**Risk Factors Comparison 2024-03-27 to 2023-03-23 Form: 10-K**

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

Risk factors that could cause actual results to differ from our expectations and that could negatively impact our financial condition and results of operations are discussed below and elsewhere in this Annual Report. Additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. If any of the risks or uncertainties described below or any additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected. Risks Relating to Our Business We have a limited operating history and we may never generate revenue or profit. We are a clinical- stage biotechnology company that commenced activities in January 2012. We ~~only~~ have a limited operating history **,** and our business plan has not been tested. Since inception, we have had no revenue and have incurred significant operating losses. We have financed our operations primarily through equity and debt offerings. To generate revenue and become and remain profitable, we need to ~~develop and commercialize gedatolisib pursuant to our license agreement with Pfizer and~~ successfully complete our existing clinical ~~trial~~ **trials ,** ~~collaborations and~~ cultivate partnerships with pharmaceutical companies **, and develop and commercialize gedatolisib pursuant to our license agreement with Pfizer** . We must also build operational and financial infrastructure to support commercial operations, train and manage employees, and market and sell our anticipated drug products and **/ or** our CELsignia tests (as a companion diagnostic and / or as a stand- alone test). We may never succeed in any of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. We expect to continue to incur significant expenses and operating losses for the foreseeable future, and the net losses we incur may fluctuate significantly from quarter to quarter. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain or expand our research and development efforts, expand our business, or continue our operations. Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize our integrated therapeutic (Rx) and companion diagnostic (CDx) strategy. We may require additional capital to finance capital expenditures and operating expenses over the next several years as we launch our integrated therapeutic and companion diagnostic strategy and expand our infrastructure, commercial operations and research and development activities. **If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to our company. Future financing activities could dilute the percentage ownership of our stockholders and could cause our stock price to fall, or could result in operating or other restrictions.** We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, **it will result in** dilution to ~~our~~ **current** stockholders ~~could result~~ . Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our existing securities. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also include restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. ~~If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to our company.~~ We will be dependent on our ability to attract and retain key personnel. Our operations will be materially dependent upon the services of our officers and key employees, including Brian F. Sullivan, our Chief Executive Officer, and Dr. Lance G. Laing, our Chief Science Officer. Successful implementation of our business plan will also require the services of other consultants and additional personnel. We cannot assure you that we will be able to attract and retain such persons as employees, independent contractors, consultants or otherwise. If we are not able to attract individuals with the skills required for our business, or if we lose the services of either Mr. Sullivan or Dr. Laing, we may be unable to successfully implement our business plan. The COVID- 19 pandemic may materially..... that may occur in the future. Risks Related to Our ~~Drug~~ Product **Strategy** ~~, Gedatolisib~~ Our ~~future strategy is~~ **near- term revenue prospects** ~~dependent~~ --- **depend** on the success of our initial drug product, gedatolisib ~~, as well as other drug products we may develop~~ . If we are unable to successfully complete clinical development of, obtain regulatory approval for or commercialize **gedatolisib** ~~our drug products~~ , or if we experience delays in doing so, our business will be materially harmed. To date, we have not yet completed any registrational clinical trials or the development of ~~any~~ **our initial** drug ~~products~~ **candidate, gedatolisib** . Our future success and ability to generate revenue ~~from our drug products~~ , which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more ~~drug~~ products **, and currently, our primary focus is to pursue approval and commercialization of gedatolisib for one or more intended uses** . We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, ~~a drug~~ **our current or future** product **candidates** if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, **gedatolisib** ~~our drug products~~ , including: ● our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that **gedatolisib is** ~~our drug products are~~ safe and effective; ● insufficiency of our

financial and other resources to complete the necessary preclinical studies and clinical trials; ● negative or inconclusive results from our preclinical studies, clinical trials or the clinical trials of others for drug products similar to ours, leading to a decision or requirement to conduct additional preclinical studies or clinical trials or abandon a program; ● product- related adverse events experienced by subjects in our clinical trials or by individuals using drugs or therapeutic biologics similar to **gedatolisib** ~~our drug products~~; ● delays in submitting applications, or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination of a clinical trial once commenced; ● conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials; ● poor effectiveness of **gedatolisib** ~~our~~ **or** ~~drug products~~ **companion therapeutics** during clinical trials; ● better than expected performance of control arms, such as placebo groups, which could lead to negative or inconclusive results from our clinical trials; ● delays in enrolling subjects in clinical trials; ● high drop- out rates of subjects from clinical trials; ● inadequate supply or quality of drug products or other materials necessary for the conduct of our clinical trials; ● greater than anticipated clinical trial or manufacturing costs; ● unfavorable FDA or comparable regulatory authority inspection and review of a clinical trial site; ● failure of our third- party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; ● delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular; or ● varying interpretations of data by the FDA and comparable foreign regulatory authorities. We were not involved in the early development of gedatolisib; therefore, we are dependent on third parties having accurately generated, collected, interpreted and reported data from certain preclinical and clinical trials of gedatolisib. We had no involvement with or control over the initial preclinical and clinical development of gedatolisib. We are dependent on third parties having conducted their research and development in accordance with the applicable protocols and legal, regulatory and scientific standards; having accurately reported the results of all preclinical studies and clinical trials conducted with respect to such drug product; and having correctly collected and interpreted the data from these trials. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of our drug product will **be delayed and may** be adversely affected. As an organization, we have never successfully completed any registrational clinical trials, and we may be unable to do so for any drug candidates we may develop. We will need to successfully complete registrational clinical trials in order to obtain the approval of the FDA or comparable foreign regulatory authorities to market our drug products. Carrying out clinical trials, including later- stage registrational clinical trials, is a complicated process. As an organization, we have not previously completed any registrational clinical trials. In order to do so, we will need to build and expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential product candidates. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission and approval of our drug products. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approval of any drug products that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our drug products. If we encounter difficulties enrolling patients in..... ● experience damage to our reputation. The successful development of ~~biopharmaceuticals~~ **our products** is highly uncertain. **Our business depends on the** ~~Successful~~ **successful** development of biopharmaceuticals **, which** is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons including, among other things, that clinical trial results may show the product candidates to be less effective than expected or to have unacceptable side effects or toxicities; we may fail to receive the necessary regulatory approvals or there may be a delay in receiving such approvals; or the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one drug product to the next and from one country to the next and may be difficult to predict. ~~Even~~ **We will incur significant research and development expenses before knowing whether our products are commercially viable, and may abandon development of a specific trial, or a product candidate, at any time for a variety of reasons. For example, we terminated the FACT- 2 Trial for our CELsignia diagnostic test in the third quarter of 2023 in response to FDA approvals of new therapeutic options for certain patients that negatively impacted enrollment. If we expend resources on products that are ultimately not commercially viable, our timing for becoming profitable and our ability to invest in other products in our pipeline would be adversely affected. In addition,** if **gedatolisib receives marketing approval for the intended uses that** we are **pursuing** ~~successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third- party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the U. S. or country specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third- party payors could require us to conduct additional studies, including post- marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. In addition, if any of our drug products receive marketing approval~~, we will **continue to** be subject to significant post- approval regulatory obligations. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post- approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our drug products post- approval could adversely affect our business, financial condition and results of operations. If

we encounter difficulties enrolling patients in any of our clinical trials,our clinical development activities could be delayed or otherwise adversely affected.The timely completion of clinical trials in accordance with their protocols depends,among other things,on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion.We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons,including:● the patient eligibility and exclusion criteria defined in the protocol;● the size of the patient population required for analysis of the clinical trial' s primary endpoints;● the proximity of patients to clinical trial sites;● the design of the clinical trial;● our ability to recruit clinical trial investigators with the appropriate competencies and experience,and the ability of these investigators to identify and enroll suitable patients;● perception of the safety profile of our drug products;● our ability to obtain and maintain patient consents;and ● the risk that patients enrolled in clinical trials will drop out of the trials before completion.Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical trials,which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.Clinical development involves a lengthy and expensive process,with an uncertain outcome.We may incur additional costs or experience delays in completing,or ultimately be unable to complete,the development and commercialization of our product candidates.To obtain the requisite regulatory approvals to commercialize any drug products,we must demonstrate through extensive preclinical studies and clinical trials that such drug product is safe and effective in humans.Clinical testing is expensive and can take many years to complete,and its outcome is inherently uncertain.We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful,and a clinical trial can fail at any stage of testing.Differences in trial design between early- stage clinical trials and later- stage clinical trials **,which involve a greater number of patients and take years to complete,** make it difficult to extrapolate the results of earlier clinical trials to later clinical trials.Moreover,clinical data are often susceptible to varying interpretations and analyses,and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.Additionally,we are conducting and plan to conduct some open- label trials,where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo.Most typically,open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels.Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in those trials are aware when they are receiving treatment.Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment.In addition,open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge.Where a randomized,placebo- controlled clinical trial is designed to allow enrolled subjects to cross- over to the treatment arm,there may be a risk of inadvertent unblinding of subjects prior to cross- over,which may limit the clinical meaningfulness of those data and may require the conduct of additional clinical trials.As such,the results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control.Successful completion of clinical trials is a prerequisite to submitting a new drug application,or NDA,to the FDA and similar marketing applications to comparable foreign regulatory authorities for each drug product and,consequently,the ultimate approval and commercial marketing of any drug products.We may experience delays in initiating ~~or~~ **our** ~~completing~~ **Phase 3** clinical ~~trials~~ **trial** ~~and preparing~~ **due to requests from the FDA** for **additional information,including additional nonclinical or clinical data,or for requests to amend the clinical trial protocol.Additional delays may be incurred once the Phase 3 clinical trial is initiated if it takes longer than expected to activate the targeted number of clinical sites,if the enrollment of patients is negatively affected by staffing shortages at clinical sites,or by other unanticipated factors,or if the FDA and other** regulatory ~~submissions~~ **authorities require us to pause our Phase 3 clinical trial due to unexpected safety issues** .We also may experience numerous unforeseen events during,or as a result of,any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our current product candidates or any future product candidates.Our costs will increase if we experience delays in clinical testing or marketing approvals.We do not know whether ~~any of~~ our clinical trials will begin **or continue** as planned,will need to be reassigned or will be completed on schedule,or at all.Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do,potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.Any delays in our clinical development programs may harm our business,financial condition and results of operations significantly. ~~For a new drug to be approved for marketing,the FDA and other regulatory authorities must determine that the drug is safe and effective.Because all drugs can have adverse effects,the data from our Phase 3 clinical study must demonstrate to the satisfaction of the FDA and other health authorities that the benefits of gedatolisib in combination with palbociclib and fulvestrant,or gedatolisib in combination with fulvestrant,outweigh its risks.Failure to demonstrate sufficient magnitude of benefit,even if the benefit is found to be statistically significant,may not support regulatory approval.If a drug meets its primary~~ We face significant competition ~~from other biopharmaceutical companies~~ , and our operating results will suffer if we fail to compete effectively. **Our** ~~The biopharmaceutical~~ industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results **than our lead product candidate, gedatolisib** . Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical **and diagnostic** companies **,** and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well- established sales forces. Smaller or early- stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that

