,053)	(179,053)
Balance as of December 31, 2023	**1,871**	**$ 30**	**$ 534,060**	**$ (590,598)**	**$ (56,508)**
Issuance of common stock, net of offering costs	1,209	19	9,907	—	9,926
Stock-based compensation	—	—	6,156	—	6,156
Issuance of stock purchase warrants	—	—	2,540	—	2,540
Repricing of stock purchase warrants	—	—	59	—	59
Issuance of pre-funded stock purchase warrants	—	—	4,379		4,379
Vesting of restricted stock units, net of employee tax obligations	22	—	(54)	—	(54)
Net loss	—	—	—	(59,599)	(59,599)
Balance as of December 31, 2024	**3,102**	**$ 49**	**$ 557,047**	**$ (650,197)**	**$ (93,101)**

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

BIOXCEL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)

	Year ended December 31,	
	2024	**2023**
OPERATING CASH FLOW ACTIVITIES:		
Net loss	$ (59,599)	$ (179,053)
Reconciliation of net loss to net cash used in operating activities		
Depreciation	309	318
Accretion of debt discount and amortization of financing costs	467	1,373
Change in fair value of derivative liabilities	(20,180)	(438)
Stock-based compensation expense	6,156	18,614
Payable-in-kind interest on Credit Agreement	6,543	1,872
Loss on disposal of equipment	—	2
Operating lease right-of-use assets	306	288
Changes in operating assets and liabilities		
Accounts receivable	(60)	177
Inventory	1,312	(6)
Prepaid expenses, other current assets and other assets	(1,872)	2,888
Accounts payable, accrued expenses, due to related parties, and other current liabilities	(4,327)	(3,219)
Accrued interest	(736)	2,497
Operating lease liabilities	(346)	(319)
Net cash used in operating activities	(72,027)	(155,006)
INVESTING CASH FLOW ACTIVITIES:		
Purchases of equipment and leasehold improvements	—	(20)
Net cash from investing activities	—	(20)
FINANCING CASH FLOW ACTIVITIES:		
Proceeds from issuance of common stock and warrants	39,688	27,032
Debt Issuance Costs	—	(180)
Payment of principal of Long-term debt	(2,500)	—
Offering costs for common stock and warrants issuance	(474)	(811)
Payment of employee tax obligations related to vesting restricted stock units	(54)	(27)
Exercise of stock options	—	508
Net cash provided by financing activities	36,660	26,522
Net decrease in cash and cash equivalents	$ (35,367)	$ (128,504)
Cash and cash equivalents, beginning of the period	65,221	193,725
Cash and cash equivalents, end of the period	$ 29,854	$ 65,221
Supplemental cash flow information:		
Issuance of stock purchase warrants	$ 2,540	$ 200
Repricing of stock purchase warrants	$ 59	$ 254
Interest paid	$ 7,968	$ 7,551
Conversion of accrued interest to long-term debt	$ —	$ 767

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

BIOXCEL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(amounts in thousands, except per share amounts and where otherwise noted)

Note 1. Nature of the Business

BioXcel Therapeutics, Inc. ("BTI" or the "Company") is a biopharmaceutical company utilizing artificial intelligence ("AI") approaches to develop transformative medicines in neuroscience and immuno-oncology. The Company is focused on utilizing cutting-edge technology and innovative research to develop high-value therapeutics aimed at transforming patients' lives. BTI employs a unique AI platform to reduce therapeutic development costs and potentially accelerate timelines. The Company's approach leverages existing approved drugs and/or clinically evaluated product candidates together with big data and proprietary machine learning algorithms to identify new therapeutic indices. BTI management believes this differentiated approach has the potential to reduce the expense and time associated with drug development in diseases with substantial unmet medical needs.

As used in these consolidated financial statements, unless otherwise specified or the context otherwise requires, the terms "BioXcel LLC" refers to the Company's former parent and current significant stockholder, BioXcel LLC and, its predecessor, BioXcel Corporation. "OnkosXcel" refers to BTI's wholly owned subsidiary for its advanced immuno-oncology assets, OnkosXcel Therapeutics, LLC.

On April 6, 2022, BTI announced that the United States ("U.S.") Food and Drug Administration ("FDA") approved IGALMI® (dexmedetomidine or "Dex") sublingual film for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. IGALMI® is approved to be self-administrated by patients under the supervision of a health care provider. On July 6, 2022, BTI announced that IGALMI®, was commercially available in doses of 120 and 180 micrograms.

The Company's most advanced clinical development program is BXCL501. In indications other than those approved by the FDA as IGALMI®, BXCL501 is an investigational proprietary, orally dissolving, film formulation of Dex for the treatment of agitation associated with psychiatric and neurological disorders.

The Company's advanced immuno-oncology asset, BXCL701, is an investigational, orally administered systemic innate immune activator for the treatment of a rare form of prostate cancer and advanced solid tumors that are refractory or treatment naïve to checkpoint inhibitors.

BTI was incorporated under the laws of the State of Delaware on March 29, 2017. The Company's principal office is in New Haven, Connecticut.

Note 2. Basis of Presentation

The accompanying consolidated financial statements include those of the Company and its subsidiaries after elimination of all intercompany accounts and transactions and have been prepared in conformity with United States ("U.S.") Generally Accepted Accounting Principles ("GAAP").

As of December 31, 2024, the Company had cash and cash equivalents of $29,854 and an accumulated deficit of $650,197. BTI has incurred substantial net losses and negative cash flows from operating activities in nearly every fiscal period since inception and expects this trend to continue for the foreseeable future. The Company recognized net losses of $59,599 and $179,053 for the years ended December 31, 2024 and 2023, respectively, and had net cash used in operating activities of $72,027 and $155,006 for the years ended December 31, 2024 and 2023, respectively.

Under ASC Topic 205-40, Presentation of Financial Statements - Going Concern, management is required at each reporting period to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

The Company's history of significant losses, its negative cash flows from operations, potential near-term increased covenant-driven amortization payments under its Credit Agreement, its limited liquidity resources currently on hand, and its dependence on its ability to obtain additional financing to fund its operations after the current resources are exhausted, about which there can be no certainty, have resulted in management's assessment that there is substantial doubt about the Company's ability to continue as a going concern for a period of at least 12 months from the issuance date of the financial statements included in this Annual Report on Form 10-K.

This going concern evaluation takes into consideration the potential mitigating effect of management's Reprioritization (as defined in Note 4, Restructuring). When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates the substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (i) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued and (ii) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans need to be approved by the Company's Board of Directors. The Company's Reprioritization was approved by the Board of Directors on August 8, 2023; however, such plans, including the additional restructuring actions taken in the second and third quarters of 2024, will not mitigate the entity's ability to continue as a going concern within one year after the date that the financial statements are issued.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business and does not include any adjustments that may result from the outcome of this uncertainty. The going concern analysis does not consider possible future amendments to or restructuring of the Credit Agreement (as defined in Note 9, Debt and Credit Facilities) or other potential sources of debt or equity capital.

Successful completion of the Company's development programs and, ultimately, the attainment of profitable operations are dependent upon future events, including obtaining adequate financing to support the Company's cost structure and operating plan. Management's plans to improve the Company's liquidity and reduce its operating expenses and capital requirements include, among other things, pursuing one or more of the following steps to raise additional capital, none of which can be guaranteed or are entirely within the Company's control:

- raise funding through the sale of the Company's equity securities;
- raise funding through third-party investments in or other strategic options for OnkosXcel;
- raise funding through debt financing and/or restructuring of its existing OFA Facilities;
- establish collaborations with potential partners to advance the Company's product pipeline;
- establish collaborations with potential marketing partners;
- reduce overhead and headcount to focus on core priorities; and/or
- any combination of the foregoing.

If the Company is unable to raise capital when needed or on acceptable terms, or if it is unable to procure collaboration arrangements to advance its programs, the Company would be forced to discontinue some of its operations or develop and implement a plan, beyond its Reprioritization initiatives, to further extend payables, reduce overhead, scale back or cease some or all of its revised operating plan until sufficient additional capital is raised to support further operations.

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect amounts reported in the consolidated financial statements and notes thereto. Estimates are used in the following areas, among others: revenue recognition, inventory valuation, derivative liabilities, stock-based compensation expense, accrued expenses and income taxes. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates.

Reverse Stock Split

On February 10, 2025, the Company completed a 1-for-16 reverse stock split of its issued and outstanding common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, each 16 shares of common stock issued and outstanding immediately prior to February 10, 2025 were automatically converted into one of a share of common stock. The Reverse Stock Split affected all common stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity, except to the extent that the Reverse Stock Split would result in a stockholder owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive a fractional share instead were entitled to receive cash in lieu of such fractional share.

The Reverse Stock Split did not change the par value of the common stock or the authorized number of shares of common stock.

All common share and per-share amounts in this Form 10-K have been retroactively restated to reflect the effect of the Reverse Stock Split.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2024 and 2023, cash equivalents were comprised primarily of money market funds. Cash and cash equivalents held at financial institutions may at times exceed federally insured amounts. BTI management believes it mitigates such risk by investing in or through major financial institutions.

Accounts Receivable, Net

Accounts receivable arise from sales of IGALMI® and represent amounts due from distributors. Payment terms generally range from 30 to 75 days from the date of the sale transaction, and accordingly, do not involve a significant financing component. Receivables from product sales are recorded net of allowances which generally include distribution fees, prompt payment discounts, chargebacks, and credit losses. Allowances for distribution fees, prompt payment discounts and chargebacks are based on contractual terms. The Company estimated the current expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about collectability, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. Based on its assessment, as of December 31, 2024, the Company determined that an allowance for credit losses was not required.

Concentrations of Credit Risk

The Company sells IGALMI® through a drop-ship program under which orders from hospitals and similar health care institutions are processed through wholesalers, but shipments of the product are sent directly to the individual hospitals and similar health care institutions. BTI also contracts directly with intermediaries such as group purchasing organizations ("GPOs"). All trade accounts receivables are due from the distributor that fulfills orders on behalf of the Company. For the years ended December 31, 2024 and 2023, one customer accounted for approximately 32% and 39% of the Company's net product revenue, respectively.

Inventory

Inventory is stated at the lower of cost or net realizable value. Cost of inventory is determined on a first-in, first-out basis.

BTI capitalizes inventory costs associated with the Company's products prior to regulatory approval, when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development expense in the Consolidated Statements of Operations.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period and writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, will be recorded within Cost of goods sold in the Consolidated Statements of Operations. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected, write-downs of inventory may be required.

Deferred Initial Public Offering Costs

Deferred initial public offering costs of $2,570, consisted of legal, accounting, and other costs that were directly related to the Company's proposed initial public offering of OnkosXcel. These costs were charged to the Consolidated Statements of Operations during the year ended December 31, 2023 as the initial public offering was delayed for an extended period of time. The costs were recorded as Selling, general and administrative expenses.

Property and Equipment

Property and equipment are recorded at cost and depreciated over the shorter of their remaining lease term or their estimated useful life on a straight-line basis as follows:

Equipment	3-5 years
Furniture	7 years
Leasehold improvements	Lesser of life of improvement or lease term

Expenditures for maintenance and repairs which do not improve or extend the useful lives of the respective assets are expensed as incurred. When assets are sold or retired, the related cost and accumulated depreciation are removed from their respective accounts and any resulting gain or loss is included within Other (income) expense, net in the Consolidated Statements of Operations.

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 undiscounted future net cash flows expected to be generated from its use and disposition. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. Assets to be disposed of are reported at the lower of the carrying amount or the fair value less costs to sell.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities, and the long-term portion of operating lease liabilities in the Consolidated Balance Sheets.

ROU assets represent BTI'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 lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses the implicit rate when readily determinable. As BTI's leases do not provide an implicit rate, it used an incremental

borrowing rate based on the information available at commencement date in determining the present value of lease payments. The operating lease ROU asset also includes any prepaid lease payments made and is reduced by lease incentives. The Company's leases may include options to extend the lease; such options are included in determining the lease term when it is reasonably certain that BTI will exercise that option. Lease expense is recognized on a straight-line basis over the lease term.

Debt and Detachable Warrants

Detachable warrants are evaluated for classification as either equity instruments, derivative liabilities, or liabilities depending on the specific terms of the warrant agreement. In circumstances in which debt is issued with equity-classified warrants, the proceeds from the issuance of debt are first allocated to the debt and then the warrants at their estimated fair values. The portion of the proceeds allocated to the warrants are accounted for as paid-in capital and a debt discount. The remaining proceeds, as further reduced by discounts created by the bifurcation of any embedded derivatives, are allocated to the debt. Detachable warrants classified as derivative liabilities are accounted for as indicated under "*Derivative Assets and Liabilities*" section of this Note and as a debt discount. The Company accounts for debt as liabilities measured at amortized cost and amortizes the resulting debt discount from the allocation of proceeds to interest expense using the effective interest method over the expected term of the debt instrument. The Company considers whether there are any embedded features in debt instruments that require bifurcation and separately accounts for them as derivative financial instruments.

