**Risk Factors Comparison 2025-03-28 to 2024-03-22 Form: 10-K**

**Legend:** **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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** ~~transitioning from a company with~~ primarily ~~a~~ **on** research and development ~~focus~~ **while continuing** to **support IGALMI ®** ~~a company also capable of undertaking~~ 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 and $ 165. 8~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~, respectively. As of December 31, ~~2023~~ **2024**, we had a stockholders' deficit of approximately $ ~~56~~ **93**. ~~5~~ **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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. ~~Food and Drug Administration (" FDA ")~~ approval for ~~IGALMITM~~ -- **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 ~~related~~ **other workforce** ~~reduction~~ **reductions** ~~in force~~ 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**. ~~We~~ **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 ~~IGALMITM~~ -- **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 %. ~~As~~ **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, ~~2023~~ **2024** ~~, the Reprioritization was substantially completed~~ **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~~ **54In** 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 ~~IGALMITM~~ -- **IGALMI ®** in the near term because our commercial force will be significantly reduced. If we are unable to commercialize ~~IGALMITM~~ -- **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 ~~56collaborator~~ -- **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 ~~. Furthermore, 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 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 ~~IGALMITM~~ -- **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 ~~resulting from COVID- 19~~ , 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~~ **55when** needed. Our failure ~~57to~~ **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 ~~, after giving effect to the Reprioritization,~~ the Company' s cash and cash equivalents of $ ~~65~~ **29** . ~~2~~ **8** million as of December 31, ~~2023~~ **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 ~~mid-~~ **the third quarter of** ~~2024~~ **2025** . However, ~~the expected cost benefit of the Reprioritization cannot be assured, and~~ 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 ~~Fourth~~ **Fifth** Amendment to our Credit Agreement ~~includes~~ **included a new capital raising** ~~covenants~~ **covenant requiring** that ~~we will~~ **the Company** receive ~~,~~ ( ~~i~~ **A** ) after ~~March 20, 2024, which is~~ the effective date of the ~~Fourth~~ **Fifth** Amendment ~~,~~ and on or ~~before April 15~~ **prior to November 27** , 2024, at least $ ~~25~~ **7** . 0 million in gross **cash** proceeds from the issuance of ~~our~~ **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 ~~in~~ **pre- funded warrants, (ii)** non- refundable cash consideration from partnering transactions entered into after ~~March 20, 2024~~ **the effective date of the Fifth Amendment** (so long as such partnering transactions would not require ~~us~~ **the Company** or any of ~~our~~ **its** subsidiaries to make any cash investments in connection with the partnering transactions and no such cash investments are made), ~~and~~ ( ~~ii~~ **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 ~~March 20, 2024~~ **the effective date of the Fifth Amendment** and on or ~~before November~~ **prior to the earlier of (x) August 15, 2025 and (y) the date that is** 30 ~~, 2024~~ **days after the final data readout of the SERENITY At- Home Phase 3 trial** , at least $ ~~50~~ **29** . 0 million **in net cash proceeds** ( ~~for~~ **" Raise 3 ") (including** the ~~avoidance of doubt, inclusive of amounts previously counted toward~~ **proceeds from Raise 1 and Raise 2) from the same permitted capital raising activities listed in** the preceding clause ( ~~i~~ **B** ) **. The Company** ~~) 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~~ **has met** ~~determined by~~ the ~~Administrative Agent (~~ **requirements of Raise 1 and Raise 2, but** ~~as~~ **has** ~~defined~~ **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** ) ~~in its sole discretion~~ from **and** ~~partnering transactions entered into~~ after **the closing of Raise 1 until** March ~~20~~ **30** , ~~2024~~ **2025** . **On March 31, 2025,** ~~Failure to perform this covenant would constitute (A) a default under~~ the ~~Credit Agreement and (B)~~ **minimum liquidity amount will increase to $ 10. 0 million,** ~~an~~ **and on September 30** ~~event of default under the Credit Agreement~~ , **2025** ~~subject to a cure period in the case of clause (i) of the preceding sentence~~ , ~~until May~~ **the minimum liquidity amount will further increase to $** 15 ~~, 2024~~ . **0 million** ~~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~~ . 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 ~~IGALMITM~~ -- **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 ~~; ● our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure~~ ; ● revenue received from commercial sales of ~~IGALMITM~~ -- **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; **56** ● 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; ~~58~~ ● 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, ~~2023~~ **2024** , we had aggregate principal indebtedness of $ ~~102~~ **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 ~~a~~ **certain** minimum cash liquidity ~~amount~~ **amounts** ~~of $ 15 million (or higher upon certain events, including as described in the Fourth Amendment to the Credit Agreement described in Note 19, Subsequent Events in the audited financial statements included elsewhere in this Annual Report on Form 10- K) and a 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, subject to cure payments of not less than $ 1. 