**gedatolisib is** ~~our product candidates are~~ also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in- license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaboration partners, may succeed in developing, acquiring or licensing on an exclusive basis ~~drug or biologic~~ products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price **,** and reimbursement **. With respect to our CELsignia platform, which is a novel approach to companion diagnostics, we will need to demonstrate compelling advantages on a cost- competitive basis, educate key opinion leaders, and successfully collaborate with partners in the discovery, development, and commercialization of our tests** . Even if we obtain regulatory approval of drug products, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. ~~Even if~~ **If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could face clinical trial delays; regulatory investigations or actions; litigation; fines and penalties, disruptions of our business operations; reputational harm; and other adverse consequences. Cyberattacks, malicious internet- based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. We rely on contract research organizations, contract manufacturing organizations, distributors, supply chain resources, and other third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, on- site systems and cloud- based data centers, systems handling human resources, financial reporting and controls, customer relationship management, regulatory compliance, and other infrastructure operations. We also communicate sensitive data, including patient data, electronically, and through relationships with multiple third- party vendors and their subcontractors. These applications and data encompass a wide variety of sensitive information, including research and development information, patient data, commercial information, and business and financial information. Our ability to monitor these third parties' security practices is limited, and these third parties may not have adequate security measures in place. If we or** any ~~drug product~~ **of our third- party service providers experience a security incident or other interruption,** we ~~develop receives marketing approval~~ **could experience adverse consequences. We cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our services. Cybersecurity threats are becoming increasingly difficult to detect** , ~~it~~ **and come from a variety of sources, including without limitation nation- state actors and activists that create disruption for geopolitical reasons and in conjunction with military conflicts and defense activities. This risk is heightened during times of war and other major conflicts, including the war between Russia and Ukraine, the state of war between Israel and Hamas and the risk of a larger regional conflict. In addition, we and the third parties upon which we rely face an evolving cybersecurity threat landscape, which includes social- engineering attacks (including through deep fakes, which** may ~~fail~~ **be increasingly more difficult** to **identify as fake** ~~achieve the degree of market acceptance by physicians~~ , ~~patients, third- party payors~~ and **phishing attacks)** ~~others in the medical community necessary for commercial success. If any future drug product we develop receives marketing approval~~ , ~~whether~~ **malicious code (such as viruses and worms), malware (including** as a ~~single agent~~ **result of advanced persistent threat intrusions), denial- of- service attacks, credential stuffing, credential harvesting, personnel misconduct** or ~~in combination with~~ **error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, attacks enhanced or facilitated by artificial intelligence (" AI "), software or hardware failures, loss of data or** other ~~therapies~~ **information technology assets** , ~~it~~ **adware, telecommunications failures, natural disasters, terrorism, and other similar threats. Many of our employees and contractors are working remotely at least part of the time. Remote work involves risks to our information technology systems and data, as individuals utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations. Ransomware attacks also continue to increase in prevalence and severity and can lead to significant interruptions in our operations, ability to provide our services, loss of data and income, reputational harm, and diversion of funds. Extortion payments** may **alleviate** ~~nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in~~ the **negative impact** ~~medical community. If the product candidates we develop do not achieve an adequate level~~ of ~~acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on~~ a **ransomware attack** ~~number of factors~~ , **but** including: ● efficacy and potential advantages..... current licensing arrangements on acceptable terms, we may be **unwilling or** unable to **make such payments due** ~~successfully develop and commercialize the affected product candidates. We are generally also subject~~ to ~~all of the same risks with respect to protection of intellectual property that we own~~ , ~~as we are~~ for ~~intellectual property that we license. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could materially suffer. If we fail to comply with our obligations under our patent license with Pfizer, we could lose license rights that are~~

~~important to our business. We are a party to a license agreement with Pfizer pursuant to which we in- license key patents for gedatolisib. This license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, Pfizer may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. We may have limited control over the maintenance and prosecution of these in- licensed rights, activities or any other intellectual property that may be related to our in- licensed intellectual property. For~~ example, ~~we cannot be certain that such activities by these licensors have been or will be conducted in compliance with~~ applicable laws ~~and~~ **or** regulations **prohibiting such** ~~or will result in valid and enforceable patents~~ **payments** ~~and other intellectual property rights~~. **While we take steps designed to identify, prevent, assess** ~~We have limited control over the manner in which our licensors initiate an~~ **and** ~~infringement proceeding against a~~ **mitigate vulnerabilities in our information systems and to mitigate related** third- party **risks** ~~infringer of the intellectual property rights~~, ~~or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves. We may not be successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which could harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby~~ ~~-~~ **there** ~~giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There~~ can be no assurance that we will be able to ~~successfully complete~~ **detect and remediate all** such ~~negotiations and~~ **vulnerabilities, including on a** ~~ultimately~~ ~~----~~ **timely** ~~acquire the rights~~ **basis. The threats and techniques used** to **exploit** the ~~intellectual property surrounding the additional product candidates~~ **vulnerability change frequently and are often sophisticated in nature. Therefore, we (or third parties on whom we rely) may be unable to detect a vulnerability until after a security incident has occurred. Further, we or third parties on which we rely may face downtime as a result of adopting new information technology systems** that **are designed to enhance compliance or reduce vulnerabilities. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. This could disrupt our clinical trials, damage our reputation, and negatively affect our ability to conduct our business in the ordinary course, including our ability to collect, process, and prepare company financial information, provide information and educational materials through our website, and manage the administrative aspects of our business. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain certain measures to protect our information technology systems and sensitive information and to notify relevant stakeholders, including affected individuals, regulatory authorities and our stockholders, of certain security incidents. The disclosure decisions are complex, may take time to determine, and may be subject to change as an investigation progresses. Providing disclosure may be costly, and the failure to comply with such requirements could also lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident,** we may ~~seek~~ **face government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal information); litigation (including class claims) and mass arbitration; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Accordingly, security incidents and attendant consequences may damage our financial position and negatively impact our ability** to ~~acquire~~ **The COVID- 19 pandemic** ~~,personnel' s,or vendor' s use of generative AI technologies.Public health matters~~ may materially and adversely impact our business,including ongoing clinical trials.The outbreak of COVID- 19 and government measures taken in response ~~demonstrated that public health matters~~ have **had** a significant impact on the global economy,with healthcare systems particularly affected.As a result of the COVID- 19 outbreak and related public health measures,we **have and may in the future** ~~experienced~~ **experience** ~~delays in the enrollment of patients in certain CELsignia- related clinical trials.Future outbreaks or variants of the virus,or the emergence of other pandemics or public health~~ disruptions ~~,~~ **that** could materially and adversely impact our clinical trials,business,financial condition and results of operations.Potential disruptions include but are not limited to:● delays or difficulties in enrolling patients in clinical trials and obtaining the results of completed clinical trials;● increased rates of patients withdrawing from clinical trials following enrollment as a result of quarantine or ~~public health~~ concerns **about COVID- 19** ;● diversion of healthcare resources away from the conduct of clinical trials;● delays in prospective clinical trial collaborations with pharmaceutical companies and sponsors;● interruption or delays in the operations of the FDA or other regulatory

authorities,which may impact review and approval timelines;● limitations on our ability to recruit and hire key personnel due to our inability to meet with candidates because of travel restrictions;and ● limitations on employee resources that would otherwise be focused on the conduct of clinical trials and research as a result of focus ~~on health matters~~ **addressing COVID- 19 mitigation** and loss of **productivity from remote work.All of the effects of COVID- 19 described herein are expected to apply to any future recurrences of COVID- 19 and any other pandemics that may occur in the future.** . Risks Related to ~~Government~~ **Product Development and Product** Regulation **If we are unable to obtain approval from the FDA or comparable foreign regulatory authorities to market our products** for ~~Gedatolisib We may~~ **their intended use, we will** not **be able** ~~obtain the necessary regulatory approvals~~ to **generate revenue** ~~commercialize our product candidate~~ . **For** ~~We will need FDA approval to commercialize our product candidate in the U. S. In order to obtain FDA approval, we must submit to the FDA~~ a new drug ~~application,~~ **to be approved** ~~or~~ **for** ~~NDA~~ **marketing** , ~~demonstrating~~ **the FDA and other regulatory authorities must determine** that the drug ~~product~~ is safe ~~For a new drug to be approved for marketing,the FDA and other regulatory authorities must determine that the drug is safe~~ and effective.Because all drugs can have adverse effects,the data from our Phase 3 clinical study must demonstrate to the satisfaction of the FDA and other health authorities that the benefits of gedatolisib in combination with palbociclib and fulvestrant,or gedatolisib in combination with fulvestrant,outweigh its risks.Failure to demonstrate sufficient magnitude of benefit,even if the benefit is found to be statistically significant,may not support regulatory approval. ~~If a drug meets its primary efficacy endpoint objective in a~~ **The marketability of our products,particularly gedatolisib,depends on securing approval from the FDA and equivalent foreign regulatory bodies.This requires rigorous pre- clinical and clinical studies,including** Phase 3 clinical **trials** for **each** ~~humans and effective for its~~ intended use **, that the benefits of the therapy outweigh its risks** . ~~This~~ **Failure to** ~~demonstration~~ **demonstrate** ~~requires~~ **sufficient magnitude of benefit, even if the benefit is found to be statistically** significant ~~research and animal tests~~ , **may not support regulatory approval** ~~which are referred to as pre- clinical studies, as well as human tests, which are referred to as clinical trials~~ . Satisfaction of the FDA' s regulatory requirements typically takes many years ~~, depends upon the type, complexity and novelty of the drug product~~ and requires substantial resources for research, development and testing. **If** ~~We cannot predict whether our research and clinical approaches will result in~~ a drug **meets its primary efficacy endpoint objective in a Phase 3 clinical trial, and the drug sponsor has additional nonclinical and clinical data required by the FDA or other regulatory authorities, the drug sponsor may submit an NDA seeking marketing approval. Upon submission of an NDA, these health authorities perform a benefit- risk assessment** that ~~to be statistically significant,may not support regulatory approval.If a drug meets its primary efficacy endpoint objective in a Phase 3 clinical trial,and the drug sponsor has additional nonclinical and clinical data required by the FDA or other regulatory authorities,the drug sponsor may submit an NDA seeking marketing approval.Upon submission of an NDA,these health authorities perform a benefit- risk assessment that~~ considers the strength and quality of evidence available and takes remaining uncertainties into account.These considerations include an assessment of the strengths and limitations of clinical trials,including design,and potential implications for assessing drug efficacy,the magnitude of benefit and interpretation of clinical importance,the benefit attributed to the drug when studied in combination with other therapies,and the clinical relevance of the study endpoints.We **are currently conducting a Phase 3 clinical trial,VIKTORIA- 1,evaluating gedatolisib in combination with fulvestrant with or without palbociclib,in patients with HR / HER2- advanced breast cancer after progression on CDK4 / 6 therapy,and a Phase 1b / 2 clinical trial,CELC- G- 201,evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer.We** have sought feedback from ~~the~~ the FDA **and other regulatory authorities on the design of gedatolisib clinical trials, with the goal of addressing these** ~~considers~~ **considerations** ~~safe for humans~~ **in the clinical trials' design. However, due to the complexity of clinical trials, the uncertainty of outcomes, and the uncertainty of how the FDA and other regulatory authorities may balance benefits and risks in their review of** ~~and~~ **an** ~~effective~~ **NDA, it may not be practical** ~~for~~ **or** ~~indicated uses~~ **possible to address all benefit- risk assessment considerations in a clinical trial so that sufficient evidence is generated to support a marketing approval, even if the primary endpoint objective is achieved in the Phase 3 stage of the trial** . The FDA **or** ~~has substantial discretion in the~~ **other regulatory authorities** ~~drug approval process and~~ may require us to **redesign or** conduct additional **unplanned** ~~pre-~~ clinical **trials before granting any** ~~and clinical testing or to perform post- marketing studies. The~~ approval ~~process~~ **and we may not get approval at all. Regulatory approval** may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. ~~Delays~~ **We cannot predict whether our research and clinical approaches will result** in ~~obtaining~~ **a drug that the FDA considers safe for humans and effective for indicated uses. The results from clinical trials that we conduct may not support approval of gedatolisib, and the results of clinical trials of other pharmaceutical collaborators may not support use of our CELsignia platform as a companion diagnostic or standalone testing tool. In addition, we may be unable to execute on our intention of using our CELsignia PI3K Activity Test in evaluating tumors in certain of our gedatolisib clinical trials. If** regulatory approvals **are delayed or not obtained, especially with respect to gedatolisib, it will negatively impact our ability to commercialize our products and generate revenue and** may ~~delay commercialization of, and our ability to derive product revenues from, our drug product; impose costly procedures on us; or~~ diminish any competitive advantages that we may otherwise enjoy. ~~Even~~ **If we are required to conduct additional clinical trials or other testing of gedatolisib beyond those that we currently contemplate,** if we ~~comply~~ **are unable to successfully complete clinical trials or other testing of gedatolisib, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: ● be delayed in obtaining marketing approval or not obtain marketing approval at all; ● obtain approval for indications or patient populations that are not as broad as intended or desired; ● obtain approval** with **labeling that includes significant use** ~~all FDA requests, the FDA may ultimately reject our~~ **or** ~~NDA. We cannot~~ **distribution restrictions or safety warnings, including boxed warnings; ●** be **subject to changes in the way** ~~sure that we will ever obtain regulatory clearance for~~ our ~~drug product~~ **products** ~~. Failure~~ **are administered; ● be required** to ~~obtain~~