The Company entered into financing arrangements, the terms of which involve significant assumptions and estimates, including future net product sales, in determining interest expense, amortization period of the debt discount, as well as the classification between current and long-term portions. In estimating future net product sales, the Company assesses prevailing market conditions using various external market data against the Company's anticipated sales and planned commercial activities. Consequently, the Company imputes interest on the carrying value of the debt and records interest expense using an imputed effective interest rate. The Company reassesses the expected payments during each reporting period and accounts for any changes through an adjustment to the effective interest rate on a prospective basis, with a corresponding impact to the classification of the Company's current and long-term portions of the debt.

Derivative Assets and Liabilities

Derivative assets and liabilities are recorded on the Company`s Consolidated Balance Sheets at their fair value on the date of issuance and are revalued on each balance sheet date until such instruments are settled or expire, with changes in the fair value between reporting periods recorded as other income or expense within Other (income) expense, net in the Consolidated Statements of Operations.

The Company does not use derivative instruments for speculative purposes or to hedge exposures to cash-flow or market risks. Certain financing facilities entered into by the Company include freestanding financial instruments and/or embedded features that require separate accounting as derivative assets and/or liabilities.

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.

Revenue Recognition

The Company's revenues consist of product sales of IGALMI®.

BTI recognizes revenue when its customers obtain control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition, BTI management performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations. The exercise of a material right may be accounted for as a contract modification or as a continuation of the contract for accounting purposes.

The Company assesses whether the goods or services promised within each contract are distinct to identify those that are performance obligations. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such goods and services are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the Company's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract.

The Company allocates the transaction price (the amount of consideration it expects to be entitled to from a customer in exchange for the promised goods or services) to each performance obligation and recognizes the associated revenue when (or as) each performance obligation is satisfied. The Company's estimate of the transaction price for each contract includes all variable consideration to which the Company expects to be entitled.

BTI distributes IGALMI® in the U.S. through arrangements with a distributor, wholesalers, and GPOs. The distributor and wholesalers help process and fulfill orders from hospitals on the Company's behalf. The Company believes the hospitals are its customers.

The Company recognizes product revenues, net of consideration payable to customers, as well as variable consideration related to certain allowances and accruals that are determined using either the expected value or most likely amount method, depending on the type of the variable consideration, in its consolidated financial statements at the point in time when control transfers to the customer, which is typically when the product has been delivered to the customer's location. The amount included in the transaction price is constrained to the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. The Company's only performance obligation identified for IGALMI® is to deliver the quantity of product ordered to the location specified by the customer's order. The Company records shipping and handling costs associated with delivery of product to its customers within Selling, general and administrative expenses on its Consolidated Statements of Operations. Under the Company's current product sales arrangements, BTI does not have contract assets (unbilled receivables), as it generally invoices its customer at the time of revenue recognition.

BTI sells IGALMI® at wholesale acquisition cost, less any agreed upon discounts and calculates product revenue net of variable consideration and consideration payable to third parties associated with distribution of product. The Company records reserves, based on contractual terms, for the following components of consideration related to product sold during the reporting period. Calculating these amounts involves estimates and judgments, and the Company reviews these estimates quarterly and records any material adjustments in the period they are identified, which affects net product revenue and earnings in the period such variances occur.

Trade Discounts and Allowances

The Company provides the distributor and wholesalers with discounts for prompt payment and pays fees to the distributor, wholesalers and GPOs related to distribution of the product. BTI expects the relevant third parties to earn these discounts and fees, and therefore it deducts such amounts from gross product revenue and accounts receivable at the time it recognizes the related revenue.

Government Rebates

IGALMI® is eligible for purchase by, or qualifies for reimbursement from, Medicaid and other U.S. government programs that are eligible for rebates on the price they pay for the product. To determine the appropriate amount to reserve for these rebates, BTI applies the applicable government discount to these sales, and estimates the portion of total rebates that it anticipates will be claimed. The Company deducts certain government rebates from gross product

revenue and accounts receivable at the time it recognizes the related revenue; other government rebates are recognized as an accrued liability at the time BTI recognizes the related revenue.

Chargebacks

BTI provides product discounts to hospitals associated with certain GPOs. The Company estimates the chargebacks that it expects to be obligated to provide based upon the terms of the applicable arrangements. BTI deducts such amounts from gross product revenue and accounts receivable at the time it recognizes the related revenue.

Product Returns

The Company provides contractual return rights to its customers including the right to return product within six months of product expiration and up to 12 months after product expiration, as well as for incorrect shipments, and damaged or defective product, which the Company expects to be rare. Management expects product returns to be minimal, thus BTI recognizes a nominal allowance for product returns at the time of each sale. In the future, if any of these factors and/or the history of product returns changes, the Company will adjust the allowance for product returns.

BTI classifies all fees paid to the distributor, other than those discussed above and those related to warehouse operations, as Selling, general and administrative expenses on its Consolidated Statements of Operations. Fees paid to the distributor for warehouse operations are classified as Cost of goods sold on BTI's Consolidated Statements of Operations.

Cost of Goods Sold

Cost of goods sold includes the cost of producing and distributing inventories that are related to product revenues during the respective period. Cost of goods sold also includes costs related to excess or obsolete inventory adjustment charges, as well as costs related to warehouse operations paid to distributors.

Stock-Based Compensation

The Company measures and recognizes stock-based compensation expense based on estimated fair value for all share-based awards made to employees, non-employee service providers, and directors, including stock options, BTI restricted stock units ("BTI RSUs"), OnkosXcel profit sharing units ("PSUs"), OnkosXcel restricted stock units ("OnkosXcel RSUs") and BTI performance stock units ("Performance Units"). The Company's 2017 Equity Incentive Plan (the "2017 Plan") became effective in August 2017. The Company's 2020 Incentive Award Plan (the "2020 Plan") became effective in May 2020. Following the effective date of the 2020 Plan, the Company ceased granting awards under the 2017 Plan; however, the terms and conditions of the 2017 Plan continue to govern any outstanding awards granted thereunder.

The Company's stock-based awards are valued at fair value on the date of grant and that fair value is recognized as an expense in the Consolidated Statements of Operations over the requisite service period using the accelerated attribution method. The estimated value of the BTI RSUs and Performance Units is based on the Company's closing stock price on the grant date. The estimated fair value of OnkosXcel RSUs are based on the OnkosXcel valuation on the grant date. The estimated fair value of stock-options and PSUs was determined using the Black-Scholes pricing model on the date of grant. For awards subject to performance-based vesting conditions, the Company recognizes stock-based compensation expense when the achievement of the performance condition becomes probable.

The Black-Scholes pricing model is affected by the Company's stock price, as well as assumptions regarding variables including, but not limited to, the strike price of the instrument, the risk-free rate, the expected stock price volatility over the term of the awards and expected term of the awards. The Company has elected to account for forfeitures as they occur, by reversing compensation cost when the award is forfeited.

Research and Development Costs

Research and development expenses include wages, benefits, non-cash stock-based compensation, facilities, supplies, external services, clinical study, manufacturing costs related to clinical trials and other expenses that are directly related to the Company's research and development activities. At the end of the reporting period, the Company estimates the progress toward completion of the research or development objectives and, depending on the amount and timing of payments to the service providers may record net prepaid or accrued expense for associated research and development costs. Such estimates are subject to change as additional information becomes available. The Company expenses research and development costs as incurred.

Most of the Company's service providers invoice BTI monthly in arrears for services performed. The Company estimates its accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to management at that time. BTI management periodically confirms the accuracy of the Company's estimates with the service providers and makes adjustments if necessary.

Although management does not expect its estimates to be materially different from amounts actually incurred, management's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in BTI reporting amounts that are too high or too low in any particular period.

Patent Costs

Costs related to filing and pursuing patent applications are recorded in Selling, general and administrative expenses in the Consolidated Statements of Operations and are expensed as incurred since recoverability of such expenditures is uncertain.

Fair Value of Financial Instruments

The Company measures certain financial assets and liabilities at fair value, which is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company applies a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources, or observable inputs, and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances, or unobservable inputs. The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). Fair value measurements must be classified and disclosed in one of the following three categories:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

- Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

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 considering counterparty credit risk in its assessment of fair value.

Income Taxes

BTI uses an asset and liability approach for financial accounting and reporting of income taxes. Deferred tax assets and liabilities are determined based on temporary differences between financial reporting and tax basis assets and liabilities and are measured by applying enacted rates and laws to taxable years in which differences are expected to be recovered or settled. Further, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that the rate changes. A valuation allowance is required when it is "more likely than not" that all or a portion of deferred tax assets will not be realized.

U.S. GAAP prescribes a comprehensive model for how a company should recognize, measure, present and disclose in its financial statements uncertain tax positions that the Company has taken or expects to take on a tax return, including a decision whether to file or not file a return in a particular jurisdiction. The Company's financial statements reflect expected future tax consequences of such positions presuming the taxing authorities' full knowledge of the position and all relevant facts.

The Company does not have any unrecognized tax benefits as of December 31, 2024 and 2023. BTI reviews all tax positions to ensure the tax treatment selected is sustainable based on its technical merits and that the position would be sustained if challenged.

Earnings (Loss) per Share

Earnings (loss) per share ("EPS") is calculated by dividing net income or loss attributable to common stockholders by the weighted average number of shares of common stock that were outstanding, including pre-funded warrants. Shares of common stock into which the pre-funded warrant may be exercised are considered outstanding for the purposes of computing EPS because the shares may be issued for little or no consideration, are fully vested and are exercisable after the original issuance date. Diluted EPS is calculated by adjusting the weighted average number of shares of common stock that were outstanding for the dilutive effect of common stock equivalents. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive.

Segment Information

The Company operates in a single segment. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. To date, the Company's chief operating decision maker has made such decisions and assessed performance at the Company level as one segment. See Note 19, *Segment Information* for further information

Recent Accounting Pronouncements

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment reporting, which requires disclosure of incremental segment information on an annual and interim basis. The standard is effective for years beginning after December 15, 2023, and interim periods beginning after December 15, 2024 and early adoption is permitted. The Company adopted the new standard in fiscal year 2024 for annual and retrospective reporting periods with all interim disclosures to begin in the first quarter of fiscal year 2025. For additional information, see Note 19, *Segment Information*.

Accounting Pronouncements effective in future periods

In December 2023, the FASB issued ASU 2023-09, Improvements to income tax disclosures, which requires disclosure of disaggregated income taxes paid by jurisdiction, enhances disclosures in the effective tax rate reconciliation and modifies other income tax-related disclosures. The amendments are effective for annual periods beginning after December 15, 2024. The Company is currently evaluating the effect of adopting this guidance on its consolidated financial statements.

Note 4. Restructuring

On August 8, 2023, the Company's Board of Directors approved a broad-based strategic reprioritization (the "Reprioritization"). The Company took actions to reduce certain operational and workforce expenses that were no longer deemed core to ongoing operations in order to extend its cash runway and drive innovation and growth in high potential clinical development and value creating opportunities. These actions included a shift in commercial strategy for IGALMI® in the institutional setting, a reduction of in-hospital commercialization expenses, a suspension of programs no longer determined to be core to ongoing operations, and a prioritization of at-home treatment setting opportunities for BXCL501.

As part of this strategy, the Company's Board of Directors approved a reduction of approximately 60% of the Company's workforce. The Company notified impacted employees on August 14, 2023 and recorded total restructuring costs of $4,163 for the year ended December 31, 2023. These costs consisted of severance and benefit costs of $4,063 and contract termination costs of $100. The Company paid $3,998 of severance and benefit costs and $100 of contract termination costs in the year ended December 31, 2023. The Reprioritization is substantially complete as of December 31, 2023, and any remaining costs are expected to be paid during the first quarter of 2024.

On May 8, 2024 the Company took additional actions as part of its continued efforts to preserve cash and prioritize investment in its core clinical programs. As part of these actions, the Company initiated a further reduction of approximately 15% of the Company's then current workforce. The Company notified impacted employees on May 8, 2024 and recorded total restructuring costs of $856 for the three months ended June 30, 2024. These costs consisted of severance and benefit costs, all of which were paid during the three months ended June 30, 2024.

On September 17, 2024, the Company approved a plan for an additional reduction in its workforce of 15 employees, or approximately 28% of the Company's headcount (the "Clinical Prioritization"), in order to extend its cash runway and prioritize investment on the clinical development of its lead neuroscience asset, BXCL501. The Company incurred aggregate charges in connection with the Clinical Prioritization of $1,586 which relate primarily to severance and benefits costs. Accordingly, the Company recorded a restructuring charge of $1,553 in the third quarter 2024, and $33 in the fourth quarter. The Company completed the Clinical Prioritization in October 2024, and paid $983 of the related costs during the fourth quarter of 2024 and expects to pay the remaining $603 in the first quarter of 2025, which is included in Accrued Expenses on the Consolidated Balance at December 31, 2024.