0 million if we fail to meet the minimum revenue requirement. The minimum revenue requirement applies beginning with the preceding six- month period ending on December 31, 2024, and ranges from approximately $ 4. 5 million for the fourth quarter of 2024 to approximately $ 47. 9 million for the first quarter of 2027. If we fail to meet the minimum revenue requirements for the preceding six- month periods ending on December 31, 2024, March 31, 2025, June 30, 2025 and September 30, 2025, we could be required to make revenue cure payments for the revenue shortfalls of up to $ 4. 5 million, $ 6. 2 million, $ 8. 5 million, and $ 8. 5 million, respectively, plus aggregate prepayment fees of $ 1. 9 million. Under the Credit Agreement, these cure payments would be due on April 21, 2025, June 6, 2025, September 5, 2025 and December 8, 2025, respectively. We are only permitted to make cure payments for revenue shortfalls up to three times during the term of the Credit Agreement, after which we would default on the Credit Agreement if we are unable to satisfy the minimum revenue requirement for any subsequent fiscal quarter~~ . 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** ~~In March 2024 we entered into a Fourth Amendment to the~~ Credit Agreement **also includes** ~~, pursuant to which the~~ **other** ~~Lenders waived~~ **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 ~~this covenant~~ **covenants** ~~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 ~~IGALMITM~~ -- **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~~ **57payments** 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 ~~respect~~ **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** ~~the~~ **other** ~~report~~ **strategic alternatives to attempt to meet our debt service obligations. We have identified conditions and events that raise substantial doubt regarding our ability to** ~~contained~~ -- **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. The Fourth Amendment to the Credit Agreement..... 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, ~~2023~~ **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 58their 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 CandidatesWe 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 ~~60any --~~ **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 ~~remains open, however, as the FDA~~ **of a single site in its TRANQUILITY II** ~~has~~ **Phase** ~~not issued~~ **3 trial is closed under 21 C. F. R. 20. 64 (d) (3)** ~~an~~ **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~~ **59Since** 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. ~~However,~~ **The primary efficacy endpoint in TRANQUILITY II was** the ~~FDA may~~ **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 ~~accept~~ **been used as a primary endpoint to support the approval of a drug candidate** ~~or~~ **for** ~~agree~~ **the treatment of agitation associated** with ~~our conclusions~~ **Alzheimer' s Disease. Prior to initiating** ~~or~~ **our** ~~analyses or may interpret or weigh their importance differently. Further, if we or the FDA determine that there are issues with data integrity and / or compliance with good clinical practice (" GCP ") requirements at the trial site, we may be unable to use some or all of the subject data generated at this clinical site to support a marketing application. Any issues identified at this trial site may also be identified at other trial sites. If all of data from this clinical trial site were discarded, the~~ TRANQUILITY II trial **, we believe we reached alignment with** ~~would no longer be adequately powered for statistical significance or would not be considered adequately well- controlled by the~~ FDA **regarding the** ~~, and in either case, we would need to conduct a new comparable clinical trial before we are able to seek any approval of BXCL501 for~~ 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 ~~acute~~ **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** ~~(non- daily) due to dementia in probable~~ Alzheimer' s ~~disease~~ **Disease** . ~~If a substantial portion of the~~ **While we believe that we have generated sufficient** data ~~were discarded~~ **to demonstrate such consistency** , ~~similar outcomes~~ **and we plan to submit these data and analyses to the FDA, if the FDA disagrees, it** may ~~also~~ **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** ~~occur~~ -- **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- ~~61dose~~ -- **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 ~~using~~ **, including through, among** ~~the~~ **other things** ~~PEC as the primary efficacy measure~~ , **conducting our planned** ~~as used in the prior TRANQUILITY~~ - **TRANQULITY** ~~II study~~ **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 ~~the~~ **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~~ **60and** 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 ~~a strategic reprioritization of our commercialization and development efforts (~~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 ~~have limited data supporting~~ **are conducting the SERENITY At- Home Phase 3 trial evaluating the safety of** BXCL501 ~~' s potential use~~ **for the acute treatment of agitation associated with bipolar disorders or schizophrenia** in the at- home setting ~~. In particular~~ , **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 ~~62trials --~~ **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~~ **61clinical** 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 ~~IGALMITM --~~ **IGALMI ®** 120 micrograms to the acute treatment of agitation associated with schizophrenia and bipolar disorders in the outpatient setting. ~~IGALMITM --~~ **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 ~~IGALMITM --~~ **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 ~~IGALMITM --~~ **IGALMI ®** 120 mcg to allow at- home use and labeling without the current LOU. Based on current FDA feedback, we **have** ~~plan to amend~~ **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 ~~amended~~ **planned** SERENITY ~~III~~ **At- home** trial is successful in demonstrating safety in the at- home setting, and even if the ~~IGALMITM --~~ **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. ~~We plan to provide further guidance regarding our plans for the SERENITY program following receipt of the final meeting minutes from the FDA. Even if the protocol for SERENITY III Part 2 is amended as described above, and even if the study produces favorable data, such data may not be sufficient for approval without additional clinical studies.~~ 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 ~~our~~ **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. ~~63In~~ **In** the near term, we are dependent on the success of ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **IGALMI ®** and it is possible that will have adverse consequences on the revenue that we are able to generate from ~~IGALMITM~~ -- **IGALMI ®** in the near term. As part of the Company' s Reprioritization, the ~~IGALMITM~~ -- **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~~ **62The** success of ~~IGALMITM~~ -- **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; ~~64~~ ● 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 ~~IGALMITM~~ -- **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~~ **63of** 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 ~~65setbacks~~ -- **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; **64** ● 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 ~~66receive~~ -- **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 ~~IGALMITM~~ -- **IGALMI ®** or our other product candidates are not as significant as we estimate, we may not generate significant revenues from sales of ~~IGALMITM~~ -- **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~~ **65per** 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; ~~67~~ ● 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; **66** ● 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 ~~68requirements~~ -- **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~~ **67If** 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. ~~69Our~~ -- **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~~ **68medical** 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 ~~IGALMITM~~ -- **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. ~~70The~~ -- **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 ~~IGALMITM~~ -- **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 69technological 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~~ **or70** ● 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 ~~71technology --~~ **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~~ **71candidate** 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. ~~72If~~ **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~~ **72If** 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 ~~73approval~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **IGALMI ®** and for any product candidates for which we obtain approval. Any regulatory approvals that we may receive for ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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~~ **73approval** . 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 ~~74authority~~ -- **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 ~~IGALMITM~~ -- **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~~ **74treatment** for some patients in varied circumstances. For example, other formulations of Dex, the active ingredient in ~~IGALMITM~~ -- **IGALMI ®** , have been approved for uses beyond those authorized in ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **IGALMI ®** for these uses. ~~75Regulatory~~ -- **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 ~~IGALMITM~~ -- **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** ~~global health concerns~~ could ~~hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise~~ prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, 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. ~~Separately~~ **Additionally** , **recent actions by the United States federal government have caused concern** in ~~response~~ **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** ~~the~~ **they withstand legal challenges** ~~COVID- 19 pandemic~~ , ~~the~~ **may significantly delay and impede our interactions with** FDA ~~postponed most inspections of domestic and foreign~~

~~manufacturing facilities at various points~~ . ~~Even though~~ **Similar results may stem from** the **recent confirmed resignations of some senior** FDA **employees with responsibility** ~~has since resumed standard inspection operations, any resurgence of the virus or~~ **for** ~~emergence~~ **regulation** of ~~new variants may lead to further inspectional delays~~ **drugs and biologics, as well as possible future layoffs and resignations** . ~~If a prolonged~~ **There are also reports that the United States federal** government **intends to request Congress to reduce** ~~shutdown occurs, or if global health concerns prevent the~~ FDA **funding in upcoming budgets. Such funding cuts may also delay the development and approval of** ~~or~~ **our product candidates** ~~other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business~~ . 