~~FDA~~ **perform additional clinical trials to support** approval ~~of our~~ **or be subject to additional post- marketing testing requirements; ● have** ~~drug product will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues. The FDA or comparable foreign~~ regulatory authorities **withdraw,** ~~may disagree with our~~ **or** ~~regulatory plan for our~~ **suspend, their approval of the** product ~~candidates. The general approach~~ **or impose restrictions on its distribution in the** ~~for~~ **form of the** FDA **' s Risk Evaluation** ~~approval of a new drug is dispositive data from one or more well- controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs~~ and **Mitigation Strategies program (" REMS ")** ~~take years to complete. Our clinical trial results may not support approval of our~~ **or through modification** ~~product candidates. In addition, our product candidates could fail~~ to **an existing REMS** ~~receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials~~ ; ● ~~we may~~ be **sued** ~~unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications~~ ; **or** ● **experience damage to** ~~we may encounter safety or~~ **our** ~~efficacy problems caused by the COVID- 19 pandemic; ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks; ● 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 the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the U. S. or elsewhere; ● 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~~ **reputation** ~~of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval~~ . Breakthrough Therapy Designation or Fast Track Designation from the FDA may not actually lead to a faster development or regulatory review or approval process. If a drug is intended for the treatment of a serious or life- threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track Designation. The designation offers the opportunity for frequent interactions with the FDA to discuss the drug' s development plan and to ensure collection of appropriate data needed to support drug approval, as well as eligibility for submission of a New Drug Application. In addition, a drug may receive Breakthrough Therapy Designation if it is intended, alone or in combination with one or more other products, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The benefits of Breakthrough Therapy Designation include more intensive guidance from the FDA on an efficient development program, access to a scientific liaison to help accelerate review time, and potential eligibility for priority review if relevant criteria are met. This designation can expedite the development and regulatory review of an investigational medicine that is intended to treat a serious or life- threatening condition. Both Fast Track and Breakthrough Therapy Designations are within the discretion of the FDA. While the FDA has granted both designations to our lead drug candidate, gedatolisib, such designations may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures, and neither designation assures ultimate approval by the FDA. In addition, the FDA may later decide that the product no longer meets the qualification conditions and may rescind either or both such designations. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, a comparable foreign regulatory authority must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U. S., including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U. S., a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. ~~We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U. S. have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions.~~ Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Even if we receive **initial** regulatory ~~approval~~ **approvals** ~~of any product candidates~~ , we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense **,** and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- marketing information, including both federal and state requirements in the U. S. and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with requirements for any clinical trials

that we conduct post- approval. Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient- reported outcome measures. The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post- marketing studies or clinical trials to assess new safety risks or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: ● restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; ● fines, warning letters or holds on clinical trials; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; ● product seizure or detention or refusal to permit the import or export of our product candidates; and ● injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. ~~The policies of the FDA and comparable foreign regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad.~~ If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. If we commercialize any product candidates,..... Risks Related to Our CELsignia Tests Our success with CELsignia is heavily dependent on the success of our first CELsignia trials **and** ~~. Our business strategy is focused~~ on **finding appropriate pharmaceutical company partners. The success of our CELsignia tests depends on our ability to** ~~attracting~~ **attract** pharmaceutical company partnerships that provide revenue from the sale of CELsignia tests during clinical trials, from milestone payments during clinical trials, from sales of our CELsignia tests as companion diagnostics or stand- alone tests thereafter, and, potentially, from royalties on the incremental drug revenues our tests enable. Our ability to obtain such partnerships and generate such revenue depends in part on the ability of our first CELsignia tests to demonstrate the potential incremental opportunity available for pharmaceutical companies **, as well as our ability to establish strategic partnerships or other arrangements with suitable pharmaceutical companies. Phase 2 trials are underway to evaluate the efficacy and safety of these therapies in CELsignia selected patients** . We do not expect to receive **final results from our FACT- 1 trial until** the first ~~interim results~~ **half of 2025. The FACT- 2 trial, which was evaluating patients with early- stage triple negative breast cancer, was terminated in the third quarter of 2023. This decision was made in response to recent FDA approvals of new therapeutic options** for ~~our prospective clinical trials for~~ **patients with early- stage triple negative breast cancer. The availability of** ~~the~~ **these** ~~CELsignia HER2 Pathway Activity Test until~~ **new therapeutic options negatively impacted enrollment, which led us to conclude that** the ~~second half of 2023~~ **study was no longer feasible** . Success of the clinical trials using the CELsignia HER2 Pathway Activity Test or CELsignia Multi- Pathway Activity Test will depend on many factors, such as successfully enrolling patients, meeting trial endpoint goals, and completing the trial in a timely manner. Our ability to complete the trial could be delayed or prevented for several reasons that are out of our control, such as the FDA withdrawing its authorization and approval to perform the study, NSABP ~~, West Cancer Center~~ , MD Anderson Cancer Center, or University of Rochester determining that the human and / or toxicology test results do not support continuing the trial, or participants having adverse reactions or side- effects to the drugs administered in the study. If we are unable to demonstrate that the CELsignia HER2 Pathway Activity Test or CELsignia Multi- Pathway Activity Test is suitable as a companion diagnostic for the targeted therapy, we will likely not be able to generate future revenue from our CELsignia HER2 Pathway Activity Test or CELsignia Multi- Pathway Activity test and may not be able to attract other pharmaceutical companies to partner with us for the development and commercialization of other CELsignia tests. Further, potential pharmaceutical company partners may delay negotiating development agreements until results of the first clinical trial using our CELsignia HER2 Pathway Activity Test trial are available. Even if the ultimate outcome of the first clinical trial using a CELsignia HER2 Pathway Activity Test trial is positive, any delays could materially and adversely affect our business. ~~We may not be successful in finding pharmaceutical company partners for continuing development of additional CELsignia tests. We intend to develop strategic partnerships with pharmaceutical companies for developing additional CELsignia tests. Many of the potential partners are global, multi- billion- dollar pharmaceutical companies with sophisticated research and development organizations and multiple priorities. We may not be successful in our efforts to establish such a strategic partnership or other alternative arrangements for our CELsignia tests because, among other things, our research and development pipeline may be insufficient, such tests may be deemed to be at too early of a stage of development for collaborative effort, or third parties may not view such tests as having the requisite potential to demonstrate efficacy. In addition, we may be restricted under collaboration agreements from entering into future agreements with other partners. Even if we are able to find suitable partners, we may not be successful in negotiating development agreements with such partners that provide revenue from the sale of our CELsignia tests, from milestone payments, and / or from royalties on the incremental drug revenues that our tests enable. If we are unable to reach agreements~~