Note 5. Inventory

Inventory consists of the following:

	December 31, 2024	December 31, 2023
Raw materials	$ 506	$ 935
Work-in-process	—	651
Finished goods	173	405
Total inventory	$ 679	$ 1,991

The Company recorded inventory write-downs due to excess inventory of $1,980 and $1,191 for the years ended December 31, 2024 and 2023, respectively.

Note 6. Property and Equipment, net

Property and equipment, net consists of the following:

	December 31, 2024	December 31, 2023
Computers and equipment	$ 202	$ 202
Furniture	575	575
Leasehold improvements	1,200	1,200
Total property and equipment	$ 1,977	$ 1,977
Accumulated depreciation	(1,502)	(1,193)
Total property and equipment, net	$ 475	$ 784

Depreciation expense was $309 and $318 for the years ended December 31, 2024 and 2023, respectively.

Note 7. Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2024	December 31, 2023
Accrued research and development expenses	$ 3,107	$ 6,406
Accrued compensation and benefits	35	163
Accrued professional fees	1,604	5,562
Accrued taxes	91	116
Other accrued expenses	322	177
Accrued restructuring costs	603	—
Total accrued expenses	$ 5,762	$ 12,424

Note 8. Transactions with BioXcel LLC

The Company entered into a Separation and Shared Services Agreement with BioXcel LLC that took effect on June 30, 2017, as amended and restated thereafter (the "Services Agreement"), pursuant to which BioXcel LLC had agreed to provide the Company with certain intellectual property prosecution and management and research and development activities.

Under the Services Agreement, the Company had an option, exercisable until December 31, 2024, to enter into a separate collaborative services agreement with BioXcel LLC pursuant to which BioXcel LLC shall perform product identification and related services for us utilizing its EvolverAI. We agreed to pay BioXcel LLC $18 per month from March 13, 2023, to December 31, 2024 in exchange for this option. This option was not exercised. However, BioXcel LLC continues to perform certain administrative services under the terms of the expired contract. We agreed to negotiate any such collaborative services agreement in good faith and to incorporate reasonable market-based terms, including consideration for BioXcel LLC reflecting a low, single-digit royalty on net sales and reasonable development and commercialization milestone payments, provided that (i) development milestone payments shall not exceed $10,000 in the aggregate and not be payable prior to proof of concept in humans and (ii) commercialization milestone payments shall be based on reaching annual net sales levels, be limited to 3% of the applicable net sales level, and not exceed $30,000 in the aggregate. We did not exercise our option to renew the agreement for product identification and related services utilizing BioXcel LLC's EvolverAI. Subsequent to December 31, 2024 no development activity has been carried out by BioXcel LLC and none is contemplated.

Service charges recorded under the Services Agreement for the years December 31, 2024 and 2023 were as follows:

	Year ended December 31,	
	2024	2023
Research and development	$ 938	$ 1,075
Selling, general and administrative	392	211
Total	$ 1,330	$ 1,286

There were no service charges due as of December 31, 2024 and December 31, 2023.

Note 9. Debt and Credit Facilities

Debt, net of unamortized discounts and financing costs, consists of the following:

	December 31, 2024	December 31, 2023
Credit Agreement and Guaranty	$ 102,319	$ 102,319
Payable-in-kind ("PIK") interest	4,403	361
Total long-term debt liability	$ 106,722	$ 102,680
Unamortized debt premiums, discounts and issuance costs	(4,214)	(2,082)
Total long-term debt	$ 102,508	$ 100,598

On April 19, 2022, the Company entered into two strategic financing agreements: (i) a Credit Agreement and Guaranty (the "Credit Agreement") by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto (the "Lenders"), and Oaktree Fund Administration LLC ("OFA") as administrative agent, and (ii) a Revenue Interest Financing Agreement (the "RIFA"; and together with the Credit Agreement, the "OFA Facilities") by and among the Company, the purchasers party thereto (the "RIFA Purchasers") and OFA as administrative agent. Under the OFA Facilities, the Lenders and the RIFA Purchasers agreed to, in the aggregate between the two OFA Facilities, provide up to $260,000 in gross funding to support the Company's commercial activities of IGALMI® sublingual film. In addition, the OFA Facilities are intended to support the expansion of clinical development efforts of BXCL501, which includes a Phase 3 program for the acute treatment of agitation in patients with Alzheimer's disease, and for general corporate purposes. The Lenders and RIFA Purchasers are comprised of affiliates of Oaktree Capital Management, L.P. and Qatar Investment Authority.

Waiver and First Amendment to Credit Agreement and Guaranty

On November 13, 2023, the Company, the lenders party to the Credit Agreement and OFA entered into a Waiver and First Amendment to Credit Agreement and Guaranty (the "First Amendment") that provided for (i) a waiver and a modification to the covenant in the Credit Agreement regarding investments in OnkosXcel and (ii) an agreement among the parties to further revise key financial terms in the Credit Agreement and terminate the RIFA. Pursuant to the First Amendment, the Lenders agreed to permit the Company to invest up to a maximum of $30,000 at any time outstanding in OnkosXcel, increased from $25,000 at any time outstanding. The First Amendment also waived any defaults or events of default arising under the Credit Agreement due to a breach prior to the date of the First Amendment of the OnkosXcel investment covenant, or a breach of the Company's obligation to notify OFA of such default. In connection with the First Amendment, the Company paid the Lenders a fee of $180 (representing 0.25% of the loans outstanding under the Credit Agreement on the date of the First Amendment) and agreed to pay to the Lenders an exit fee equal to 0.25% of the loans under the Credit Agreement repaid upon maturity or prepayment of the loans.

Second Amendment to Credit Agreement and Guaranty and Termination of the RIFA

On December 5, 2023, (the "Second Amendment Effective Date"), the Company entered into the Second Amendment to Credit Agreement and Guaranty and Termination of Revenue Interest Financing Agreement (the "Second Amendment"), which further amended the Credit Agreement. On the Second Amendment Effective Date, the Credit Agreement was amended to provide up to $202,319 in senior secured term loans, including the initial Tranche A of $70,000, which was funded on April 28, 2022, and related capitalized interest on Tranche A through the Second Amendment Effective Date in the amount of $72,319. In addition, the $30,000 in financing previously provided to the Company under the RIFA on July 8, 2022 was converted to a term loan under the Credit Agreement (the "Tranche A-2 Term Loan"). The RIFA and all commitments for potential future funding thereunder were terminated. In addition, pursuant to the Second Amendment, the Lenders agreed to permit the Company to invest up to a maximum of $30,865 at any time outstanding in OnkosXcel, increased from $30,000. In connection with the Second Amendment, the Company agreed to pay to the Lenders an exit fee equal to 0.25% of the loans under the Credit Agreement repaid upon maturity or prepayment of the loans (which exit fee is in addition to, and not in lieu of, the exit fee provided for by the First Amendment). As of September 30, 2024, $100,000 in commitments under the Credit Agreement remains unfunded, and Oaktree has an Equity Investment Right (as defined below) to purchase up to $5,000 of Common Stock from the Company. The blended effective interest rate on the Tranches A-1 and A-2 as of December 31, 2023 was approximately 13.5%.

The remaining tranches may be borrowed at the Company's option prior to December 31, 2024, subject to satisfaction of certain conditions, including regulatory and financial milestones. Tranche B of the Credit Agreement is $20,000 and is available upon satisfaction of certain conditions and financial milestones. Tranche C of the Credit Agreement is $30,000 and is available upon satisfaction of certain conditions, including receipt of certain regulatory and financial milestones. Tranche D of the Credit Agreement is $50,000 and is available upon satisfaction of the Tranche C Term Loans conditions precedent to, and the funding of Tranche C Loans, including specified minimum net sales of the Company attributable to sales of BXCL501 for a trailing twelve consecutive month period, on or before December 31, 2025.

The loans under the Credit Agreement do not amortize and mature on April 19, 2027. The Company may, at its option, no earlier than September 21, 2026 and no later than October 21, 2026, request an extension of the maturity date to April, 19, 2028, provided that the Company satisfies certain conditions including receipt of certain regulatory and financial milestones. Borrowings under the Credit Agreement are issued at a 200-basis point original issue discount and bear interest at a variable annual rate of TERM SOFR (but not less than 2.5% or more than 5.5%) plus 7.5%, payable quarterly. The rate resets every three months based on the current Term SOFR rate. Of such interest, above 8% per annum is, at the Company's option, payable in kind by capitalizing and adding such interest to the outstanding principal amount of loans from the first payment date on which such interest is owed through March 31, 2025, unless, with respect to any payment date, the Company elects to pay all or a portion of such interest in cash. The Company is required to pay a ticking fee equal to 0.75% per annum on the undrawn amount of the commitments, payable quarterly commencing 120 days after April 22, 2022 through the termination of the commitments, which is expensed as incurred and recognized as interest expense in the Consolidated Statements of Operations. The Company may voluntarily prepay the Credit Agreement at any time subject to a prepayment fee.

The Company's obligations under the Credit Agreement are guaranteed by BTI's existing and subsequently acquired or organized subsidiaries, subject to certain exceptions. BTI's obligations under the Credit Agreement and the related guarantees thereunder are secured, subject to customary permitted liens and other agreed upon exceptions, by (i) a pledge of all of the equity interests of all of the Company's existing and any future direct subsidiaries, and (ii) a perfected security interest in all of its and the guarantors' tangible and intangible assets (except that the guarantees provided by the BXCL701 Subsidiaries (as defined below) are unsecured).

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of other indebtedness, and dividends and other distributions, subject to certain exceptions, including specific exceptions with respect to product commercialization and development activities. The Company must also comply with certain financial covenants, including (i) maintenance of cash or permitted cash equivalent investments in accounts controlled by OFA for the Lenders, of at least (a) initially, $15,000, (b) from and after the funding of the Tranche B

loans, $20,000, and (c) from and after the Company's satisfaction of the funding conditions for the Tranche C loans, $15,000, provided, that the liquidity covenant applicable at any time will be increased upon certain events related to a sale of OnkosXcel (up to a maximum amount equal to $37,500), provided that the minimum liquidity amount will in no event exceed 50% of the aggregate amount of loans outstanding under the Credit Agreement at any time; and (ii) a minimum revenue test, measured quarterly beginning with the Company's fiscal quarter ending on December 31, 2024 (such six-month period the "Revenue Covenant Measurement Period"), that requires it and its subsidiaries' consolidated net revenue for the six consecutive month period ending on the last day of each such fiscal quarter to not be less than a minimum revenue amount specified in the Credit Agreement (such testing date, the "Revenue Covenant Measurement Testing Date" and the covenant described in this clause (ii) the "Revenue Covenant"). The Company's failure to comply with the financial covenants will result in an event of default, subject to certain cure rights with respect to the Revenue Covenant. If, as of a Revenue Covenant Measurement Testing Date, the Company's revenue for the applicable Revenue Covenant Measurement Period is less than the minimum revenue amount specified for the applicable period then required under the Revenue Covenant, the Company would have a right to cure such shortfall for a total of three fiscal periods by making a revenue cure payment (which would be treated as prepayments of the loans subject to a prepayment fee) to the Lenders in an amount equal to the difference between such minimum required revenue amount and the Company's actual revenues for such Revenue Covenant Measurement Period, such payment to not be less than $1,000. If paid, the Company will be deemed to have complied with the Revenue Covenant as of such Revenue Covenant Measurement Testing Date. Any such payment will be applied to the prepayment of the loans under the Credit Agreement.

Notwithstanding the foregoing, the Credit Agreement permits OnkosXcel (together with OnkosXcel Employee Holdings, LLC ("Employee Holdings"), a subsidiary of BTI, and their respective subsidiaries, the "BXCL701 Subsidiaries") to receive third-party investment or transfer all or substantially all of their assets to an unaffiliated third party, in each case subject to terms and conditions set forth in the Credit Agreement, including the escrow of certain proceeds received by BTI and its subsidiaries (other than the BXCL701 Subsidiaries) in respect of these disposition events and, under circumstances set forth in the Credit Agreement, the mandatory prepayment of such escrowed amounts. The Company's equity interests in the BXCL701 Subsidiaries have been pledged in support of its obligations under the Credit Agreement, and the BXCL701 Subsidiaries have provided direct guarantees of BTI's obligations under the Credit Agreement on an unsecured basis. However, the pledge, guarantee and other obligations of the BXCL701 Subsidiaries under the Credit Agreement will be released upon certain agreed upon events, including an initial public offering by the BXCL701 Subsidiaries or the ownership by unaffiliated third parties of at least 20% of the equity interests in the BXCL701 Subsidiaries.