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~~ **75study** 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 ~~76authority~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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~~ **76determine** 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 ~~77regulatory~~ -- **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; **77** ● 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; ~~78~~ ● 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 ~~IGALMITM~~ -- **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~~ **78Risks** Related to Commercialization of Our Product CandidatesIf 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; ~~79~~ ● 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 ~~TM~~ **®** 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 ~~TM~~ **®** and it is possible that will have adverse consequences on the revenue that we are able to generate from IGALMI ~~TM~~ **®** . Revenues for IGALMI ~~TM~~ **®** for the year ended December 31, ~~2023~~ **2024** were $ ~~1~~ **2** . ~~4~~ **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 ~~TM~~ **®** 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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **IGALMI ®** . Our ability to accurately forecast demand for ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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~~ **79Our** 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 ~~80research~~ -- **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~~ **80seven** 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. ~~81Even~~ - **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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~~ **81We** 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. ~~82Many~~ -- **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 ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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. ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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; **82** ● 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. ~~83Significant~~ -- **Significant** uncertainty exists as to the coverage and reimbursement status of ~~IGALMITM~~ -- **IGALMI ®** or any product candidate for which we obtain regulatory approval. In the U. S. and other countries, sales of ~~IGALMITM~~ -- **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. ~~IGALMITM --~~ **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 ~~IGALMITM --~~ **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 ~~IGALMITM --~~ **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~~ **83Since** 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 ~~84remain --~~ **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 ~~IGALMITM~~ **IGALMI ®** and any other drug products for which we may obtain ~~regulatory~~ **84regulatory** 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 ~~85and~~ **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 ~~IGALMITM~~ **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~~ **85if** 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 ~~86publishes~~ -- **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~~ **86which** 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 LLCBioXcel 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, ~~2023~~ **2024** , BioXcel LLC owned approximately ~~29~~ **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 ~~87and~~ -- **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 ~~have~~ **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~~ **87payable** 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. ~~88On~~ **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, ~~2023~~ **2024** , Dr. Mehta, through his beneficial ownership of BioXcel LLC, beneficially owned approximately ~~31~~ **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~~ **88Any** 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; ~~89~~ ● 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~~ **89ability** 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 PartiesWe are substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates and our commercial supplies of ~~IGALMITM~~ -- **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 ~~IGALMITM~~ -- **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 ~~90delays~~ -- **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~~ **90encounter** 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 ~~. Moreover, as a result of the COVID- 19 pandemic, third- party manufacturers have been and may in the future be affected, which could disrupt their activities and, as a result, we could face difficulty sourcing key components necessary to produce supply of our commercial product and product candidates, which may negatively affect our preclinical and clinical development activities~~ . 