with suitable strategic partners on a timely basis, on acceptable terms or at all, we may have to curtail the development of additional CELsignia tests, our expected revenue opportunities may be significantly smaller than expected and our business may fail. While our CELsignia HER2 Pathway Activity Test and CELsignia Multi- Pathway Activity Test are commercially ready, we have not attempted to market these to physicians or their patients as stand- alone tests and have no ability to determine if these tests or any of our other tests will be commercially viable. While our CELsignia HER2 Pathway Activity Test and CELsignia Multi- Pathway Activity Test are analytically validated, conducted in our CLIA certified and CAP accredited laboratory, and currently ready for commercial use as an LDT, we have not attempted to market them to physicians or their patients. Furthermore, we have commenced only limited communications with KOLs to build awareness and credibility of our CELsignia diagnostic platform and CELsignia tests. Accordingly, we have no ability to determine whether our CELsignia HER2 Pathway Activity Test, CELsignia Multi- Pathway Activity Test or any other future CELsignia tests, will be commercially viable as stand- alone tests. We may never be successful in generating revenue from our CELsignia tests as stand- alone tests, and if we are unable to build pharmaceutical partnerships that enable us to market the CELsignia HER2 Pathway Activity Test, the CELsignia Multi- Pathway Activity Test, and other tests as companion diagnostic tests, we may never generate any revenue and our business may fail. Developing our CELsignia tests involves a lengthy and complex process that may not be successful. Our CELsignia tests may take several years to develop from the time they are discovered to the time they are available for patient use, if ever. In order to develop additional CELsignia tests into commercially ready products, we need to successfully complete a variety of activities, including, among others, conducting substantial research and development, conducting extensive analytical testing, and maintaining our CLIA certified and CAP accredited laboratory. In addition, our business strategy is focused on our CELsignia tests being sold as companion diagnostics. This will require obtaining and maintaining partnerships with pharmaceutical companies and successfully completing clinical studies that demonstrate the suitability of the applicable CELsignia test as a companion diagnostic for their targeted therapies. These activities will require us to expend significant resources. Based on comparable companies in this industry, few research and development projects result in commercially viable products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate for several reasons, such as a clinical validation study failing to demonstrate the prospectively defined endpoints of the study. We may also be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. Clinical trials are expensive and complex with uncertain outcomes, which may prevent or delay commercialization of our CELsignia tests. For our CELsignia tests to become a companion diagnostic for a matching targeted therapy, we must conduct clinical trials to demonstrate that patients who have an abnormal signaling pathway, as identified by our CELsignia tests, respond to treatment with a matching targeted therapy. Clinical testing is expensive, is difficult to design and implement, and can take many years to complete, and its outcome is inherently uncertain. As a company, we have limited experience in conducting or participating in clinical trials. We cannot be certain that any future clinical trials will conclusively demonstrate that any CELsignia test is effective as a companion diagnostic. If our trials do not yield positive results, we may be unable to maintain the pharmaceutical company partnerships we build or find additional partners, we may not be able to successfully commercialize our CELsignia tests or generate any revenue, our business may fail, and you may lose part or all of your investment. We cannot be certain that our existing clinical trial or future clinical trials, if any, will begin or be completed on time, if at all. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to commercialize our CELsignia tests, such as: ● delay or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with planned trial sites and / or strategic partners; ● delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design, in obtaining authorization from such authorities to commence the trial, and / or in complying with conditions or other requirements imposed by such regulatory authorities with respect to the trial; ● delay or failure in recruiting and enrolling suitable subjects to participate in one or more clinical trials, or in such participants completing a trial or returning for follow- up during or after the trial; ● clinical sites, investigators or other third- parties deviating from the trial protocol, failing to conduct the trial in accordance with regulatory and contractual requirements, and / or dropping out of a trial; ● regulatory imposition of a clinical hold for any of our clinical trials, where a clinical hold in a trial in one indication would result in a clinical hold for clinical trials in other indications; and ● changes in governmental regulations or administrative actions. Significant nonclinical or clinical trial delays could prevent us from maintaining and / or developing new pharmaceutical company partnerships. Delays could also shorten any periods during which we may have the exclusive right to commercialize our CELsignia tests or allow our competitors to bring products to market before we do. As such, any delays could impair our ability to successfully commercialize our CELsignia tests and may materially and adversely affect our business, financial condition, results of operations and prospects. Even if our CELsignia tests achieve positive clinical trial results, they may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any of our potential CELsignia tests, including our first CELsignia HER2 Pathway Activity Test and CELsignia Multi- Pathway Activity Test, achieve positive clinical trial results, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. For example, conventional genomic- or proteomic- based analyses are commonly used today to diagnose cancer and prescribe cancer medications, and physicians may continue to rely on these diagnostic tests instead of adopting the use of a CELsignia test. The degree of market acceptance of our CELsignia tests will depend on a number of factors, including: ● their efficacy and other potential advantages compared to alternative diagnostic tests; ● our ability to offer them for sale at competitive prices; ● their convenience and ease of obtaining patient specimens compared to alternative diagnostics; ● the willingness of the target patient population to try new diagnostics and of physicians to initiate such diagnostics; ● the strength of marketing and distribution support; ● the availability of third- party coverage and adequate reimbursement for our diagnostic tests; and ● our ability to partner with pharmaceutical companies to

develop companion diagnostic programs for the new cancer sub- types we discover. If our CELsignia tests do not achieve an adequate level of acceptance, we may never generate significant product revenues and we may not become profitable. Our CELsignia related business, operational and financial goals may not be attainable if the market opportunities for our CELsignia tests or our pharmaceutical company partners are smaller than we expect. Our internal research and estimates on market opportunities have not been verified by independent sources, and we have not independently verified market and industry data from third- parties that we have relied on. The total market opportunities that we believe exist are based on a variety of assumptions and estimates, including the number of potential companion diagnostic programs we will be able to successfully pursue, the amount of potential milestone payments that we could receive in companion diagnostic programs, the number of patients we will test in clinical trials, the price we will be able to charge for our tests and the total annual number of cancer patients with undiagnosed abnormal cell signaling. In addition, we have relied on third- party publications, research, surveys and studies for information related to determining market opportunities, including without limitation, information on the number of cancer patients and those receiving various forms of treatment, the cost of drug therapy, the amount of revenue generated from various types of drug therapy, the objective response rates of drug therapies, the number of deaths caused by cancer and the expected growth in cancer drug therapy and diagnostic markets. Our internal research and estimates on market opportunities have not been verified by independent sources, and we have not independently verified market and industry data from third- parties that we have relied on. Any or all of our assumptions and / or estimates may prove to be incorrect for several reasons, such as inaccurate reports or information that we have relied on, potential patients or providers not being amenable to using our CELsignia platform for diagnostic testing or such patients becoming difficult to identify and access, limited reimbursement for companion diagnostics, pricing pressure due to availability of alternative diagnostic tests, or an inability of the CELsignia tests' companion drugs to obtain the necessary regulatory approvals for new indications. If any or all of our assumptions and estimates prove inaccurate, we and our companion diagnostic pharmaceutical partners may not attain our business, operational and financial goals. The expected selling price range of our CELsignia tests is an estimate. We have not yet sold any such tests and the actual price we are able to charge may be substantially lower than our expected price range. We have estimated the selling price range of our CELsignia tests based on the pricing of other diagnostic tests currently available and assumptions regarding the efficacy and market acceptance of our tests. We have not yet sold our CELsignia tests and cannot be certain of the actual price we may be able to charge. The availability and price of our competitors' products could limit the demand and the price we are able to charge. We may not achieve our business plan if acceptance is inhibited by price competition, if pharmaceutical companies refuse to pay our expected prices for CELsignia tests in clinical trials, if physicians are reluctant to switch from other diagnostic tests to our CELsignia tests or if physicians switch to other new products or choose to reserve our CELsignia tests for use in limited circumstances. Furthermore, reductions in the reimbursement rate of third- party payors have occurred and may occur in the future. Each of these factors could cause our selling price to be substantially lower than expected, and we may fail to generate revenue or become profitable. The insurance coverage and reimbursement status of new diagnostic products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for CELsignia tests could limit our ability to market those CELsignia tests and decrease our ability to generate revenue. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive diagnostic tests and treatments. Sales of any of our potential CELsignia tests will depend substantially, both in the United States and internationally, on the extent to which the costs of our CELsignia tests will be paid by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. Reimbursement by a payor may depend on a number of factors, including a payor' s determination that the CELsignia tests are neither experimental nor investigational, appropriate for the specific patient, cost- effective, supported by peer- reviewed publications, and included in clinical practice guidelines. If reimbursement is not available, or is available only to a limited amount, we may not be able to successfully commercialize our CELsignia tests at expected levels, or potentially at all. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our research and development investment. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved diagnostic products. In the United States, the principal decisions about reimbursement for new diagnostic products and services are typically made by CMS. CMS decides whether and to what extent a new product or service will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. As such, a significant portion of our potential revenue depends on CMS approving coverage and reimbursement of our CELsignia tests. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of diagnostic tests such as our potential CELsignia tests. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time. To obtain reimbursement or pricing approval in some countries, we may be required to demonstrate the cost- effectiveness of our CELsignia tests relative to other available diagnostic tests. The prices of products under such systems may be substantially lower than in the United States. Other countries allow companies to fix their own prices for products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our CELsignia tests. Accordingly, in markets outside the United States, the reimbursement for our potential CELsignia tests may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profit. Moreover, increasing efforts by governmental and third- party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our potential CELsignia tests. The downward pressure on

healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. We expect to experience pricing pressures in connection with the sale of any CELsignia tests due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. We may encounter difficulties in commercializing and marketing our CELsignia products, including in hiring and retaining a qualified sales force. In order to commercialize any CELsignia test, we must build marketing, sales, managerial and other non- technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. For each CELsignia test we develop, we intend to pursue development agreements with the pharmaceutical companies that provide matching targeted therapies. Once we have completed the analytical validation of a CELsignia test, we plan to target KOLs to build product awareness. Once we have clinical validation data available, we expect to expand our sales and marketing efforts to target the broader market and coordinate our go- to- market activities with those of our partner pharmaceutical companies. These activities will be expensive and time consuming and will require significant attention of our executive officers to manage. In particular, there is intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales. Furthermore, there is no guarantee that any new drug indications will require our CELsignia tests as a companion diagnostic or that any pharmaceutical company will effectively coordinate sales and marketing activities with us. Any failure or delay in these activities, including if we are unable to develop our marketing and sales networks or if our sales personnel do not perform as expected, would adversely impact the commercialization our CELsignia platform, and our business, financial condition, results of operations and prospects may be materially and adversely affected. We face significant competition from other diagnostic companies and our operating results will suffer if we fail to compete effectively. The diagnostic testing industry is intensely competitive. We have competitors both in the United States and abroad, including universities and other research institutions and providers of diagnostics that focus on developing genomic or proteomic analyses of a patient' s diseased cells or theranostic tests to predict specific patient responses to a drug therapy. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and well- established marketing and sales forces. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products or services that are more effective or less costly than the CELsignia tests that we are currently developing or that we may develop. In addition, established medical technology, biotechnology and / or pharmaceutical companies may invest heavily to accelerate discovery and development of diagnostic tests that could make our CELsignia tests less competitive. Our ability to compete successfully will depend largely on our ability to: ● discover and develop CELsignia tests for cancer sub- types that are superior to other products in the market; ● demonstrate compelling advantages in the efficacy and convenience of our CELsignia tests on a cost competitive basis; ● attract qualified scientific, product development and commercial personnel; ● obtain and maintain patent and other proprietary protection as necessary for our CELsignia platform; ● obtain required U. S. and international regulatory approvals; ● successfully collaborate with research institutions and pharmaceutical companies in the discovery, development and commercialization of our current and future CELsignia tests; and ● successfully expand our operations and build a sales force to support commercialization. If our sole laboratory facility becomes inoperable, we will be unable to perform our tests and our business will be harmed. We do not have redundant laboratory facilities. We perform all of our diagnostic services in our laboratory located in Minneapolis, Minnesota. Our facility and the equipment we use to perform our tests would be costly to replace and could require substantial lead time to repair or replace. The facility may be harmed or rendered inoperable by physical damage from fire, floods, tornadoes, power loss, telecommunications failures, break- ins and similar events, which may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In order to rely on a third party to perform our tests, we could only use another facility with established state licensure and CLIA accreditation under the scope of which our potential CELsignia tests could be performed following validation and other required procedures. We cannot assure you that we would be able to find another CLIA- certified facility willing to adopt CELsignia tests and comply with the required procedures, or that this laboratory would be willing to perform the tests for us on commercially reasonable terms. Our instrument or reagent suppliers may fail to meet our quality requirements for the items we purchase or fail to provide a continuous supply of the items we utilize to perform our CELsignia tests. We utilize highly specialized reagents and instruments to perform our CELsignia tests. We may be unable to find suitable replacement reagents and instruments on a timely basis, if at all. Interruption in the supply of these items or degradation in their quality could delay analytical and clinical studies, and / or render us unable to deliver CELsignia tests. This would interrupt sales and adversely affect our business, results of operations and financial condition. Performance issues or price increases by our shipping carriers could adversely affect our business, results of operations and financial condition, and harm our reputation and ability to provide our CELsignia tests on a timely basis. Expedited, reliable shipping is essential to our operations. Should our shipping carrier encounter delivery performance issues such as loss, damage or destruction of a sample, such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis. There are only a few providers of overnight nationwide transport services, and there can be no assurance that we will be able to maintain arrangements with providers on acceptable terms, if at all. Our CELsignia tests represent a novel approach to companion diagnostics, which could result in heightened regulatory scrutiny, delays in clinical development, or delays in our ability to commercialize any products. Our unique and proprietary CELsignia technology is the first cancer diagnostic platform we are aware of that can detect the underlying signaling dysfunction driving a patient' s cancer. Because this is a novel approach to