The Credit Agreement contains events of default that are customary for financings of this type relating to, among other things, payment defaults, breach of covenants, breach of representations and warranties, cross default to material indebtedness, bankruptcy-related defaults, judgment defaults, breach of the financial covenants described above, and the occurrence of certain change of control events. In certain circumstances, events of default are subject to customary cure periods. The Credit Agreement also contains certain regulatory-related events of default, which do not have cure periods. Following an event of default and any applicable cure period, the Lenders will have the right upon notice to terminate any undrawn commitments and may accelerate all amounts outstanding under the Credit Agreement, in addition to other remedies available to them as the Company's secured creditors.

Waiver and Third and Fourth Amendments to Credit Agreement and Guaranty

On February 12, 2024, the Company entered into the Third Amendment to Credit Agreement and Guaranty (the "Third Amendment"), which amended the Credit Agreement. Pursuant to the Third Amendment, the Lenders agreed to waive the covenant that the Company shall not receive a report and opinion from the Company's independent auditors that contains a "going concern" or like qualification or exception or emphasis of matter of going concern footnote with respect to the Company's financial statements for the fiscal year ended December 31, 2023 and, as a result, such event shall not be an event of default. As a condition to the effectiveness of the Third Amendment, among other things, the Company shall have received at least $40,000 in gross proceeds from a registered public sale of the Company's common stock, warrants and/or pre-funded warrants on or before February 20, 2024. The Company did not meet this condition and therefore the Third Amendment did not become effective.

On March 20, 2024 (the "Effective Date"), the Company entered into the Fourth Amendment to the Credit Agreement and Guaranty (the "Fourth Amendment"), which amended the Credit Agreement. Pursuant to the Fourth Amendment, the Lenders agreed to waive the covenant that the Company shall not receive a report and opinion from the Company's independent registered public accounting firm that contains a "going concern" or similar qualification with respect to the Company's financial statements for the year ended December 31, 2023. Accordingly, while the Company's independent registered public accounting firm's report contained in the Annual Report on Form 10-K for the fiscal year ended December 31, 2023 contains a "going concern" explanatory paragraph, it does not constitute an event of default under the Credit Agreement.

The Fourth Amendment includes a covenant that the Company will receive, (i) after the Effective Date and on or before April 15, 2024, at least $25,000 in gross proceeds from the issuance of its common stock, warrants and/or pre-funded warrants, and/or in non-refundable cash consideration from partnering transactions entered into after the Effective Date (so long as such partnering transactions would not require the Company or any of its subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made) and (ii) after the Effective Date and on or before November 30, 2024, at least $50,000 (for the avoidance of doubt, inclusive of amounts previously counted toward the preceding clause (i)) in gross proceeds from the issuance of its common stock, warrants and/or pre-funded warrants, and/or in cash and/or non-cash consideration (measured at fair market value, as determined by the Administrative Agent (as defined in the Credit Agreement) in its sole discretion) from partnering transactions entered into after the Effective Date. Failure to perform this covenant would constitute (A) a default under the Credit Agreement and (B) an event of default under the Credit Agreement, subject to a cure period, solely in the case of clause (i) of the preceding sentence, until May 15, 2024. For the avoidance of doubt, failure to perform clause (ii) of the preceding sentence would constitute an immediate event of default under the Credit Agreement without any cure or grace period.

In addition, the Fourth Amendment provides that if the Company has not, after the Effective Date and on or before September 30, 2024, received at least $40,000 in gross proceeds from the issuance of its common stock, warrants and/or pre-funded warrants, and/or cash and/or non-cash consideration (measured at fair market value, as determined by the Administrative Agent in its sole discretion) from partnering transactions entered into after the Effective Date, the "Minimum Liquidity Amount" (as defined in the Credit Agreement) that the Company is required to maintain at all times will increase to $25,000 from $15,000, unless and until the Company has received, after the Effective Date and on or before November 30, 2024, at least $50,000 in gross proceeds from the issuance of the Company's common stock, warrants and/or pre-funded warrants, and/or in cash and/or non-cash consideration (measured at fair market value, as determined by the Administrative Agent in its sole discretion) from partnering transactions entered into after the Effective Date. On March 27, 2024, the Company received $25,000 in gross proceeds from the issuance of its common stock, warrants, and pre-funded warrants discussed in Note 11, *Common Stock Financing Activities*, satisfying the April 15, 2024 covenant requirement of the Fourth Amendment. During the third quarter of 2024, the Company received $467 of gross proceeds from the issuance of the Company's common stock. As of September 30, 2024, the Company had satisfied $30,943 of the $40,000 required to maintain the Minimum Liquidity Amount and the $50,000 gross proceeds requirement. As a result, at September 30, 2024, the Minimum Liquidity Amount increased to $25,000. As of September 30, 2024, we were in compliance with all restrictive and financial covenants under the Credit Agreement.

Waiver and Fifth Amendment to Credit Agreement and Guaranty

On November 21, 2024, the Company entered into the Fifth Amendment to Credit Agreement and Guaranty and First Amendment to Fourth Amendment to Credit Agreement and Guaranty (the "Fifth Amendment"), which amended the Credit Agreement and Guaranty, dated April 19, 2022, by and among the Company, as the borrower, certain subsidiaries of the Company from time to time party thereto as subsidiary guarantors, the lenders party thereto (the "Lenders"), and Oaktree Fund Administration LLC ("OFA") as administrative agent (as amended by the Waiver and First Amendment to Credit Agreement and Guaranty, dated as of November 13, 2023, the Second Amendment to Credit Agreement and Guaranty and Termination of Revenue Interest Financing Agreement, dated as of December 5, 2023, the Third Amendment to Credit Agreement, dated as of February 12, 2024, and the Fourth Amendment to Credit Agreement and Guaranty, dated as of March 20, 2024 (the "Fourth Amendment"), the "Existing Credit Agreement").

Pursuant to the Fifth Amendment, the Lenders agreed to, among other things, (i) waive the Credit Agreement's covenant that the report and opinion the Company will receive from its independent registered public accounting firm with respect to the financial statements for the year ending December 31, 2024 will not contain a "going concern" or similar qualification, (ii) permanently waive the Credit Agreement's minimum revenue covenant, and (iii) waive the Fourth Amendment's requirement that the Company raise, after the effective date of the Fourth Amendment and on or before November 30, 2024, at least $50,000 in gross cash proceeds from the issuance of its common stock, warrants, and/or pre-funded warrants, and/or in cash and/or non-cash consideration from newly entered-into partnering transactions.

The Fifth Amendment includes a new capital raising covenant requiring that the Company receive (A) after the effective date of the Fifth Amendment and on or prior to November 27, 2024, at least $7,000 in gross cash proceeds from the issuance of the Company's common stock, warrants and/or pre-funded warrants("Raise 1"), (B) after the effective date of the Fifth Amendment and on or before March 15, 2025 (provided that the Company was required to use its commercially reasonable efforts to satisfy the requirement by February 15, 2025), at least $18,000 in net cash proceeds (including the proceeds of Raise 1) from (i) the issuance of the Company's common stock, warrants and/or pre-funded warrants, (ii) non-refundable cash consideration from partnering transactions entered into after the effective date of the Fifth Amendment (so long as such partnering transactions would not require the Company or any of its subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made), (iii) the issuance of the Company's subordinated debt (subject to terms set forth in the Fifth Amendment), and/or (iv) asset sales permitted pursuant to the Credit Agreement or consented to by the Lenders (such capital raise, "Raise 2"), and (C) after the effective date of the Fifth Amendment and on or prior to the earlier of (x) August 15, 2025 and (y) the date that is 30 days after the final data readout of the SERENITY At-Home Phase 3 trial, at least $29,000 in net cash proceeds (including the proceeds from Raise 1 and Raise 2) from the same permitted capital raising activities listed in the preceding clause (B).

In connection with the Fifth Amendment and the required capital raises described in the preceding paragraph, the Lenders agreed to modify the Credit Agreement's minimum liquidity covenant to require minimum cash liquidity of $7,500 (instead of $25,000) from and after the closing of Raise 1until March 30, 2025. On March 31, 2025, the minimum liquidity amount will increase to $10,000 and on September 30, 2025, the minimum liquidity amount will further increase to $15,000.

In connection with the Fifth Amendment, the Company paid a one-time amortization payment of $2,500 principal amount, together with accrued and unpaid interest and a portion of the prepayment fee and other fees payable in December 2024.

The Fifth Amendment also modifies the interest rate of the loans provided under the Credit Agreement from a floating rate of Term SOFR plus 7.50% per annum, to a fixed rate of 13% per annum, retroactive to and effective as of September 30, 2024. For the quarterly payment dates ending December 31, 2024, March 31, 2025, and June 30, 2025, the Company will have the ability to make interest payments of up to 10% per annum "in-kind" by capitalizing and adding such interest to the outstanding principal amount of the loans under the Credit Agreement. In addition, pursuant to the Fifth Amendment, the Company will be required to make quarterly amortization payments equal to 5.0% of the principal amount of funded loans, together with applicable prepayment fees, beginning on March 31, 2026.

On the effective date of the Fifth Amendment and as a condition to effectiveness thereof, the Company's wholly owned subsidiaries OnkosXcel Therapeutics, LLC and OnkosXcel Employee Holdings, LLC (collectively, "OnkosXcel"), which previously provided unsecured guarantees of the Company's obligations under the Credit Agreement, granted security interests in substantially all of their assets to support such obligations.

The Fifth Amendment amends the negative covenants under the Credit Agreement to remove flexibility the Company and its subsidiaries previously had thereunder to undertake various transactions, including, without limitation, with respect to potential dispositions of OnkosXcel or out-licenses by OnkosXcel of its intellectual property.

Pursuant to the Fifth Amendment, the Company committed to appoint a new independent board director (subject to customary background checks, applicable law, confirmation of independence and Nasdaq rules), and to provide the independent director with various privileges and committee memberships on the board of directors of the Company

(including the appointment of such director on committee to be formed to focus on capital raising and evaluate strategic options). The Company also agreed to engage an investment banker reasonably acceptable to OFA and the Lenders to assist the Company and its board of directors with evaluating and exploring strategic options.

The Company also agreed to covenants requiring that the Company's cash expenditures be monitored by the Lenders according to a board-approved budget provided to the Lenders prior to the signing of the Fifth Amendment, which cash budget will be updated on a bi-weekly basis going forward. The Company will not be permitted to make disbursements for any two-week period in excess of 115% of the aggregate budgeted amount of disbursements for the applicable period. Finally, pursuant to the Fifth Amendment, the Company is restricted from paying cash bonuses for its employees or executives during the fiscal years 2024 and 2025 without OFA's consent or increasing the cash compensation for fiscal year 2025 for certain senior officers of the Company from their compensation for fiscal year 2024.

Revenue Interest Financing Agreement

As noted, the RIFA was terminated when the Company entered into the Second Amendment, which amended the Credit Agreement (as amended by the First Amendment). The $30,000 Tranche A previously provided to the Company under the RIFA was converted to the Tranche A-2 Term Loan. Prior to termination, the RIFA provided up to $120,000 in potential financing in exchange for a capped revenue interest on net sales of IGALMI®, and other future BXCL501 products, if any, that received regulatory approval for sale. The initial Tranche A of $30,000 was funded on July 8, 2022.

Under the terms of the RIFA, the Purchasers were to receive tiered revenue interest payments on U.S. net sales of IGALMI®, and other future BXCL501 products, if any, that receive regulatory approval for sale, equal to a royalty ranging from 0.375% to 7.750% of net sales of IGALMI®, and other future BXCL501 products, if any, approved for sale in the U.S., subject to a hard cap equal to 1.75x the total amount funded. The Company would also have been required to make certain additional payments to the Purchasers from time to time to ensure that the aggregate amount of payments received by the Purchasers under the RIFA were at least equal to certain agreed upon minimum levels as of certain specified dates, subject to terms and conditions set forth in the RIFA. Revenue interest payments due under the RIFA were payable quarterly based on net sales.