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 ~~91at~~ **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 ~~IGALMITM --~~ **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~~ **91We** 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 ~~92any --~~ **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~~ **92Risks** Related to Our Business and **IndustryUnfavorable** ~~IndustryPandemics, epidemics or outbreaks of an infectious disease, such as COVID- 19, may materially and adversely impact our business, including our preclinical studies and clinical trials. As a result of outbreaks from variants of COVID- 19, or other pandemics, epidemics or outbreaks of infectious disease, we may experience disruptions that could severely impact our business, preclinical studies and clinical trials, including: ● delays or difficulties in initiating, operating and completing our clinical trials; ● interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints; ● interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; ● interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and93 ● other interruptions or delays to our sourced discovery and clinical activities. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions from COVID- 19 or other pandemics, epidemics or outbreaks of infectious disease, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. Unfavorable~~ global political or economic events and conditions could adversely affect our business, financial condition or results of operations. Our **business** ~~results of operations~~ could be adversely affected by ~~general~~ **unstable economic and political** conditions ~~in~~ **within** the ~~world~~ **United States and foreign jurisdictions** , **including as a result of** ~~and~~ **an** ~~their impact on the global economy~~ **economic downturn** and **geopolitical events, such as changes** in **U** ~~the global financial markets~~ . ~~The~~ **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. ~~94We~~ **93We** 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; ~~95~~ **94** ● 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 ~~96described~~ **95described** 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 ~~IGALMITM~~ -- **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. ~~97Actual~~ **96Actual** 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 ~~. 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. New laws regulating AI are at an advanced stage of the legislative process in the EU, and it is possible that new laws and regulations will be adopted in the United States and in other non- U. S. jurisdictions, or that existing laws and regulations may be interpreted in ways that would affect the operation of our learning platforms, online testing business and data analytics and the way in which we use AI and machine learning technology. In Europe, on December 8, 2023, the European Union legislators reached a political agreement on the EU Artificial Intelligence Act (" EU AI Act ") which establishes a comprehensive, risk- based governance framework for artificial intelligence in the EU market. The EU AI Act is expected to enter into force in 2024, and the majority of the substantive requirements will apply two years later. The EU AI Act will apply to companies that develop, use and / or provide artificial intelligence in the EU and includes requirements around transparency, conformity assessments and monitoring, risk assessments, human oversight, security, accuracy, general purpose artificial intelligence and foundation models, and proposes fines for breach of up to 7 % of worldwide annual turnover. In addition, on September 28, 2022, the European Commission proposed two Directives seeking to establish a harmonized civil liability regime for AI in the EU. Once fully applicable, this regulatory framework is expected to have a material impact on the way AI is regulated in the EU, and together with developing guidance and / or decisions in this area, may affect our use of AI and our ability to provide, improve or commercialize our services, require additional compliance measures and changes to our operations and processes, result in increased compliance costs and potential increases in civil claims against us, and could adversely affect our business, operations and financial condition. 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~~ . 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, ~~98among~~ -- **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~~ **97the** 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 ~~99elect~~ **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; **98** ● 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. ~~100Our~~ **Our** ability to use our net operating losses and tax credits to offset future taxable income and income tax liabilities may be limited. **At** ~~As of~~ December 31, ~~2023~~ **2024** ~~,~~ the Company had **approximately $ 432. 6 million of gross** federal **and $ 443. 5 million of gross state** net operating loss **carry-** ~~carryforwards~~ ----- **forwards. Tax Cuts and Jobs Act** (“ ~~NOLs~~ **TCJA** ”) ~~of approximately $ 351. 3 million and state NOLs of approximately $ 360. 1 million. If not utilized, the federal and state NOLs, which are subject to expiration, will begin to expire~~ in ~~2037~~ **2017 amended the net operating losses carryforward rules** .