companion diagnostics, there can be no assurance as to the length of a clinical trial period, the number of patients the FDA or another applicable regulatory authority will require to be enrolled in the trials in order to establish the safety and efficacy of our CELsignia tests and the companion drugs, or that the data generated in these trials will be acceptable to the FDA or another applicable regulatory authority to support marketing approval of new indications for the companion drugs. This could delay or prohibit our clinical trials and / or commercialization of our CELsignia tests. If the FDA were to begin regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval. Most **laboratory developed tests (“** LDTs **”)** are not currently subject to FDA regulation, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. We believe that the CELsignia tests are LDTs, which is a term that describes tests that are designed and performed within a single laboratory. As a result, we believe the CELsignia tests are not currently subject to regulation by the FDA in accordance with the FDA’ s current policy of exercising enforcement discretion regarding LDTs . Historically, the FDA has not required laboratories that furnish only LDTs to comply with the agency’ s requirements for medical devices (e. g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post- market controls). In mid- 2014, the FDA published a draft Guidance Document describing a proposed approach for a regulatory framework for LDTs, but in late 2016, the FDA indicated it did not intend to finalize the LDT Guidance Document at that time . It is not clear when or if the FDA will seek to alter the current LDT regulatory framework in the future. We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. We cannot predict with certainty the timing or content of future legislation enacted or guidance issued regarding LDTs, or how it will affect our business. If premarket review is required by the FDA at a future date or if we decide to voluntarily pursue FDA premarket review of our CELsignia tests, there can be no assurance that our CELsignia tests or any tests we may develop in the future will be cleared or approved by the FDA on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our CELsignia tests. If our CELsignia tests are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are more limited than we expect, reimbursement may be adversely affected and we may not be able to sell our CELsignia tests. Compliance with FDA regulations would increase the cost of conducting our business and subject us to heightened regulation and scrutiny by the FDA and penalties for failure to comply with these requirements. If we fail to obtain required federal and state laboratory licenses, we could lose the ability to perform our tests. Clinical laboratory tests, including our CELsignia tests, are regulated under CLIA. CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific standards for laboratories in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third- party payers, for any tests we launch. We will also be required to maintain state licenses in certain states to conduct testing in our laboratories. While we currently have CLIA certification for our Minnesota laboratory, failure to maintain this certification would adversely affect our ability to launch our CELsignia tests. CELsignia Risks Related to Intellectual Property new therapies and of physicians to prescribe these therapies;● the strength of marketing and distribution support;● the ability to obtain sufficient third- party coverage,market access and adequate reimbursement;and ● the prevalence and severity of any side effects.Risks Related to Intellectual Property for Gedatolisib We depend on intellectual property licensed from third parties,including from Pfizer for our lead product candidate,and termination of this license could result in the loss of significant rights,which would harm our business.We are dependent on patents,know- how and proprietary technology,both our own and licensed from others.All patents covering gedatolisib and any combination therapies using our product candidates are licensed from third parties.Any termination of a product license could result in the loss of significant rights and would cause material adverse harm to our ability to commercialize our product candidates.Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement,including:● the scope of rights granted under the license agreement and other interpretation- related issues;● whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;● our right to sublicense patent and other rights to third parties under collaborative development relationships;● our diligence obligations with respect to the use of licensed technology in relation to our development and commercialization of our product candidates and what activities satisfy those diligence obligations;and ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.If disputes over intellectual property that we 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 product candidates.We are generally also subject to all of the same risks with respect to protection of intellectual property that we own,as we are for intellectual property that we license.** If we are unable **or our licensors fail** to obtain and maintain **adequately protect this** intellectual property protection **, our ability to commercialize products could materially suffer. If we fail to comply with our obligations under our patent license with Pfizer, we could lose license rights that are important to our business. We are a party to a license agreement with Pfizer pursuant to which we in- license key patents** for **gedatolisib. This license imposes various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, Pfizer may have the right to terminate the license, in which event we would not be able to develop** our - **or market** CELsignia technology, or if the scope of the **products covered by such licensed** intellectual property **. We may have limited control over the maintenance and** protection **prosecution** obtained is not sufficiently broad **of these in- licensed rights** , **activities** our - **or any other intellectual property that** competitors could develop and commercialize technology and diagnostic tests similar or identical to ours, and our ability to successfully

~~commercialize our technology and diagnostic tests~~ may be **related** ~~impaired. Our ability~~ to ~~compete successfully~~ **our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or** will ~~depend~~ **be conducted** in ~~part on~~ **compliance with applicable laws and regulations** ~~our~~ **or** ~~ability to obtain~~ **will result in valid** and ~~enforce~~ **enforceable** ~~patent~~ **patents** ~~protection for our products, preserve our trade secrets~~ and ~~operate without infringing the~~ **other** ~~proprietary~~ **intellectual property** rights ~~of third parties~~. We have **limited control** ~~applied for patents that protect our technology. Our patent portfolio includes six issued U. S. patents and 30 issued international patents. Each patent and patent application covers~~ **over the manner in which** ~~methods of use. However, we cannot assure you that~~ our **licensors initiate an infringement proceeding against a third- party infringer of the** intellectual property **rights,** ~~position will not be challenged~~ or **defend certain of the intellectual property** that ~~all patents~~ **is licensed to us. It is possible that the licensors' infringement proceeding** ~~for~~ **or defense activities** ~~which we have applied will be granted. The validity and breadth of claims in patents involve complex legal and factual questions and, therefore,~~ may be **less vigorous** ~~highly uncertain. Uncertainties and risks that~~ **than had** we **conducted** ~~face include the~~ **them ourselves. We** ~~following: ● our pending or future patent applications may not result in the issuance of patents; ● the scope of any existing or future patent protection may not exclude competitors or provide competitive advantages to us; ● our patents~~ may not be ~~held valid if subsequently challenged;~~ ● **successful in obtaining or maintaining necessary rights to develop any future product candidates on acceptable terms. Our clinical trials and** other ~~parties~~ **programs currently, and** may ~~claim~~ **in the future, involve additional product candidates** that **require the use of,** ~~our~~ **or reliance on,** ~~products and designs infringe the~~ proprietary rights ~~of others~~ **held by third parties. Accordingly** , ~~and even if we are successful~~ **the growth of our business depends** in ~~defending~~ **part on our ability to acquire, in- license** ~~our~~ **or** ~~patents and~~ **use these** proprietary rights **. We** ~~, such litigation~~ may be ~~costly; and~~ ● **unable to acquire or in- license any compositions, methods of use, processes or** other **third- party intellectual property rights from third** parties **that we identify as necessary or important to our business operations. We** may ~~develop similar products, duplicate our products, or design around our patents. The patent prosecution process is expensive and time- consuming, and we may not be able to file~~ **fail to obtain any of these** ~~, prosecute, maintain, enforce or license~~ **licenses** ~~all necessary or desirable patent applications~~ at a reasonable cost or **on reasonable terms** ~~in a timely manner~~ , ~~or in~~ **if at** all ~~jurisdictions~~ **, which could harm our business** . We may **need** ~~choose not~~ to ~~seek patent protection~~ **cease use of the compositions** ~~for~~ **or methods covered by such third- party** ~~certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other~~ intellectual property rights **, and** may **need to seek to develop alternative approaches** ~~be unavailable or limited in scope. It is also possible~~ that ~~we will fail to identify patentable aspects of our discovery and nonclinical development output before it is too late to obtain patent protection. The patent position of companies like ours is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. The U. S. Patent and Trademark Office, or U. S. PTO, has not established a consistent policy regarding the breadth of claims that it will allow in medical technology patents. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. For example, India and China~~ do not **infringe on** ~~allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of~~ such ~~inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or CELsignia tests, in whole or in part, or which effectively prevent others from commercializing competitive technologies and diagnostic tests. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. Moreover, we may be subject to a third- party pre- issuance submission of prior art to the U. S. PTO or patent offices in foreign jurisdictions, or become involved in opposition, derivation, reexamination, inter parties review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology and compete directly with us, without payment to us, or result in our inability to commercialize CELsignia platform without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to develop or commercialize current or future CELsignia tests. Even if our owned patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned patents by developing similar or alternative technologies or products in a non- infringing manner. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and potential diagnostic tests. Given the amount of time required for the development, testing and regulatory review of new diagnostic tests, patents protecting such tests might expire before or shortly after such candidates are commercialized. As a result, our owned patent portfolio may not provide us with sufficient rights to exclude others from commercializing diagnostic tests similar or identical to ours. Third parties may initiate legal proceedings alleging that we are infringing their~~ intellectual property rights ~~, the outcome of~~ which ~~would be uncertain and could have a material adverse effect on the success of our business. The commercial success of CELsignia tests depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our CELsignia tests and use our proprietary technologies without infringing the proprietary rights~~