Warrants and Equity Investment Right

In connection with the closing of the Second Amendment, on the Second Amendment Effective Date, the Company amended and restated the warrants granted to the Lenders on April 19, 2022 to purchase up to 17 shares of the Company's common stock at an exercise price of $320.6 per share (the "Closing Date Warrants"). Pursuant to the amendment and restatement of the Closing Date Warrants, dated December 5, 2023 (the "Amended and Restated Closing Date Warrants"), the exercise price of the Closing Date Warrants has been reduced to $58.3232 per share. In addition, the Company granted new warrants to the Lenders to purchase up to 4 shares of the Company's common stock (the "2023 Warrant Shares") at an exercise price of $58.3232 per share (the "2023 Warrants" and together with the Amended and Restated Closing Date Warrants, the "Warrants"). The Amended and Restated Closing Date Warrants and the 2023 Warrants will expire on April 19, 2029 and may be net exercised at the holders election. In addition, pursuant to the Credit Agreement, the Lenders have the right to purchase shares of the Company's common stock after the Second Amendment Effective Date, so long as borrowings under the Credit Agreement are outstanding, for a purchase price of $5,000 at a price per share equal to a 10% premium to the volume-weighted average price of the common stock over the 30 trading days prior to the Lenders' election to proceed with such equity investment (the "Equity Investment Right"). BTI entered into a registration rights agreement (the "Registration Rights Agreement") with the Lenders and filed a registration statement on Form S-3 to register the shares issuable upon exercise of the Warrants and, if issued, the shares related to the Equity Investment Right, for resale. The maximum shares of the Company's common stock issuable under the Warrants (including the Closing Date Warrants and the 2023 Warrants) and Lenders' Equity Investment Right was 366 as of March 31, 2024. On the Second Amendment Effective Date, Company amended and restated its Registration Rights Agreement (the "Amended and Restated Registration Rights Agreement") with the Lenders, dated April 19, 2022, pursuant to which the Company agreed to register the 2023 Warrant Shares for resale.

As part of the Credit Agreement, OnkosXcel, a wholly owned subsidiary of BTI, granted warrants to the Lenders to purchase 175 individual limited liability company units (which number of units is not in thousands; referred to herein as

the "OnkosXcel Warrants"). The strike price of the OnkosXcel Warrants is formulaic based on the value of OnkosXcel at the time of exercise and can only be exercised upon occurrence of an equity related liquidity event for OnkosXcel of at least $20,000. The exercise price per unit of the OnkosXcel Warrants will be set upon the earlier of the closing of the next sale (or series of related sales) by OnkosXcel of equity securities of OnkosXcel with aggregate proceeds of not less than $20,000 to unrelated third parties (the "Next Equity Financing") at an exercise price per unit equal to a 10% premium over the price per unit of the equity securities sold by OnkosXcel in such Next Equity Financing or, in the event of a sale of OnkosXcel prior to the Next Equity Financing or an initial public offering constituting the Next Equity Financing, the lesser of (x) 75% of the fair value of the consideration to be paid for a unit upon the consummation of such transaction and (y) 150% of the valuation applicable to the initial profits units issued by OnkosXcel after the closing of the Credit Agreement. The OnkosXcel Warrants are transferable with approval from BTI, which cannot be unreasonably withheld, expire on April 19, 2029, and may be net exercised at the holder's election.

In connection with the closing of the Fourth Amendment discussed below, the Company granted new warrants to the Lenders to purchase up to 6 shares of its common stock (the "2024 Warrant Shares") at an exercise price of $49.1568 per share (the "2024 Warrants"), which represents a 10% premium over the arithmetic average of the volume-weighted average price of the Company's common stock on the Nasdaq Capital Market during the 30 trading days preceding the Effective Date. The 2024 Warrants will expire on April 19, 2029 and may be net exercised at the holder's election. On the Effective Date, the Company amended and restated its Amended and Restated Registration Rights Agreement (the "Second Amended and Restated Registration Rights Agreement") with the Lenders, originally dated April 19, 2022. Pursuant to the Second Amended and Restated Registration Rights Agreement, the Company agreed to register the 2024 Warrant Shares for resale.

Fifth Amendment Warrants, Registration Rights Agreement and Equity Investment Right Termination

Prior to the Fifth Amendment, pursuant to the Credit Agreement, the Lenders had the right to purchase shares of our common stock, so long as borrowings under the Credit Agreement are outstanding, for a purchase price of $5,000 at a price per share equal to a 10% premium to the volume-weighted average price of the common stock over the 30 trading days prior to the Lenders' election to proceed with such equity investment (the "Equity Investment Right"). The Equity investment Right was terminated as part of the Fifth Amendment. We entered into a registration rights agreement with the Lenders (as amended and restated in connection with the Second Amendment, the "Amended and Restated Registration Rights Agreement") and filed registration statements on Form S-3 to register the shares issuable upon exercise of the Closing Date Warrants, 2023 Warrants and the New Warrants for resale. The maximum shares of our common stock issuable under the Closing Date Warrants, the 2023 Warrants and the Lenders' Equity Investment Right was 366. On the Effective Date, we further amended and restated the Amended and Restated Registration Rights Agreement (the "Second Amended and Restated Registration Rights Agreement") with the Lenders. Pursuant to the Second Amended and Restated Registration Rights Agreement, we agreed to register the 2024 Warrant Shares for resale.

In connection with the closing of the Fifth Amendment, the Company agreed to, substantially concurrently with the closing of Raise 1, grant new warrants to the Lenders to purchase an aggregate of 313 shares of common stock on the closing date of the Fifth Amendment, at an exercise price of $0.16 per share (the "New Warrants"). The New Warrants will expire on the seventh anniversary of their issuance.

In addition, the Company agreed to, substantially concurrently with the closing of Raise 1, amend and restate all warrants to purchase stock of the Company issued to the Lenders prior to the effective date of the Fifth Amendment, to revise the exercise price thereunder to an exercise price equal to the lower of (i) the price per share of the common stock of the Company issued in Raise 1 and (ii) arithmetic average of the volume-weighted average price of the Company's common stock on the Nasdaq Capital Market during the 30 trading days preceding Raise 1 (such existing warrants, as amended and restated, the "Original Warrants"). The Original Warrants provide the Lenders with the right to purchase a total of 28 shares of common stock of the Company, and the exercise prices of $58.3232 per share and $49.1568 per share were reduced to $7.68 per share.

On the date of issuance of the New Warrants, the Company agreed to amend and restate its Second Amended and Restated Registration Rights Agreement with the Lenders, dated March 20, 2024. Pursuant to such amendment and restatement (the "Third Amended and Restated Registration Rights Agreement"), the Company will agree to register the shares of common stock issuable under the New Warrants, in addition to all Original Warrants, for resale.

As part of entering into the Credit Agreement, OnkosXcel, a wholly owned subsidiary of BTI, granted the OnkosXcel Warrants to the Lenders to purchase 175 individual limited liability company units. The strike price of the OnkosXcel Warrants is formulaic based on the value of OnkosXcel at the time of exercise and can only be exercised upon occurrence of an equity related liquidity event for OnkosXcel of at least $20,000. The exercise price per unit of the OnkosXcel Warrants will be set upon the earlier of the closing of the next sale (or series of related sales) by OnkosXcel of equity securities of OnkosXcel with aggregate proceeds of not less than $20,000 to unrelated third parties (the "Next Equity Financing") at an exercise price per unit equal to a 10% premium over the price per unit of the equity securities sold by OnkosXcel in such Next Equity Financing or, in the event of a sale of OnkosXcel prior to the Next Equity Financing or an initial public offering constituting the Next Equity Financing, the lesser of (x) 75% of the fair value of the consideration to be paid for a unit upon the consummation of such transaction and (y) 150% of the valuation applicable to the initial profits units issued by OnkosXcel after the closing of the Credit Agreement. The OnkosXcel Warrants are transferable with approval from BTI, which cannot be unreasonably withheld, expire on April 19, 2029, and may be net exercised at the holder's election.

Maturities of long-term debt are expected to be as follows:

	December 31, 2024
2025	$ —
2026	$ 22,431
2027	$ 84,291
Thereafter	$ —

Interest expense was as follows:

	Year ended December 31,	
	2024	2023
Interest expense	$ 14,662	$ 11,941
Accretion of debt discount and amortization of financing costs	467	1,373
Total interest expense	$ 15,129	$ 13,314

Note 10. Derivative Financial Instruments

BTI identified certain freestanding financial instruments and/or embedded features that require separate accounting from the borrowings under the OFA Facilities. This includes the OnkosXcel Warrants and Equity Investment Right held by the Lenders, along with certain put/call options. The OnkosXcel Warrants and Equity Investment Right do not meet certain scope exceptions under U.S. GAAP, primarily because the exercise prices and number of shares of the Company's common stock issuable under the instruments are variable, and the instruments meet the definition of a derivative instrument. Therefore, these instruments are recorded as Derivative liabilities in the Consolidated Balance Sheets. The respective derivative liabilities are recorded at fair value on the date of issuance and are revalued on each balance sheet date until such instruments are settled or expire, with changes in the fair value between reporting periods recorded within Other (income) expense, net in the Company's Consolidated Statements of Operations. As discussed in Note 9, *Debt and Credit Facilities*, the Equity Investment Right was terminated on November 25, 2024 in connection with the Fifth Amendment to the Credit Agreement. The Company recorded the termination gain of $1,263 within Other (income) expense, net in the Company's Consolidated Statements of Operations for the carrying value of the Equity Investment Right.

With respect to the Securities Purchase Agreement discussed in Note 11, *Common Stock Financing Activities*, BTI determined that the Accompanying Warrants fail the equity classification criteria and are therefore classified as liabilities in accordance with ASC 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC 815, Derivatives and Hedging ("ASC 815"). The Accompanying Warrants failed to meet the requirements to be indexed to equity and equity

classified, and meet the definition of a derivative instrument. Therefore, these instruments are recorded as Derivative liabilities in the Consolidated Balance Sheet as of December 31, 2024. The respective derivative liabilities were recorded at fair value on the date of issuance in the amount of $19,347 and are revalued on each balance sheet date until such instruments are settled or expire, with changes in the fair value between reporting periods recorded within Other (income) expense, net in the Company's Consolidated Statements of Operations. We value the Accompanying Warrants using the Black-Scholes option pricing model as discussed in Note 14, *Fair measurements*.

On November 21, 2024, the exercise price of 534 of the Accompanying Warrants was reduced from $51.20 to $9.136 per share. As a result of the repricing, the Company recorded the increase in fair value of $1,000 as an increase to the carrying value of Derivative liabilities, recorded as an increase to their carrying value, and as a loss in Other (income) expense, net, in the Company's Consolidated Statements of Operations. For the year ended December 31, 2024, the Company recorded total net gains of $17,027, including the $1,000 repricing loss, in Other (income) expense, net, in the Company's Consolidated Statements of Operations. As of December 31, 2024, the fair value of the Accompanying Warrants was $2,320.

On November 25, 2024, as discussed below, the Company issued additional warrants (the "November 2024 Accompanying Warrants"). The November 2024 Accompanying Warrants failed to meet the requirements to be indexed to equity and equity classified, and meet the definition of a derivative instrument. Therefore, these instruments are recorded as Derivative liabilities in the Consolidated Balance Sheet as of December 31, 2024. The respective derivative liabilities were recorded at fair value on the date of issuance in the amount of $5,562 and are revalued on each balance sheet date until such instruments are settled or expire, with changes in the fair value between reporting periods recorded within Other (income) expense, net in the Company's Consolidated Statements of Operations. For the year ended December 31, 2024, the Company recorded total net gains of $1,289 in Other (income) expense, net, in the Company's Consolidated Statements of Operations. As of December 31, 2024, the fair value of the November 2024 Accompanying Warrants was $4,273.

Note 11. Common Stock Financing Activities

In May 2021, the Company entered into an Open Market Sale Agreement (as amended, supplemented and/or restated from time to time, the "Sale Agreement") with Jefferies LLC ("Jefferies") pursuant to which the Company could offer and sell shares of its common stock, having an aggregate offering price of up to $100,000, from time to time, through an "at the market offering" program under which Jefferies will act as sale agent. In November 2023, the Company amended the Sale Agreement to increase the size of the "at the market offering" program to $150,000. For the year ended December 31, 2023, the Company sold 88 shares of its common stock for a gross amount of $27,032, incurred issuance costs of $811, and received net proceeds of $26,221. For the year ended December 31, 2024, the Company sold 240 shares of its common stock for a gross amount of $7,682, incurred issuance costs of $231, and received net proceeds of $7,451.

On March 25, 2024, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with the purchasers named therein (collectively, the "Purchasers"). Pursuant to the Purchase Agreement, the Company agreed to issue and sell to the Purchasers in a registered direct offering (the "Offering") under an effective shelf registration statement on Form S-3 (File No. 333-275261) and a related prospectus supplement filed with the Securities and Exchange Commission on March 25, 2024 (the "Prospectus Supplement") an aggregate of 191 shares (the "Shares") of common stock, par value $0.001 per share, and accompanying warrants (the "Accompanying Warrants") to purchase up to 191 shares of common stock at a combined offering price of $4.416 per Share and Accompanying Warrant and pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 348 shares of common stock and Accompanying Warrants to purchase up to 348 shares of common stock, at a combined offering price of $46.40 per share underlying each Pre-Funded Warrant and Accompanying Warrant, which equals the offering price per Share and Accompanying Warrant less the $0.016 exercise price per share of the Pre-Funded Warrants. The Pre-Funded Warrants and Accompanying Warrants are not listed on the Nasdaq Capital Market or any other securities exchange or trading system and the Company does not intend to list them. On March 27, 2024, The Company received $25,000 of gross proceeds from the Offering, incurred issuance costs of $248, and received net proceeds of $24,752.