~~Federal NOLs~~ **Net operating losses** generated ~~in taxable years beginning~~ after December 31, 2017 **,** may be carried forward indefinitely ~~but~~ **, subject to certain limitations on their use. Net operating losses generated prior to 2018** may ~~only~~ be **carried forward for twenty** ~~used to offset 80 % of our taxable income in future taxable~~ years ~~beginning~~ **. 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** ~~2020. As of December 31~~ **, and will be carried forward indefinitely; the balance of the federal net operating losses are subject to expiration no later than** ~~2023~~ **2037** ~~, we also had~~ **. 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 $ ~~14~~ **16** . ~~3~~ **0** million of federal orphan drug credits and research and development credits ~~and $ 1. 2 million of state research and development credits,~~ which will begin to expire in 2037 if not utilized. The ~~utilization~~ **Company also has approximately $ 1. 5 million** of ~~such NOLs~~ **state research** and ~~tax~~ **development** credits ~~and realization of tax benefits~~ **which will begin to expire** in **2040 if not utilized** ~~future years depends upon our having taxable income and income tax liabilities~~. In addition, ~~in general,~~ under ~~Sections~~ **sections** 382 and 383 of the ~~Internal Revenue~~ Code ~~of 1986~~ , **our federal net operating losses and tax credit carryforwards, such** as ~~amended~~ **research / development credits and orphan drug credits** , ~~a corporation that undergoes~~ **may become subject to** an ~~"~~ **annual limitation in the event of certain cumulative changes in the** ownership **interest** ~~change "~~ ~~is subject to limitations on its ability to utilize its pre- ownership change NOLs and tax credits to offset future taxable income or income tax liabilities. For these purposes, an ownership change generally occurs where the aggregate change in stock ownership,~~ of **significant** ~~one or more~~ stockholders **(** or groups of stockholders ~~owning at least 5~~ **) in excess of 50** % ~~of a corporation' s stock, exceeds 50 percentage points~~ over a rolling three- year period. ~~We~~ **Similar state provisions** may ~~have experienced~~ **also exist. These** ownership changes ~~in~~ **may limit** the ~~past,~~ **amount of the net operating losses** and **tax credit carryforwards that can be utilized annually to offset** future ~~changes in our stock ownership~~ **taxable income and income tax** , ~~many of which~~ **respectively. Entities** are ~~outside of~~ **also required to evaluate, measure, recognize and disclose any uncertain federal** ~~our~~ **or** ~~control~~ **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 ~~result in ownership changes in~~ **apply from that date because** the ~~future~~ **utilization of net operating losses from prior years opens the relevant tax year to audit by The U** . ~~Our~~ **S. Internal Revenue Service (" IRS ") and / or** state ~~NOLs or~~ **taxing authorities. The Company did not have any unrecognized** tax **benefits and has** ~~credits may also be impaired under state law. Accordingly, even if we attain profitability, we may~~ not **accrued any interest** ~~be able to utilize a material portion of our~~ **or** NOLs **penalties** ~~or~~ **for** ~~tax credits. We have recorded a full valuation allowance related to our NOLs and other~~ **the 12 months ended December 31, 2024 and 2023** ~~deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets~~. ~~Risks~~ **99Risks** Related to Our Intellectual PropertyIt 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 ~~101obtain~~ **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; **100** ● 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 ~~102of~~ **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~~ **101In** 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, ~~103patent~~ --- **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~~ **102products** 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 ~~104for~~ **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 ~~IGALMITM~~ -- **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~~ **103property** 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 ~~105property~~ --- **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~~ **104Third** 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 ~~106found~~ --- **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~~ **105substantial** 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. ~~If we do not obtain patent term extension in the United States under the Hatch- Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for IGALMITM, or our product candidates, our business may be materially harmed. Following the approval by the FDA for our NDA to market IGALMITM, we became eligible to seek and sought patent term restoration under the Hatch- Waxman Act for one of the U. S. patents covering our approved product or the use thereof. The Hatch- Waxman Act allows a maximum of one patent to be extended per FDA approved product. Patent term extension also may be available in certain foreign countries upon regulatory approval of our product candidates. 107Despite seeking patent term extension for our product candidates, we may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request.