~~of third parties. There is considerable intellectual property litigation in the medical technology, biotechnology and pharmaceutical industries. We~~ may **entail additional costs** ~~become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our CELsignia platform, including interference or derivation proceedings before the U. S. PTO~~ and ~~similar bodies in other jurisdictions. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing~~ **development delays** ~~and marketing our CELsignia platform and CELsignia tests. However~~ , ~~we may not be able to obtain any required license on commercially reasonable terms or at all. Even~~ **even** if we were able to **develop such alternatives, which may not be feasible. Even if we are able to** obtain a license, it ~~could~~ **may** be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. ~~We could~~ **In that event, we may** be **required** ~~forced, including by court order,~~ to ~~cease commercializing the infringing~~ **expend significant time and resources to develop or license replacement** technology ~~or product~~ . ~~In addition~~ **The licensing and acquisition of third- party intellectual property rights is a competitive area** , **and companies that may be more established or have greater resources than** we ~~could~~ **do may also** be ~~found liable~~ **pursuing strategies to license** ~~for~~ **or acquire third- party intellectual property rights** ~~monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our CELsignia platform or force us to cease some of our business operations, which could materially harm our business. Claims~~ that we ~~have misappropriated the confidential information~~ **may consider necessary or attractive in order to commercialize** ~~or~~ **our** ~~trade secrets of third parties could~~ **product candidates. More established companies may** have a ~~similar negative impact on our business~~ **competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire** . If we are not able to prevent disclosure of our trade secrets and other proprietary information, the value of our **products** ~~CELsignia platform~~ could be significantly diminished. We rely on trade secret protection to protect our interests in proprietary know- how and in processes for which patents are difficult to obtain or enforce. We may not be able to protect our trade secrets adequately. We have a policy of requiring our consultants, advisors and strategic partners to enter into confidentiality agreements and our employees to enter into invention, non- disclosure and non- compete agreements. However, no assurance can be given that we have entered into appropriate agreements with all parties that have had access to our trade secrets, know- how or other proprietary information. There is also no assurance that such agreements will provide meaningful protection of our trade secrets, know- how or other proprietary information in the event of any unauthorized use or disclosure of information. Furthermore, we cannot provide assurance that any of our employees, consultants, contract personnel, or strategic partners, either accidentally or through willful misconduct, will not cause serious damage to our programs and / or our strategy, for example by disclosing important trade secrets, know- how or proprietary information to our competitors. It is also possible that our trade secrets, know- how or other proprietary information could be obtained by third parties as a result of breaches of our physical or electronic security systems. Any disclosure of confidential data into the public domain or to third parties could allow our competitors to learn our trade secrets and use the information in competition against us. In addition, others may independently discover our trade secrets and proprietary information. Any action to enforce our rights is likely to be time consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. These risks are accentuated in foreign countries where laws or law enforcement practices may not protect proprietary rights as fully as in the United States. Any unauthorized disclosure of our trade secrets or proprietary information could harm our competitive position. ~~we may not become profitable.~~ If we commercialize any product candidates,we will be subject to U.S.and foreign governmental regulations as well as private payor policies that mandate price controls or limitations on patient access to our products or establish prices paid by government entities or programs for our products.Our business,and our future results could be adversely affected by changes in such regulations. ~~Even if we or our partners are successful in obtaining marketing approval,commercial success of any approved products will also depend in large part on the availability of insurance coverage and adequate reimbursement from third- party payors,including government payors such as the Medicare and Medicaid programs and managed care organizations in the U.S.or country specific governmental organizations in foreign countries.~~ Government and private payors routinely seek to manage utilization and control **the** costs **of our products** ,and there is considerable public and government scrutiny of pharmaceutical ~~and diagnostic~~ pricing.Efforts by states and the federal ~~governments~~ **government** to regulate prices or payment for pharmaceutical products,including proposed actions to facilitate drug importation,limit reimbursement to lower international reference prices,require deep discounts,and require manufacturers to report and make public price increases and sometimes provide a written justification for such price increases,could adversely affect our business if implemented. ~~Availability of reimbursement may~~ **U.S.and foreign governmental regulations that mandate price controls or limitations on patient access to our products or establish prices paid by government entities or programs for our products could impact our business,and our future results could** be **adversely** affected by **changes in such regulations or policies.The adoption of restrictive price controls in new jurisdictions,more restrictive controls in** existing **jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue.We expect pricing pressures will continue globally.In the U.S.,pharmaceutical product pricing is subject to government** and ~~future healthcare~~ **public scrutiny and calls for** reform ~~measures~~ **,and many of our products are subject to increasing pricing pressures as a result.We expect to see continued focus by the federal government on regulating pricing which could result in legislative and regulatory changes** designed to **control** ~~reduce the cost~~ **costs** ~~of healthcare~~ **.For example** , ~~including~~ **in August 2022,** the ~~Inflation Reduction Act~~ **IRA was signed into law** ,which **,among other things,** requires manufacturers of certain drugs to engage in price negotiations with Medicare,imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation,and

replaces the Part D coverage gap discount program with a new discounting program.Some states have implemented,and others are considering implementing,patient access constraints or cost cutting under the Medicaid program,and some are considering measures that would apply to broader segments of their populations that are not Medicaid- eligible.State legislatures also have continued to focus on addressing drug costs,generally by increasing price transparency or limiting drug price increases. **Measures** ~~Third- party payors also could require us~~ to ~~conduct additional studies~~ **regulate prices or payment for pharmaceutical products** ,including **legislation** ~~post- marketing studies related to the cost effectiveness of a product and appropriateness for specific patient populations,to qualify for reimbursement,which could be costly and divert our resources.If government and other healthcare payors do not provide coverage and adequate reimbursement for our products once approved,market acceptance and commercial success would be reduced.Even if coverage is provided,the approved reimbursement amount may not be high enough to support pricing that results in a sufficient return~~ on **drug importation,could adversely affect** our ~~research and development~~ **business.Risks Related to Our CELsignia Tests** Other Risks Related to Government Regulation for Our Business Failure to comply with the HIPAA security and privacy regulations may increase our operational costs. A portion of the data that we obtain and handle for or on behalf of our clients is considered protected health information, or PHI, subject to HIPAA. Under HIPAA and our contractual agreements with our HIPAA- covered entity health plan customers, we ~~are~~ **may be** considered a " business associate " to those customers and are required to maintain the privacy and security of PHI in accordance with HIPAA and the terms of our business associate agreements with our clients, including by implementing HIPAA- required administrative, technical and physical safeguards. We are also required to maintain similar business associate agreements with our subcontractors that have access to PHI of our customers in rendering services to us or on our behalf. We will incur significant costs to establish and maintain these safeguards and, if additional safeguards are required to comply with HIPAA regulations or our clients' requirements, our costs could increase further, which would negatively affect our operating results. Furthermore, we cannot guarantee that such safeguards have been and will continue to be adequate under applicable laws. If we have failed, or fail in the future, to maintain adequate safeguards, or we or our agents or subcontractors use or disclose PHI in a manner prohibited or not permitted by HIPAA, our subcontractor business associate agreements, or our business associate agreements with our customers, or if the privacy or security of PHI that we obtain and handle is otherwise compromised, we could be subject to significant liabilities and consequences. Compliance with global privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. ~~The regulatory framework~~ **In addition to PHI, we collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) personal data and other sensitive information. Accordingly, we are,** ~~for~~ **or may become, subject to numerous federal, state, local and foreign privacy and security laws regulating** the collection, use, safeguarding, transfer and other processing of information ~~is rapidly evolving and is likely to remain uncertain for the foreseeable future~~ . Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European ~~Union~~ **Economic Area (the " EEA ")** , including personal health data, is subject to the EU General Data Protection Regulation (the " GDPR "), which ~~took effect across all member states of the European Economic Area (the " EEA ") in May 2018. The GDPR~~ is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to the processing of health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and, as a result, increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and / or impose substantial fines for violations of the GDPR, which can be up to 4 % of global revenue or € 20 million, whichever is greater, and it also confers a private right of action on data subjects and consumer associates to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data. ~~Similar actions are either in place or under way in the United States. There are a broad variety of data protection laws that are applicable to our activities, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws are also being considered at both the state and federal levels. For example, the California Consumer Privacy Act (the " CCPA "), which went into effect on January 1, 2020, and was amended by the California Privacy Rights Act (the " CPRA "), effective January 1, 2023, secure new privacy rights for consumers and impose new obligations on us. Many other states have implemented or are considering similar legislation which will change the privacy law landscape in the United States. For example, Virginia, Colorado, Utah and Connecticut have all adopted privacy laws, which take effect in 2023. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. There also is the threat of consumer class actions related to these laws and the overall protection of personal data.~~ Given the breadth and depth of changes in data protection obligations, preparing for and complying with these requirements is rigorous and time intensive and requires significant resources and a review of our technologies,

systems and practices, as well as those of any third- party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. ~~The GDPR and~~ **Similar actions are either in place or underway in** ~~other~~ -- **the** ~~changes in laws~~ **United States.** ~~or~~ **For example** ~~regulations associated with the enhanced protection of certain types of sensitive data~~ , ~~such as healthcare data or other~~ -- **the California Consumer Privacy Act of 2018 (the " CCPA ") applies to** personal information **of consumers, business representatives, and employees, and requires covered businesses to provide specific disclosures related to a business' s processing of personal data, new operational practices, and requirements to respond to certain requests** from **California residents related** ~~our clinical trials, could require us~~ to ~~change~~ **their personal data. There is uncertainty about how the CCPA and other similar laws may be implemented and applied, and inconsistencies across jurisdictions complicate our compliance efforts. Accordingly, the CCPA and other similar laws may impact** our business ~~practices~~ **activities** and **increase our** ~~put in place additional~~ compliance ~~mechanisms~~ **costs** , **as well as our legal risks. The regulatory framework for the collection, use, safeguarding, transfer and other processing of information is rapidly evolving and is likely to remain uncertain for the foreseeable future. Evolving data privacy regulations** may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations ~~. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws~~ . Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business. We will also need to expend a considerable amount of resources complying with other federal, state and foreign laws and regulations. If we are unable to comply or have not complied with such laws, we could face substantial penalties or other adverse actions. Our operations are subject, directly or indirectly, to other federal, state and foreign laws and regulations that are complex and their application to our specific products, services and relationships may not be clear and may be applied to our business in ways that we do not anticipate. Compliance with laws and regulations will require us to expend considerable resources implementing internal policies and procedures for compliance and ongoing monitoring and will require significant attention of our management team. This will be challenging as an early- stage company with limited financial resources and human capital. These laws include, for example: ● Title XI of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, which prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in cash or in kind, in return for or to reward the referral of patients or arranging for the referral of patients, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered, in whole or in part, by a federal healthcare program such as Medicare or Medicaid; ● The civil False Claims Act, that forbids the knowing submission or " causing the submission " of false or fraudulent information or the failure to disclose information in connection with the submission and payment of claims for reimbursement to Medicare, Medicaid, federal healthcare programs or private health plans; ● The federal Physician Self- referral Law, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of " designated health services " with whom the physician or a member of the physician' s immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies, and similar state equivalents that may apply regardless of payor; and ● The U. S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, and the USA PATRIOT Act, which among other things, prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. Many states and foreign governments have adopted similar laws and regulations. Violations of law could subject us to civil or criminal penalties, monetary fines, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations. We could also be required to change or terminate some portions of operations or business or could be disqualified from providing services to healthcare providers doing business with government programs ~~. Risks Related to Our Reliance on Third Parties We will rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for, or commercialize, any potential product candidates. We will depend upon third parties to conduct certain aspects of our preclinical studies and depend on third parties, including independent investigators, to conduct our clinical trials, under agreements with universities, medical institutions, contract research organizations, or CROs, strategic partners and others. We expect to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We continue to build our infrastructure and hire personnel necessary to execute our operational plans. We will rely especially heavily on third parties over the course of our clinical trials, and, as a result, may have limited control over the clinical investigators and limited visibility into their day- to- day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of clinical trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical~~