The Pre-Funded Warrants have an exercise price per share of common stock equal to $0.016 per share. The exercise price and the number of shares of common stock issuable upon exercise of the Pre-Funded Warrants are subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. The Pre-Funded Warrants are exercisable at any time after the date of issuance. For the year ended December 31, 2024, 348 Pre-Funded Warrants were exercised and the same number of shares of common stock were issued in exchange for $6 of proceeds received.

The Accompanying Warrants have an exercise price per share of common stock equal to $51.20 per share. The exercise price and the number of shares of common stock issuable upon exercise of the Accompanying Warrants are subject to appropriate adjustments in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting the common stock. The Accompanying Warrants will be exercisable at any time after the date of issuance and will expire on the fifth anniversary of the date of issuance. The Accompanying Warrants do not meet certain scope exceptions under U.S. GAAP, primarily because they did not meet the requirements to be indexed to equity and equity classified, and the instruments meet the definition of a derivative instrument. Therefore, these instruments are recorded as Derivative liabilities in the Consolidated Balance Sheet as of December 31, 2024.

On November 22, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Canaccord Genuity LLC, as underwriter (the "Underwriter"), in connection with the issuance and sale by the Company in a public offering of (i) 350 shares of the Company's common stock, and accompanying warrants (the "November 2024 Accompanying Warrants") to purchase 350 shares of Common Stock, at a combined public offering price of $7.68 per share, and, in lieu thereof to certain investors, (ii) pre-funded warrants to purchase 563 shares of Common Stock, and accompanying warrants (the "November 2024 Accompanying Warrants") to purchase 563 shares of Common Stock, at a combined public offering price of $7.664 per pre-funded warrant, which equals the public offering price per share of Common Stock and accompanying warrant less the $0.016 exercise price per share of the pre-funded warrants, less underwriting discounts and commissions, pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-275261) and a related prospectus supplement filed with the Securities and Exchange Commission. For the year ended December 31, 2024, 80 pre-funded warrants were exercised and the same number of shares of common stock were issued in exchange for $1 of proceeds received.

Each of the November 2024 Accompanying Warrants in the offering is subject to customary beneficial ownership limitations on exercisability, is exercisable at any time after the date of issuance of such warrant and, in the case of the accompanying warrants, will expire on the fifth anniversary of the date of issuance. Each of the November 2024 Accompanying Warrants will have an exercise price of $7.68 per underlying share of Common Stock.

The Company received net proceeds from the offering of approximately $6,128, after deducting underwriting discounts and commissions and offering expenses of $871. The Company intends to use the net proceeds of the offering to fund the SERENITY At-Home trial, prepare for the initiation of the TRANQUILITY In-Care trial, working capital and general corporate purposes.

Note 12. Stock-Based Compensation

2017 Equity Incentive Plan

The Company's 2017 Plan became effective in August 2017. Following the effective date of the Company's 2020 Plan, the Company ceased granting awards under the 2017 Plan, however, the terms and conditions of the 2017 Plan continue to govern any outstanding awards granted thereunder.

2020 Incentive Award Plan

The Company's 2020 Plan was approved and became effective at the Company's 2020 annual meeting of stockholders on May 20, 2020, and unless earlier terminated by the Board of Directors, will remain in effect until March 26, 2030. The 2020 Plan originally authorized for issuance the sum of (i) 57 shares of the Company's common stock and (ii) 15 shares of the Company's common stock, which represents the number of shares that remained available for

issuance under the 2017 Plan immediately prior to the approval of the 2020 Plan by the Company's stockholders. Any shares of common stock which, immediately prior to the approval of the 2020 Plan by the Company's stockholders, were subject to awards granted under the 2017 Plan that are forfeited or lapse unexercised and are not issued under the 2017 Plan will increase the number of shares of common stock available for grant under the 2020 Plan. In addition, the number of shares available for issuance under the 2020 Plan will increase on the first day of each calendar year, beginning January 1, 2021 and ending on and including January 1, 2030, by a number of shares equal to the lesser of (A) 4% of the aggregate number of shares of the Company's common stock outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares of common stock as determined by the Board of Directors. The shares available for issuance under the 2020 Plan increased by 75 shares and 70 shares on January 1, 2024 and 2023, respectively.

Stock-based awards granted under the 2020 Plan have a term of ten years. The vesting schedule of all awards granted under the 2020 Plan is determined by the Board of Directors, which is generally four years. Stock-based awards granted under the 2020 Plan include stock options, BTI RSUs, and Performance Units.

As of December 31, 2024, there were 42 shares available to be granted under the 2020 Plan.

BTI Restricted stock units

The table below summarizes activity relating to BTI RSUs.

	Number of shares
Outstanding as of January 1, 2024	12
Granted	22
Cancelled	(1)
Vested	(6)
Outstanding as of December 31, 2024	27

In 2024, the Company granted 22 time-based BTI RSUs to certain employees, executives, and board members. The RSUs granted to employees and executives vest 100% at the one-year anniversary of the grant date. The weighted average grant date fair value per share for the BTI RSUs granted to employees and executives in 2024 was $23.43. Unrecognized stock-based compensation expense related to these awards was $13 as of December 31, 2024. The RSUs granted to board members vest monthly over a 12-month period, beginning in November 2024. The weighted average grant date fair value per share for the BTI RSUs granted to board members was $9.12. Unrecognized stock-based compensation expense related to these awards was $185 as of December 31, 2024. Unrecognized stock-based compensation expense related to awards issued prior to 2024 was $575 and $1,715 as of December 31, 2024 and 2023, respectively.

BTI Performance stock units

The table below summarizes activity relating to Performance Units related to BTI common stock.

	Number of shares
Outstanding as of January 1, 2024	33
Granted	87
Cancelled	(27)
Exercised	(23)
Outstanding as of December 31, 2024	70

In July 2024, the Company granted 87 Performance Units to employees. The Performance Units vest on the one-year anniversary of the grant date, provided certain performance criteria are met. The weighted average value per share

of Performance Units granted in 2024 was $19.20. None of the Performance Units had vested as of December 31, 2024. Unrecognized stock-based compensation expense related to these Performance Units expected to vest was zero as of December 31, 2024 since it is uncertain whether any performance criteria will be met.

OnkosXcel Profit sharing units

The table below summarizes activity relating to the PSUs associated with OnkosXcel as described below.

	Number of units	Weighted average price per unit (in whole dollars)
Outstanding as of January 1, 2024	1,240	$ 5,626
Granted	15	$ 10,176
Cancelled	(89)	$ 5,506
Forfeited	—	$ —
Outstanding as of December 31, 2024	1,166	
Vested units as of December 31, 2024	941	$ 5,570

During 2024, OnkosXcel Employee Holdings, LLC, a management holding company used to facilitate the grant of equity interests to service providers of OnkosXcel granted 15 individual (not in thousands) time-based PSUs related to OnkosXcel to certain employees of the Company in consideration for services provided to OnkosXcel. The PSUs represent indirect equity interests in OnkosXcel. These PSUs vest ratably over 48 months.

The fair values of the PSUs granted in 2024 was $8 per unit, and was estimated at the date of grant using a Black-Scholes option pricing model. The total fair value of the PSUs vested during the year ended December 31, 2024 was $1,165.

	2024 grant profit share unit valuation inputs
Expected volatility	97.4 %
Risk-free rate of interest	3.6 %
Expected dividend yield	— %
Expected term	5.8 years

Unrecognized stock-based compensation expense related to the PSUs was $377 as of December 31, 2024.

OnkosXcel restricted stock units

The table below summarizes activity relating to the OnkosXcel RSUs.

	Number of units
Outstanding as of January 1, 2024	225
Granted	—
Vested	(41)
Cancelled	(8)
Outstanding as of December 31, 2024	176

As of December 31, 2024, the Company had 176 OnkosXcel Restricted Stock Units outstanding. Unrecognized stock-based compensation expense related to the awards expected to vest was approximately $210 as of December 31, 2024.

BTI Stock options

A summary of the Company's stock option activity for the year ended December 31, 2024, is presented below.

	Number of shares	Weighted average price per share
Outstanding as of January 1, 2024	311	$ 296.36
Granted	40	$ 20.00
Forfeited	(24)	$ 214.56
Cancelled	(16)	$ 339.74
Exercised	—	$ —
Outstanding as of December 31, 2024	311	$ 265.36
Options vested and exercisable as of December 31, 2024	249	$ 291.94

As of December 31, 2024, the intrinsic value of options outstanding was $0. The intrinsic value for stock options is calculated based on the difference between the exercise prices of the underlying awards and the quoted stock price of the Company's common stock as of the reporting date.

The total intrinsic value of stock options exercised for the year ended December 31, 2024 was $0. The total intrinsic value of stock options exercisable as of December 31, 2024 was $0.

The weighted average grant date fair value of options granted during the year ended December 31, 2024 was $16.63.

The weighted average grant date fair value of options vested as of December 31, 2024 was $215.98.

The weighted average remaining contractual life is 4.9 years for options exercisable as of December 31, 2024. The weighted average remaining contractual life was 5.6 years for options outstanding as of December 31, 2024.

Unrecognized compensation expense related to unvested stock option awards as of December 31, 2024, was $7,691 and will be recognized over the remaining vesting periods of the underlying awards. The weighted-average period over which such compensation is expected to be recognized is 0.9 years.

Stock-Based Compensation

The fair value of options granted during the years ended December 31, 2024 and 2023 was estimated using the Black-Scholes pricing model with the following assumptions:

	Year ended December 31, 2024			Year ended December 31, 2023		
Expected term	5.5 years	-	6.1 years	5.5 years	-	6.1 years
Expected stock price volatility	108.0 %	-	112.5 %	96.9 %	-	109.9 %
Risk-free rate of interest	4.0 %	-	4.5 %	3.5 %	-	4.7 %
Expected dividend yield	0.0 %	-	0.0 %	0.0 %	-	0.0 %

In 2024, the Company continued using the historical volatility of its common stock to estimate volatility. Prior to 2023, volatility was estimated using a combination of the historical volatility of publicly traded peer companies and that of the Company's common stock. The expected term of the awards is estimated based on the simplified method, which calculates the expected term based upon the midpoint of the term of the award and the vesting period. The Company uses the simplified method because it does not have sufficient option exercise data to provide a reasonable basis upon which to estimate the expected term. The expected dividend yield is zero percent as the Company has no history of paying dividends nor does management expect to pay dividends over the contractual terms of these options. The risk-free interest rates are determined by reference to the U.S. Treasury yield curve in effect at the time of grant, with maturities approximating the expected term of the stock options. The fair value of the underlying common stock is generally determined as the closing price of the Company's common stock on The Nasdaq Capital Market on the grant date, with consideration of whether there is material nonpublic information that could impact that estimated fair value when it is released.

The Company recognized stock-based compensation expense related to awards issued under the 2017 Plan and the 2020 Plan, as well as the OnkosXcel PSUs and OnkosXcel RSU's, of $6,156 and $18,614 for the years ended December 31, 2024 and 2023, respectively, which were comprised as follows:

	Year ended December 31,	
	2024	2023
Research and development	$ 2,251	$ 6,324
Selling, general and administrative	3,905	12,290
Total	$ 6,156	$ 18,614

2020 Employee Stock Purchase Plan

The Company's 2020 Employee Stock Purchase Plan (the "ESPP") was also approved and became effective at the Company's 2020 annual meeting of stockholders on May 20, 2020. The ESPP is designed to assist eligible employees of the Company with the opportunity to purchase the Company's common stock at a discount through accumulated payroll deductions during successive offering periods. The aggregate number of shares that may be issued pursuant to rights granted under the ESPP is 6 shares of common stock. In addition, the number of shares available for issuance under the ESPP will increase on the first day of each calendar year, beginning on January 1, 2021 and ending on and including January 1, 2030, by a number of shares of common stock equal to the lesser of (a) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by the Board of Directors. The number of shares that may be issued or transferred pursuant to rights granted under the component of the ESPP that is intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Internal Revenue Code (the "Section 423 Component") shall not exceed 31 shares. The purchase price will be determined by the administrator of the ESPP and, for purposes of the Section 423 Component, shall not be less than 85% of the fair value of a share on the first trading day or on the last trading day of the applicable offering period, whichever is lower. The shares available for issuance under the ESPP increased by 19 shares and 18 shares on January 1, 2024 and 2023, respectively. To date, no shares have been sold under the ESPP. There were 75 shares available for issuance as of December 31, 2024.