~~ 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~~ **106If** 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 " ~~IGALMITM~~ **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 ~~108rejections~~ **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~~ **107confidential** 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 ~~109able~~ **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~~ **108engagement** . 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. ~~110Furthermore~~ --- **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~~ **109Changes** 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 ~~our~~ patents **we own** ~~and those of our~~ **or** ~~licensor~~ **license and** ~~, BioXcel LLC,~~ 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 StockThe 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: ~~111~~ ● 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; **110** ● 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; ~~112~~ ● 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~~ **111stock** 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** ~~Because certain of our stockholders control a significant number of shares~~ of our common stock, **including** ~~they may have significant influence over actions requiring stockholder approval. As of December 31, 2023, our directors, executive officers and BioXcel LLC, and their respective affiliates, beneficially owned approximately 35 % of our outstanding shares of~~ common stock ~~. As a~~ **that may be sold following exercise of outstanding warrants, would** result ~~,~~ **in additional dilution of** ~~these -- the~~ **the percentage ownership of our** stockholders **and** ~~, acting together, would~~ **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 ~~significant control over~~ **sold, and in the future may sell, common stock, convertible securities or** ~~the~~ **other** ~~outcome of matters submitted~~ **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** ~~for approval, including the election of directors and any merger, consolidation or sale of all or substantially -- substantial all of~~ **dilution, and new investors could gain rights superior to** our ~~assets~~ **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** ~~these -- the stockholders~~ **Fifth Amendment of our Credit Agreement (see Note 9** , ~~acting together~~ **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** ~~would~~ **could** have **a negative effect on** ~~significant control over the management and affairs of our Company. Accordingly, this concentration of ownership might harm~~ the market price of our common stock **and make it more difficult** ~~by: ● delaying, deferring or~~ **for** ~~preventing a change in corporate control; ● impeding a merger, consolidation, takeover or other business combination involving~~ us ~~;~~ **to raise funds through future equity offerings. In the event these warrants are exercised,** ~~or~~ **our** ~~● discouraging a potential acquirer from making a tender offer~~ **stockholders will experience additional dilution. To the extent outstanding stock options or warrants are exercised, there would be further dilution to** ~~or our otherwise attempting to obtain control~~ **existing stockholders, which could impact the price** of ~~us~~ **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 ~~113items --~~ **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~~ **112make** 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 ~~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. ~~Defendants~~ **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 ~~a~~ **an opposition to the** motion ~~to dismiss~~ on ~~February 6~~ **March 17** , ~~2024~~ **2025 . Plaintiffs' reply is due April 7** , **2025** ~~which has not been decided~~ . 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 ~~above- captioned~~ consolidated action is currently stayed. ~~114On~~ **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~~ **113Mehta** 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 ~~Company expects to seek a stay in the above- captioned~~ 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 ~~investigation~~ **investigator** ~~by~~ **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 ~~115may~~ **114may** 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 FactorsIf 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~~ **future ,** ~~sales and issuances of our~~ **or** ~~common~~ **, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our** stock **price** could **decline significantly** ~~result in additional dilution of the percentage ownership of our stockholders~~ and **raising capital** could ~~cause~~ **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,** ~~our~~ **or** ~~share~~ **, if we discover material weaknesses and other deficiencies in our internal control and accounting procedures, our stock** price **could decline** ~~to fall. We expect that significant~~ **significantly** ~~additional~~ **and raising** capital ~~will~~ **could** be ~~needed in the future to continue our planned operations, including increased marketing, hiring new personnel, commercializing our products, and continuing activities as an operating public company. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or~~ more **difficult** ~~transactions at prices and in a manner we determine from time to time~~ . **115** ~~If we sell common stock, convertible 116~~