Note 13. Leases

BTI leases office space for its corporate headquarters at 555 Long Wharf Drive, New Haven, Connecticut (the "HQ Lease") under an operating lease that expires in February 2026. The Company has an option to renew the HQ Lease for one additional five-year term. Payments under the HQ Lease are fixed.

The Company also leases equipment such as copiers and information technology equipment.

The future minimum annual lease payments under operating leases, as of December 31, 2024, were as follows:

Year ending December 31,	Amount
2025	$ 391
2026	65
Thereafter	—
Total lease payments	$ 456
Imputed interest	(17)
Total lease liability	$ 439
Less current portion of lease liability	(374)
Long-term portion of operating lease liability	$ 65

The current portion of the Company's operating lease liability of $374, as of December 31, 2024, is included in Other current liabilities on the Consolidated Balance Sheets.

Lease expense was $394 and $392 for the years ended December 31, 2024 and 2023, respectively.

Lease renewal options are not included in the ROU asset or lease liability.

Note 14. Employee Benefit Plan

The Company maintains a defined contribution retirement plan for its employees that complies with Section 401(k) of the Internal Revenue Code (the "401(K) Plan"). Employees are eligible to participate in the 401(K) Plan and can contribute a portion of their pay into the 401(K) Plan, subject to annual limits established by the U.S. Internal Revenue Service. Participating employees receive an employer matching contribution equal to 50% of eligible employee contributions on the first 5% of eligible compensation contributed. Employer contributions to the 401(K) Plan were $289 and $788 for the years ended December 31, 2024 and 2023, respectively.

Note 15. Fair Value Measurements

The Company groups its assets and liabilities measured at fair value in three levels based on the nature of the inputs and assumptions used to determine fair value. Refer to Note 3, Summary of Significant Accounting Policies, for additional information on the accounting policies related to fair value.

The carrying amounts of Cash and cash equivalents, Accounts receivable, net and Accounts payable approximate fair value due to the short-term nature of these instruments. As of December 31, 2024 and 2023, the Company had $29,036 and $64,860, respectively, primarily in money market funds that hold U.S. government cash equivalent instruments (included in Cash and cash equivalents) which were valued based on Level 1 inputs. There were no transfers between levels within the hierarchy during the years ended December 31, 2024 and 2023.

Derivative liabilities measured at fair value on a recurring basis are summarized below.

	Year ended December 31, 2024				
	Fair Value	Level 1	Level 2	Level 3	Total
Derivative liability - BTI Warrants	$ 6,593	$ —	$ 6,593	$ —	$ 6,593
Derivative liability - OnkosXcel Warrants	40	—	—	40	40
Total derivative liabilities	$ 6,633	$ —	$ 6,593	$ 40	$ 6,633

	Year ended December 31, 2023				
	Fair Value	Level 1	Level 2	Level 3	Total
Derivative liability - BTI Warrants	$ 1,193	$ —	$ —	$ 1,193	$ 1,193
Derivative liability - OnkosXcel Warrants	712	—	—	712	712
Total derivative liabilities	$ 1,905	$ —	$ —	$ 1,905	$ 1,905

Derivative liabilities are comprised of the OnkosXcel Warrants and Equity Investment Right held by the Lenders. The fair value of the derivative liabilities was determined using Monte Carlo simulation models for the Equity Investment Right, and Binomial Option Pricing and Distribution models for the OnkosXcel Warrants. As discussed in Note 9, *Debt and Credit Facilities*, the Equity Investment Right was terminated on November 25, 2024 in connection with the Fifth Amendment to the Credit Agreement.

The following table presents changes in Level 3 liabilities measured at fair value for the year ended December 31, 2024. Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category.

	Year ended December 31,	
	2024	2023
Derivative liabilities, Balance - January 1	$ 1,905	$ 2,343
Termination of Derivative liabilities - Equity Investment Right	(1,263)	—
Change in fair value	(602)	(438)
Derivative liabilities, Balance - December 31	$ 40	$ 1,905

The derivative liabilities were reported at their fair values in the Consolidated Balance Sheets. The changes in the fair value of the derivative liabilities were reported as gains in the Consolidated Statements of Operations as Other (income) expense, net, for the years ended December 31, 2024 and 2023, in the amounts of $20,181 and $438, respectively.

Inputs used to calculate the estimated fair value of the Equity Investment Right were as follows:

	Equity Investment Right
Strike price relative to volume weighted 30-day average	110.0 %
Volatility (annual)	112.3 %
Probability of exercise	91.0 %
Time period	1.3 years
Estimated premium to 30-day average	24.0 %
Discount rate	4.26 %

The changes in fair value of the Equity Investment Right up to its termination date were recorded in the Consolidated Statements of Operations as Other (income) expense, net. The final carrying value of the Equity Investment Right of $1,263 upon derecognition was recorded was recorded as a reduction of derivative liability with the offset recorded as a gain in Other (income) expense, net, in the Consolidated Statements of Operations.

In estimating the fair value of the derivative liability related to the OnkosXcel Warrants, inputs included third-party fair value estimates of OnkosXcel limited liability company units along with the volatility of those units (which was set at 100% based on the historical volatility of the Company's stock, along with a peer group of comparable publicly traded companies), and the timing and probability of the relevant capital transactions occurring.

The estimated fair value of the Credit Agreement as of December 31, 2024, was $94,204. Both observable and unobservable inputs were used to determine the fair value of long-term debt, which was classified within the Level 3 category.

The following table presents the BTI warrants issued by the Company and the corresponding balance sheet classification:

Warrant Recipient	Warrant Type	Issue Date	Exercise Price	Number of Warrants	Classification
Lenders and RIFA Purchasers	Closing Date Warrants	4/19/2022	$ 7.68	17	Equity
Lenders and RIFA Purchasers	2023 Warrants	12/5/2023	$ 7.68	4	Equity
Lenders and RIFA Purchasers	2024 Warrants	3/20/2024	$ 7.68	6	Equity
Lenders and RIFA Purchasers	New Warrants	11/25/2024	$ 0.16	313	Equity
Armistice Capital Master Fund Ltd.	Accompanying Warrants	3/25/2024	$ 9.136	534	Derivative Liability
Armistice Capital Master Fund Ltd.	Accompanying Warrants	3/25/2024	$ 51.20	5	Derivative Liability
Armistice Capital Master Fund Ltd.	November 2024 Accompanying Warrants	11/25/2024	$ 7.68	846	Derivative Liability
Heights Capital Management	November 2024 Accompanying Warrants	11/25/2024	$ 7.68	27	Derivative Liability
Hudson Bay Capital Management	November 2024 Accompanying Warrants	11/25/2024	$ 7.68	27	Derivative Liability
IntraCoastal Capital, LLC	November 2024 Accompanying Warrants	11/25/2024	$ 7.68	13	Derivative Liability
Total warrants issued				1,792	

The fair value of the Closing Date Warrants, which was a non-recurring fair value, was determined as of the date of issuance using a Black-Scholes pricing model and the fair value of $3,245 was recorded as a component of stockholders' equity in Additional-paid-in-capital in the Consolidated Balance Sheets, with the offset recorded as a discount on the amounts funded under the OFA Facilities. This non-recurring measurement is classified as Level 2. The inputs used were a strike price of $320.64, the Company's stock price of $238.88, volatility of 95%, term of 7 years and risk-free rate of 2.95%.

As discussed in Note 9, Debt and Credit Facilities, in connection with the closing of the Second Amendment of the Credit Agreement, on the Second Amendment Effective Date, the Company amended and restated the Closing Date Warrants granted to the Lenders to have an exercise price of $58.3232 per share.

Using a Black-Scholes pricing model, the Company determined that the Closing Date Warrants' fair values at the original strike price of $320.64 and the amended strike price of $58.3232 were $548 and $802, respectively, as of the Second Amendment Effective Date. The Closing Date Warrants' incremental increase in fair value for the repricing of $254, was recorded as a component of stockholders' equity in Additional-paid-in-capital in the Consolidated Balance Sheets, with the offset recorded as a discount on the amounts refinanced under the Credit Agreement.

In connection with the Second Amendment, the Company issued 4 "2023 Warrants" at a strike price of $58.3232 per share. The fair value of the 2023 Warrants, which is a non-recurring fair value, was determined as of the date of issuance using a Black-Scholes pricing model and the fair value of $200 was recorded as a component of stockholders' equity in Additional-paid-in-capital in the Consolidated Balance Sheets, with the offset recorded as a discount on the amounts funded under the Credit Agreement. This non-recurring measurement is classified as Level 2. The inputs used were a strike price of $58.3232, the Company's stock price of $59.36, volatility of 99%, term of 5.4 years and risk-free rate of 4.14%.

In connection with the Fourth Amendment, the Company issued 6 "2024 Warrants" at a strike price of $49.1568 per share. The fair value of the "2024 Warrants", which was a non-recurring fair value, was determined as of the date of issuance using a Black-Scholes pricing model and the fair value of $224 was recorded as a component of stockholders' equity in Additional-paid-in-capital in the Consolidated Balance Sheets, with the offset recorded as a discount on the amounts funded under the OFA Facilities. This non-recurring measurement is classified as Level 2. The inputs used were a strike price of $49.1568, the Company's stock price of $44.48, volatility of 112.2%, term of 5 years and risk-free rate of 4.25%.

In addition, in connection with the Fifth Amendment of the Credit Agreement, on the Fifth Amendment Effective Date of November 25, 2024, the Company amended and restated the Closing Date Warrants, 2023 Warrants, and 2024 Warrants granted to the Lenders to have an exercise price of $7.68 per share.

Using a Black-Scholes pricing model, the Company determined that the Closing Date Warrants, 2023 Warrants, and 2024 Warrants' fair values at the previously amended strike price of $58.3232 and original strike price of $49.1568 the amended strike price of $7.68 were $105 and $164, respectively, as of the Fifth Amendment Effective Date. The Closing Date Warrants, 2023 Warrants, and 2024 Warrants' incremental increase in fair value for the repricing of $59, was recorded as a component of stockholders' equity in Additional-paid-in-capital in the Consolidated Balance Sheets, with the offset recorded as a discount on the amounts refinanced under the Credit Agreement.

The fair value of the Accompanying Warrants at issuance on March 25, 2024 was determined using a Black-Scholes pricing model and the fair value of $19,347 was recorded as a derivative liability with the offset recorded as a component of stockholders' equity in Additional-paid-in-capital in the Consolidated Balance Sheets. This fair value measurement is classified as Level 2. The valuation inputs used were a strike price of $51.20, the Company's stock price of $44.96, volatility of 112.2%, a term of 5 years and a risk-free rate of 4.2%. On November 25, 2024, 534 of the 539 Accompanying Warrants' strike price were amended to $9.136, as part of the consideration provided to one of the investors in the November 2024 Equity raise discussed in Note 11, Common Stock Financing Activities. The increase in fair value due to the amended strike price of $1,000 was recorded as an increase in the carrying value of the Derivative liability, with the offset recorded as a loss in Other (income) expense, net, in the Company's Consolidated Statements of Operations. We remeasured the Accompanying Warrants' fair value at December 31, 2024 of $2,320 and recorded a net gain of $17,027, including the repricing loss of $1,000 for the year ended December 31, 2024, respectively within Other (income) expense, net in the Company's Consolidated Statements of Operations. The valuation inputs used as of December 31, 2024 were a strike prices of $9.136 and $51.20 for 534 and 5 Accompanying Warrants, respectively, the Company's stock price of $5.984, volatility of 112.3%, term of 4.2 years and risk-free rate of 4.4%.

The fair value of the November 2024 Accompanying Warrants at issuance on November 25, 2024 was determined using a Black-Scholes pricing model and the fair value of $5,562 was recorded as a derivative liability with the offset recorded as a component of stockholders' equity in Additional-paid-in-capital in the Condensed Consolidated Balance Sheets. This fair value measurement is classified as Level 2. The valuation inputs used were a strike price of $7.68, the Company's stock price of $7.52, volatility of 112.5%, a term of 5 years and a risk-free rate of 4.2%. We remeasured the fair value at December 31, 2024 of $4,273 and recorded an unrealized gain of $1,289 for the year ended December 31, 2024, respectively within Other (income) expense, net in the Company's Consolidated Statements of Operations. The valuation inputs used as of December 31, 2024 were a strike price of $7.68, the Company's stock price of $5.984, volatility of 112.3%, term of 4.9 years and risk-free rate of 4.4%.

Note 16. Income Taxes

The significant components of the Company's net deferred tax assets at December 31, 2024 are shown below. In determining the realizability of the Company's net deferred tax assets, the Company considered numerous factors, including historical profitability, estimated future taxable income, and the industry in which it operates. Based on this

information the Company has provided a valuation allowance for the full amount of its net deferred tax asset because the Company has determined that it is more likely than not that they will not be realized.

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Federal net operating losses	$ 90,853	$ 73,770
State net operating losses	23,152	21,255
Stock options	14,601	13,915
Tax credits	17,188	15,048
Capitalized research & development	44,377	49,603
Accrued expense	202	—
Depreciation	103	73
Lease accounting - liability	115	212
Disallowed charitable contributions	1	
Deferred Costs	674	
Cancellation of debt	1,483	
Valuation allowance	(192,149)	(173,679)
Total deferred tax assets	$ 600	$ 197
Deferred tax liabilities:		
Debt amendment	$ (500)	—
Unrealized loss	—	$ (12)
Right-of-use assets	(100)	(185)
Total deferred tax liabilities	$ (600)	$ (197)
Net deferred tax asset (liability)	$ —	$ —

The income tax expense/(benefit) for the year ended December 31, 2024 differed from the amounts computed by applying the U.S. federal income tax rate of 21% to loss before tax benefit as a result of tax credits generated and changes in the Company's valuation allowance.

A reconciliation between the Company's effective tax rate and the federal statutory rate are as follows:

	2024	2024	2023	2023
Federal statutory rate	(12,516)	21.0 %	(37,601)	21.0 %
Stock based compensation	381	(0.6)%	(573)	0.3 %
Warrant mark-to-market	(4,238)	7.1 %	—	— %
Federal and state credits	(1,870)	3.2 %	(4,082)	2.3 %
State taxes	(343)	0.6 %	(14,261)	8.0 %
Other	116	(0.3)%	1,210	(0.7)%
Change in valuation allowance	18,470	(31.0)%	55,307	(30.9)%
	—	— %	—	— %

At December 31, 2024 the Company had approximately $432,634 of gross federal and $443,454 of gross state net operating loss carry-forwards. If not utilized, the federal and state net operating loss carry-forwards will begin to expire in 2037. The federal net operating loss of $429,988 incurred after December 31, 2017 will carryforward indefinitely. The utilization of such net operating loss carry-forwards and realization of tax benefits in future years depends predominantly upon having taxable income. The Company has approximately $15,965 of federal orphan drug credits and research and development credits which will begin to expire in 2037 if not utilized. The Company also has approximately $1,548 of state research and development credits which will begin to expire in 2040 if not utilized.

Utilization of the NOL and research tax credit carryforwards may be subject to a substantial annual limitation due to ownership limitations that has occurred or that could occur in the future, as required by section 382 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of the NOL and research credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a

three year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a by certain stockholders or public groups.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax positions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2024, there were no uncertain positions. The Company's U.S. federal and state NOLs have occurred since its inception in 2017 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the U.S. Internal Revenue Service and/or state taxing authorities. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the years ended December 31, 2024 and 2023.

Note 17. Net Loss Per Share

Basic and diluted net loss per share are as follows:

	Year ended December 31,	
	2024	2023
Net loss (numerator)	$ (59,599)	$ (179,053)
Weighted average shares (denominator)	2,535	1,821
Basic and diluted net loss per share	$ (23.51)	$ (98.33)

Potentially dilutive securities outstanding consists of stock options, RSUs and performance units, and BTI warrants. The Company had common stock equivalents outstanding are as follows:

	As of December 31,	
	2024	2023
Stock options	311	311
Restricted stock units	27	12
Performance stock units	70	31
BTI Warrants	1,792	22
Total common stock equivalents	2,200	376

Note 18. Commitments and Contingencies

From time to time, in the ordinary course of business, the Company may be subject to litigation and regulatory examinations as well as information gathering requests, inquiries and/or investigations. Other than the below, the Company is not currently subject to any matters where it believes there is a reasonable possibility that a material loss may be incurred.

On July 7, 2023, plaintiff Katelyn Martin filed a class action complaint against the Company and certain executives in the United States District Court for the District of Connecticut, captioned *Martin v. BioXcel Therapeutics, et al.*, 3:23-cv-00915 (D. Conn). The case has since been renamed to *Hills et al v. BioXcel Therapeutics, Inc. et al.* On October 4, 2023, pursuant to the Private Securities Litigation Reform Act, the court appointed two co-Lead Plaintiffs. The co-Lead Plaintiffs filed an amended complaint on December 5, 2023, alleging violations of Sections 10(b) and 20A of the Securities and Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder. On July 11, 2024, the Court dismissed the amended complaint without prejudice and, on August 1, 2024, co-Lead Plaintiffs filed a second amended complaint. The second amended complaint alleges that defendants made false or misleading statements regarding the TRANQUILITY II trial and the development of BXCL501 for an expanded indication related to the treatment of certain Alzheimer's-related agitation. The Company moved to dismiss the second amended complaint on

September 6, 2024. On February 24, 2025, while the Company's motion to dismiss remained pending, Plaintiffs moved for leave to further amend their complaint. The Company filed an opposition to the motion on March 17, 2025. Plaintiffs' reply is due April 7, 2025.

On November 28, 2023, Plaintiffs Pratheesan Panancherry and Jeffrey Bastress filed a stockholder derivative complaint in the United States District Court for the District of Connecticut purportedly on behalf of the Company and against Vimal Mehta, Richard I. Steinhart, Peter Mueller, June Bray, Sandeep Laumas, Michael Miller, Michal Votruba, and Krishnan Nandabalan as Defendants, and the Company as Nominal Defendant under the caption *Panancherry et al v. Mehta et al*, 3:23-cv-1554. Following the initial action, Plaintiffs Maria Vomvolakis (3:24-cv-3) and Kelly Fowler (3:24-cv-203) each filed separate stockholder derivative complaints in the District of Connecticut raising similar claims as Panancherry and Bastress, including business torts and violations of the Securities Exchange Act of 1934. The cases have been consolidated under the caption *In re BioXcel Therapeutics, Inc. Stockholder Derivative Litigation*, 3:23-cv-1554 (D. Conn.). The consolidated action is currently stayed.

On January 11, 2024, Plaintiff Jeremy Smith filed a stockholder derivative complaint in the United States District Court for the District of Delaware purportedly on behalf of the Company and against Vimal Mehta, Peter Mueller, June Bray, Sandeep Laumas, Michael Miller, Michal Votruba, Richard I. Steinhart, Robert Risinger, and Krishnan Nandabalan as Defendants, and the Company as Nominal Defendant under the caption *Smith v. Mehta et al,* 1:24-cv-00041. Following the initial action, Plaintiff Janice Korff filed a stockholder derivative complaint in the District of Delaware raising similar claims as Smith (1:24-cv-130), including business torts and violations of the Securities Exchange Act of 1934. The cases have been consolidated under the caption *In re BioXcel Therapeutics, Inc. Derivative Litigation*, 1:24-cv-00041 (D. Del.). The consolidated action is currently stayed.

At this time, the Company does not believe the claims in the above-captioned matters have merit, and intends to vigorously defend against them; however, the potential costs and liabilities associated with this litigation are uncertain.

In April 2022, the Company signed a commercial supply agreement that requires minimum annual payments for the first three years of the agreement that in aggregate total $10,000 for the three-year period, of which $5,000 was originally due in year ended 2024. On July 11, 2024, the Company entered into an amendment to the commercial supply agreement (the "Product Supply Agreement Amendment") that reduces the specified minimum annual payment over the next three years starting in the year ended 2024 and, thereafter, for a specified interval, provides for minimum annual payments to the extent that the Company receives approval of a supplemental new drug application (sNDA) or a new drug application (NDA) from the FDA for enumerated indications. The Company's renegotiated agreement reduced the minimum commitment for 2024 to $1,000 and thereafter for the term of the agreement in annual amounts ranging from $2,000 to $5,000 subject, in certain instances, to the extent that the Company receives approval of an sNDA or NDA from the FDA for enumerated indications. In accordance with the Product Supply Agreement Amendment, the minimum commitments were reduced to $1,000, $2,000 and $2,000 in the years 2024, 2025, and 2026. In addition, the Company agreed to make a reconciliation payment of $1,200, paid in the third quarter of 2024 for full settlement for amounts due prior to the July 11, 2024 amendment.

Note 19. Segment Information

The Company views its operations and manages its business as one operating and reportable segment, utilizing artificial intelligence ("AI") to develop transformative medicines in neuroscience and immuno-oncology. We are focused on utilizing cutting-edge technology and innovative research to develop high-value therapeutics aimed at transforming patients' lives. We employ various AI platforms to reduce therapeutic development costs and potentially accelerate development timelines.

Consistent with the operational structure, the Chief Executive Officer, as the chief operating decision maker ("CODM"), reviews weekly cash usage and allocates resources based on consolidated net loss that also is reported on the consolidated statements of operations. The measure of segment assets is reported on the balance sheet as total consolidated assets. The CODM utilizes consolidated net loss by comparing actual results against budgeted amounts on a quarterly basis. As part of this process, consolidated net loss is a critical performance measure used to evaluate the Company's operating performance and guide strategic decisions and resource allocations, including additional investments in research and development and commercialization activities.

The following table provides information about the Company's one reportable segment and includes the reconciliation to consolidated net loss.

	Year ended December 31,	
	2024	2023
Product revenue, net	$ 2,266	$ 1,380
Less:		
Cost of goods sold	$ 2,143	$ 1,260
Research and development costs:		
Personnel and related costs	$ 9,796	$ 16,351
Non-cash stock-based compensation	2,251	6,324
Professional fees	5,067	14,590
Clinical trials expense	9,384	35,094
Chemical, manufacturing and controls cost	1,927	8,687
Other expenses	2,010	3,280
Total research and development costs	$ 30,435	$ 84,326
Commercial costs:		
Personnel and related costs	2,516	19,331
Non-cash stock-based compensation	(401)	1,081
Professional fees	554	965
Commercial and marketing	1,389	12,485
Travel related expenses	309	2,004
Other expenses	906	2,038
Total commercial costs	$ 5,273	$ 37,904
Selling, general and administrative costs:		
Personnel and related costs	$ 5,340	$ 7,840
Non-cash stock-based compensation	4,306	11,209
Professional fees	15,583	21,345
Commercial and marketing	—	—
Travel related expenses	446	982
Other expenses	3,544	4,133
Total selling, general and administrative costs	$ 29,219	$ 45,509
Restructuring costs	2,441	4,163
Total operating expenses	$ 69,511	$ 173,162
Other (income) expense		
Interest expense	15,129	13,314
Interest income	(2,602)	(5,649)
Other (income) expense, net	(20,173)	(394)
Segment net loss	$ (59,599)	$ (179,053)
Adjustments and reconciling items	—	—
Consolidated Net Loss	$ (59,599)	$ (179,053)

Note 20. Subsequent Events

As discussed in Note 11, *Common Stock Financing Activities*, in connection with the November 2024 issuance and sale in a public offering of (i) 350 shares of the Company's common stock, and the November 2024 Accompanying Warrants to purchase 350 shares of Common Stock, and (ii) pre-funded warrants to purchase 563 shares of Common Stock, in February 2025, certain investors exercised the remaining 483 pre-funded warrants to purchase 483 shares of Common Stock.

On March 3, 2025, the Company entered into the Purchase Agreement with the Purchaser named therein. Pursuant to the Purchase Agreement, the Company agreed to issue and sell to the Purchaser and the Purchaser agreed to buy in a registered direct offering (i) an aggregate of 188 shares (the "Shares") of common stock, par value $0.001 per share and accompanying warrants to purchase up to 188 shares of Common Stock at a combined offering price of $3.50 per Share and accompanying warrant, and (ii) the Pre-Funded Warrants to purchase up to 3,812 shares of Common Stock and accompanying warrants to purchase up to 3,812 shares of Common Stock, at a combined offering price of $3.499 per share underlying the Pre-Funded Warrants and accompanying warrant, which equals the offering price per Share and accompanying warrant less the $0.001exercise price per share of the Pre-Funded Warrants, pursuant to an effective registration statement on Form S-3 (File No. 333-275261), including the base prospectus included therein, and prospectus supplement filed with the SEC on March 4, 2025. As of March 28, 2025, 1,688 Pre-Funded Warrants were exercised. In the 2025 Offering, the Company also issued to the Purchaser warrants (the "Option Warrants"), to purchase up to 4,000 shares of Common Stock (or pre-funded warrants in lieu thereof) and accompanying warrants to purchase up to 4,000 shares of Common Stock to the Purchaser. The pre-funded warrants and accompanying warrants issuable upon exercise of the Option Warrants will have substantially identical terms as the Pre-Funded Warrants and the accompanying warrants. The exercise price of the Option Warrants is $3.50 per underlying share of Common Stock and accompanying warrant to purchase one share of Common Stock, or $3.499 per underlying pre-funded warrant to purchase one share of Common Stock and accompanying warrant to purchase one share of Common Stock. The Option Warrants expired on March 18, 2025 without being exercised.

On March 26, 2025, we and Jefferies terminated that certain Open Market Sales Agreement, dated May 10, 2021, as amended on November 1, 2023.