trials must be conducted with product produced under cGMP requirements and may require a large number of patients. Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting aspects of our preclinical studies or our clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed or precluded entirely. The pharmaceutical companies that we partner with may not be successful in receiving regulatory approval for drug indications or may not commercialize their companion therapies for our expected companion diagnostic programs. While we intend to provide our pharmaceutical company partners with new patient populations for such partners' existing or investigational targeted therapies, there can be no assurances that such partners will be able to obtain regulatory approval for new indications to treat these patient populations or otherwise be successful in commercializing these new therapies. The pharmaceutical companies we partner with: ● may not meet clinical trial endpoint targets in evaluating efficacy of a targeted therapy in the patient population; ● may encounter regulatory or production difficulties that could constrain the supply of the companion therapies; ● may have difficulties gaining acceptance of the use of the companion therapies in the clinical community; ● may not pursue commercialization of any companion therapies; ● may elect not to continue or renew commercialization programs based on changes in their strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; ● may not commit sufficient resources to the marketing and distribution of such companion therapies; or ● may terminate their relationship with us. Any of these factors could adversely affect our commercialization strategy, business, results of operations and financial condition. Our reliance on third parties to formulate and manufacture our drug product will expose us to a number of risks that may delay the development, regulatory approval and commercialization of our drug product or result in higher product costs. We have no direct experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. Instead, we will contract with one or more manufacturers to manufacture, supply, store and distribute drug supplies for our clinical trials. If our drug product receives FDA approval, we will rely on one or more third- party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third- party manufacturers exposes us to risks that, among other things, we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor; our third- party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and / or commercial needs, if any; our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products; and our contract manufacturers may fail to comply with good manufacturing practice and other government regulations and corresponding foreign standards. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenues. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U. S. PTO recently developed new regulations and procedures to govern administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Depending on future actions by the U. S. Congress, the federal courts, and the U. S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, there may be patent law reforms in foreign jurisdictions that could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents in those foreign jurisdictions. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Our current and future employees may have been previously employed at universities or other biotechnology, diagnostic technology or pharmaceutical companies, including our competitors or potential competitors and strategic partners. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require our employees 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 develops intellectual property that we regard as our own. Our and their assignment agreements may not be self- executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. Any lawsuits relating to infringement of intellectual property rights necessary to defend ourselves or enforce our rights will be costly and time consuming and could be unsuccessful. Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming, and could distract our technical and management personnel from their normal responsibilities. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent' s claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, 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~~ . Risks Relating to Our Common Stock Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors will be responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: ● allow the authorized number of our directors to be changed only by resolution of our board of directors; ● limit the manner in which stockholders can remove directors from our board of directors; ● establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors; ● require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; ● limit who may call stockholder meetings; ● authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and ● require the approval of the holders of at least two- thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws. Moreover, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Any of these provisions of our charter documents or Delaware law could, under certain circumstances, depress the market price of our common stock. The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock or could subject us to securities litigation. Our stock price may be extremely volatile. The stock market in general and the market for smaller medical technology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell our common stock at or above the price they paid for such stock. The market price for our common stock may be influenced by many factors, including: ● the success of competitive products or technologies; ● results of ~~planned~~ **existing or future** clinical trials ~~of our Phase 3 (VIKTORIA- 1), CELsignia HER2 Pathway Activity Test, CELsignia Multi- Pathway Activity Test or other CELsignia tests may develop in the future~~ ; ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key personnel; ● the level of expenses related to any of our **products** ~~CELsignia tests~~ or clinical development programs; ● actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; ● operating results that fail to meet expectations of securities analysts that cover our company; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in the structure of healthcare payment systems; ● market conditions in the pharmaceutical, biotechnology and medical technology sectors; ● sales of our stock by us, our insiders and our other stockholders; ● general economic and market conditions; and ● the other factors described in this " Risk Factors " section. Additionally, companies that have experienced volatility in the market price of their stock have been subject to an increased incidence of securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. Future sales of shares of our common stock, including by us and significant stockholders, could negatively affect our stock price. Sales of a substantial number of shares of our common stock in the public market could occur at any time. ~~Such sales~~ **Since December 2022** , **we have issued 1, 034, 500**

~~or the perception in the market that the holders of a large number of~~ shares of ~~our~~ common stock ~~intend to sell their shares, could reduce the trading price of our common stock. On December 9, 2022, we issued 6, 182, 574 shares of common stock, 1, 120, 873 shares of Series A Preferred Stock and warrants exercisable for 6, 956, 450 shares of common stock to certain institutional and other accredited investors in a private placement~~ pursuant to **equity financing arrangements** ~~a securities purchase agreement entered into on May 15~~ , **including** ~~2022. Each share of Series A Preferred Stock is convertible at the option of the holder, subject to the Beneficial Ownership Limitation described below, into 10 shares of common stock. Under the terms of the Series A Preferred Stock and the warrants, we will not effect the conversion of any Series A Preferred Stock or the exercise of any such warrant, and the investor will not have the right to convert any portion of the Series A Preferred Stock or to exercise any portion of any warrant, to the extent that, after giving effect to an attempted conversion or exercise, the aggregate number of shares of common stock beneficially owned by the investor, together with its affiliates, would exceed 9. 99 % of the number of shares of common stock outstanding immediately after giving effect to the conversion or exercise, which percentage may be reset at the investor' s election to a higher percentage, not to exceed 19. 9 %, upon 61 days' notice to us, or to a lower percentage, effective immediately after notice to us. We refer to such percentage limitation as the Beneficial Ownership Limitation. We filed a registration statement on Form S- 3 covering the resale of up to 24, 347, 754 shares of common stock, consisting of (i) 6, 182, 574 shares of common stock purchased by the investors under the securities purchase agreement, (ii) 11, 208, 730 shares of common stock issuable upon conversion of the Series A Preferred Stock and (iii) 6, 956, 450 shares of common stock issuable upon exercise of the warrants, which was declared effective in January 2023. The Form S- 3 covers the resale of the number of shares of common stock issued or issuable to the investors without giving effect to the Beneficial Ownership Limitation, but the investors may not convert or exercise, and subsequently resell the underlying shares of common stock of, any portion of the Series A Preferred Stock or the warrants to the extent such conversion or exercise would result in the investor exceeding the applicable Beneficial Ownership Limitation. The investors may resell all, some or none of the shares of common stock registered~~ pursuant to ~~the Form S- 3 at any time or~~ **our** ~~in their discretion, subject to the Beneficial Ownership Limitation. On February 4, 2022, we entered into an~~ Open Market Sale AgreementSM with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $ 50, 000, 000. ~~On October 12, 2022, pursuant to this agreement, we sold 500, 000 shares of common stock in a single transaction at a price of $ 10. 35 per share, generating gross proceeds of $ 5. 2 million ($ 4. 8 million net of commissions and offering expenses).~~ At December 31, ~~2022~~ **2023** , $ ~~44~~ **29** . 8 million of common stock remains available for sale under the Jefferies agreement. **We may enter into additional equity financing arrangements in the future.** The ~~extent~~ **shares of common stock that we have issued pursuant** to **equity financings, or may issue in the future, may be resold at any time in the discretion of the investors. In addition, an aggregate of 21, 552, 860 shares of common stock are issuable upon conversion or exercise of currently outstanding preferred stock and financing warrants, subject to certain beneficial ownership limitations,** which ~~we utilize~~ **the investors may subsequently resell into the market, and 2, 815, 392 shares of common stock are issuable upon exercise of awards granted under our 2017 Stock Incentive Plan and 2012 Equity Incentive Plan. Under our Innovatus Loan Agreement, Innovatus also has the right, at its election, to convert up to $ 6. 6 million of outstanding principal of our Innovatus loans into common stock at a price of $ 10. 00 per share. Based on our outstanding principal as of March 27, 2024, Innovatus has the right to acquire 300, 000 shares of common stock pursuant to this provision. Sales of substantial amounts of shares of our common stock or other securities by these investors or our other stockholders or by us under** the Open Market Sale AgreementSM ~~as~~ **, or the perception in the market that the holders of** a **large** ~~source of funding will depend on a~~ number of **shares** ~~factors, including the prevailing market price~~ of our common stock **intend** ~~, general market conditions and the extent~~ to **sell** ~~which we are able to secure funds from other~~ **their** ~~sources. Sales of substantial amounts of~~ shares ~~of our common stock or other securities by our stockholders , by us under the Open Market Sale AgreementSM, by the private placement investors pursuant to the Form S- 3 or through any other means~~ could **reduce** ~~also lower~~ the ~~market~~ **trading** price of our common stock, make it more difficult for you to sell your shares at a price that you desire and impair our ability to raise capital through the sale of equity or equity- related securities. Our Series A Preferred Stock has rights, preferences, and privileges that are not held by, and are preferential to, the rights of holders of our common stock **. We issued 1, 120, 873 shares of Series A Preferred Stock in a financing transaction in December 2022, and 854, 134 shares of Series A Preferred Stock were outstanding as of December 31, 2023** . The Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock provides that, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or in the event of a Deemed Liquidation Event (as defined in the Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock), the holders of Series A Preferred Stock are entitled to be paid from assets of the Company available for distribution to its stockholders, before any payment is made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the original issue price ($ 5. 75 on an as- converted- to- common stock basis), plus all accrued and unpaid dividends and (ii) the amount that the holder would have been entitled to receive at such time if the Series A Preferred Stock were converted into common stock. The Company may not, without the consent of holders of a majority of the outstanding shares of Series A Preferred Stock, amend its charter in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock or issue or obligate itself to issue shares of any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company and the payment of dividends. If securities or industry analysts do not publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their

opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline. We incur increased costs as a result of operating as a public company, and our management ~~will be required to devote~~ **devotes** substantial time to new compliance initiatives and corporate governance practices. As a public company, we ~~will~~ incur significant legal, accounting and other expenses that we did not incur as a private company **and that private company competitors do not incur** . The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the continued listing requirements of The Nasdaq Stock Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel ~~will need to~~ devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our ongoing legal and financial compliance costs and ~~will~~ make some activities more time- consuming and costly. Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. Depending upon our filer status, we could also be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm as required by Section 404 (b). While we, as of December 31, ~~2022~~ **2023** , concluded that our internal control over financial reporting was effective, we may need to dedicate additional internal resources and engage outside consultants to maintain compliance with Section 404 in the future. Any material weaknesses that we may identify in the future could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. ITEM 1B. Unresolved Staff Comments None **. ITEM 1C. Cybersecurity Risk Management and Strategy Our cybersecurity risk management process is a component of our overall approach to managing material risks that could impact our operations, including cybersecurity threats. In general, we seek to manage material internal and third- party cybersecurity risks through an approach that focuses on: (i) protecting information systems and the information residing therein; (ii) identifying, preventing, and mitigating cybersecurity threats; and (iii) assessing and responding to cybersecurity incidents when they occur. Maintaining, monitoring, and updating our information security program — in an effort to ensure that it remains reasonable and appropriate in light of changes in the security threat landscape, available technology, and applicable legal and contractual requirements — is an ongoing effort. We have implemented and maintain various processes, procedures, and measures to support our overall risk management strategy and to manage and mitigate the material risks posed by cybersecurity threats to our systems and data. With respect to cybersecurity, these measures include conducting risk assessments of our operations and using a risk register to assess identified risks; developing business continuity, disaster recovery and incident response plans; implementing technical safeguards and tools; conducting ongoing cybersecurity awareness training; and using contractual protections where appropriate. Our incident response plan outlines the procedures for reporting, investigating, and remediating cybersecurity incidents, including a framework to facilitate the escalation to our management team and board of cybersecurity incidents, so that our management team is alerted in a timely manner to material information that would be required to be disclosed or reported. Our Chief Financial Officer works with our IT Director regarding incident prevention and response, as well as disclosure determinations, and is accountable at the management level for our overall risk management program. She receives information about cybersecurity from our IT Director to consider as part of that program. Additionally, our Chief Executive Officer receives updates from the Chief Financial Officer and IT Director about significant threats and incidents involving cybersecurity and data protection. We use third- party service providers for a variety of services throughout our business, ranging from infrastructure support and maintenance, cybersecurity incident response, data protection and privacy compliance. In addition, we engage with contract research organizations, contract manufacturing organizations, distributors, and other supply chain resources. We believe that the use of external service providers improves our operational capabilities, and we have implemented a vendor qualification and management program that applies to our service providers that handle protected health information, personal information, or other information subject to protection under applicable privacy and data protection regulations. This program is designed to address and mitigate cybersecurity and data protection risks that arise from our use of such service providers. We do not have full visibility into the cybersecurity risk management processes of our service providers. We rely on our third- party service providers to provide notification of, and remediate, significant cybersecurity threats and cybersecurity incidents that jeopardize the confidentiality, integrity, or availability of information that we own or use. We periodically evaluate, test, and update our policies, standards, and processes to mitigate cybersecurity threats and manage incidents effectively. These efforts include risk assessments, vulnerability assessments and remediations, phishing tests and employee education, and external scans. Additionally, to enhance our capabilities, we periodically engage third- party service providers, including cybersecurity consultants, to incorporate threat intelligence into our processes. As of the date of this Form 10- K, we are not aware of any risks from cybersecurity threats, including those resulting from any previous cybersecurity incidents experienced by us or, to our knowledge, by any of our third- party service providers, that have materially affected, or are reasonably likely to materially affect, our business strategy, results of operations, or financial condition. For further discussion of cybersecurity and data privacy risks that may materially affect the Company and how they may do so, see " Risk Factors — If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could face clinical trial delays; regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse consequences, " included in Item 1A of this Annual Report on Form 10- K. Governance The Board oversees Celcuity' s management of risks arising from cybersecurity threats. Our management team is implementing processes for delivering periodic briefings to the Board on material cybersecurity risks that are pertinent to our business operations. Additionally, we have processes to promptly**

**notify the Board of a significant cybersecurity incident and to inform the Board of remediation progress, as appropriate. The IT Director has overall responsibility for our information security program, with support from our management team and specialized partners in cybersecurity incident response and privacy. The process includes managing our incident response strategy. If a cybersecurity incident meets certain criteria, however, our CEO and CFO will become involved with the response strategy, including decisions about public disclosure and reporting. Our IT Director also coordinates with our CEO and CFO to determine strategic cybersecurity priorities and to establish compliance procedures. We believe our business leaders have the appropriate expertise, background and depth of experience to manage risks arising from cybersecurity threats. Our IT Director has served in various roles in information technology and information security for over a decade, which includes experience in the biotech, pharmaceutical and healthcare industries and experience in cybersecurity risk management and data privacy compliance. In the ordinary course of our business, we, and the third parties upon which we rely, collect, process, receive, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share and store (collectively, " process ") proprietary, confidential, and sensitive information, including protected health information, personal information, credit card and other financial information, or other sensitive information owned or controlled by ourselves or our customers, payors, and other parties** . ITEM 2. Properties We currently lease and occupy approximately 16, 000 square feet in Minneapolis, Minnesota, which includes our clinical laboratory and offices. On March 13, 2023, we signed the fourth amendment to our lease agreement, which expires in April 2026. The lease provides for monthly rent, real estate taxes and operating expenses. We believe that this leased space is adequate to meet current and anticipated future requirements and that additional or substitute space will be available as needed to accommodate any expansions that our operations require. ITEM 3. Legal Proceedings From time to time we may be involved in disputes or litigation relating to claims arising out of our operations. We are not currently a party to any legal proceedings that could reasonably be expected to have a material adverse effect on our business, financial condition and results of operations. ITEM 4. Mine Safety Disclosures Not applicable. PART II ITEM 5. Market For Registrant' s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities. Market Price Information Our common stock has been listed on The Nasdaq Capital Market under the symbol " CELC " since September 20, 2017. As of March ~~14~~ **12** , ~~2023~~ **2024** , there were approximately ~~54~~ **55** holders of record of our common stock. The actual number of holders of common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and nominees. The number of holders of record also does not include stockholders whose shares may be held in trust by other entities. Dividends We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the operation and expansion of our business. We do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any. Recent Sales of Unregistered Securities **In November 2023, an accredited investor exercised warrants to purchase 2, 369 shares of our common stock at an exercise price of $ 9. 50 per share, resulting in cash proceeds of approximately $ 22, 505. No underwriters were involved in such issuance of securities. The securities were issued to an accredited investor in reliance upon the exemption from registration requirements of the Securities Act, as set forth in Section 4 (a) (2) under the Securities Act, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.** Issuer Purchases of Equity Securities Equity Compensation Plan Information The information required by this Item concerning equity compensation plans is incorporated herein by reference from Part III, Item 11 of this Annual Report. ITEM 6. Reserved. ITEM 7. Management' s Discussion and Analysis of Financial Condition and Results of Operations You should read the following discussion and analysis of our financial condition and results of operations together in conjunction with our financial statements and the related notes included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and expected financial results, includes forward- looking statements that involve risks and uncertainties. You should review the " Risk Factors " discussed in Item 1A of Part I of this Annual Report. ~~OVERVIEWCelcuity~~ **OVERVIEW Celcuity** is a clinical- stage biotechnology company focused on **the** development of targeted therapies for **oncology** ~~treatment of multiple solid tumor indications~~ . The Company' s lead therapeutic candidate is gedatolisib, a pan- PI3K / mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR alone or together. The Company initiated VIKTORIA- 1, a Phase 3 study evaluating gedatolisib in patients with HR / HER2- advanced breast cancer in 2022 **and is currently enrolling patients. In addition to the Phase 3 study, the Company recently announced that it received U. S. Food and Drug Administration (" FDA ") clearance for its Investigational New Drug (IND) submission for the clinical development of gedatolisib in combination with Nubeqa ® (darolutamide), for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC). The Company initiated a Phase 1b / 2 study, CELC- G- 201, in the first quarter of 2024** and is currently enrolling patients. Its CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved targeted therapies. Gedatolisib, is a potent, well- tolerated, small molecule reversible dual inhibitor, administered intravenously, that selectively targets all Class I isoforms of PI3K and mammalian target of rapamycin (mTOR). In April 2021, we obtained exclusive global development and commercialization rights to gedatolisib under a license agreement with Pfizer, Inc. We believe gedatolisib' s unique mechanism of action, differentiated chemical structure, favorable pharmacokinetic properties, and intravenous formulation offer distinct advantages over currently approved and investigational therapies that target PI3K or mTOR alone or together. ● Overcomes limitations of therapies that only inhibit a single Class I PI3K isoform or only one mTOR kinase complex. Gedatolisib is a pan- class I isoform PI3K inhibitor with low nanomolar potency for the p110α, p110β, p110γ, and

p110δ isoforms and mTORC1 and mTORC2 complexes. Each PI3K isoform and mTOR complex is known to preferentially affect different signal transduction events that involve tumor cell survival, depending upon the aberrations associated with the linked pathway. When a therapy only inhibits a single Class I isoforms (e. g., alpelisib, a PI3K- α inhibitor) or only one mTOR kinase complex (e. g., everolimus, an mTORC1 inhibitor), numerous feedforward and feedback loops between the PI3K isoforms and mTOR complexes cross- activates the uninhibited sub- units. This, in turn, induces compensatory resistance that reduces the efficacy of isoform specific PI3K or single mTOR kinase complex inhibitors. Inhibiting all four PI3K isoforms and both mTOR complexes, as gedatolisib does, thus prevents the confounding effect of isoform interaction that may occur with isoform- specific PI3K inhibitors and the confounding interaction between PI3K isoforms and mTOR. ● Better tolerated by patients than oral PI3K and mTOR drugs. Gedatolisib is administered intravenously (IV) on a four- week cycle of three weeks- on, one week- off, in contrast to the orally administered pan- PI3K or dual PI3K / mTOR inhibitors that are no longer being clinically developed. Oral pan- PI3K or PI3K / mTOR inhibitors have repeatably been found to induce significant side effects that were not well tolerated by patients. This typically leads to a high proportion of patients requiring dose reductions or treatment discontinuation. The challenging toxicity profile of these drug candidates ultimately played a significant role in the decisions to halt their development, despite showing promising efficacy. By contrast, gedatolisib stabilizes at lower concentration levels in plasma compared to orally administered PI3K inhibitors, resulting in less toxicity, while maintaining concentrations sufficient to inhibit PI3K / mTOR signaling. Isoform- specific PI3K inhibitors administered orally were developed to reduce toxicities in patients. While the range of toxicities associated with isoform- specific inhibitors is narrower than oral pan- PI3K or PI3K / mTOR inhibitors, administering them orally on a continuous basis still leads to challenging toxicities. The experience with an FDA approved oral p110- α specific inhibitor, Piqray, illustrates the challenge. In its Phase 3 pivotal trial Piqray was found to induce a Grade 3 or 4 adverse event (AE) related to hyperglycemia in 39 % of patients evaluated. In addition, 26 % of patients discontinued alpelisib due to treatment related adverse events. By contrast, in the 103- patient dose expansion portion of the Phase 1b clinical trial with gedatolisib, only 7 % of patients experienced Grade 3 or 4 hyperglycemia and less than 10 % discontinued treatment. As of December 31, ~~2022~~ **2023** , 492 patients with solid tumors have received gedatolisib in eight clinical trials sponsored by Pfizer. Of the 492 patients, 129 were treated with gedatolisib as a single agent in three clinical trials. The remaining 363 patients received gedatolisib in combination with other anti- cancer agents in five clinical trials. Additional patients received gedatolisib in combination with other anti- cancer agents in nine investigator sponsored clinical trials. A Phase 1b trial (B2151009) evaluating patients with ER / HER2- metastatic breast cancer was initiated in 2016 and subsequently enrolled 138 patients. ~~Seven~~ **Five** patients from this study continue to receive study treatment, as of December 31, ~~2022~~ **2023** , each of which have received study treatment for more than ~~four~~ **five** years. The B2151009 clinical trial was an open label, multiple arm Phase 1b study that evaluated gedatolisib in combination with palbociclib (CDK4 / 6 inhibitor) and fulvestrant or letrozole in patients with HR / HER2- advanced breast cancer. Thirty- five patients were enrolled in two dose escalation arms to evaluate the safety and tolerability and to determine the maximum tolerated dose (MTD) of gedatolisib when used in combination with the standard doses of palbociclib and endocrine therapy (letrozole or fulvestrant). The MTD was determined to be 180 mg administered intravenously once weekly. A total of 103 patients were subsequently enrolled in one of four expansion arms (A, B, C, D). High objective overall response rates **(ORR)** were observed in all four expansion arms and were comparable in each arm for PIK3CA WT and PIK3CA MT patients. ~~In~~ **As of the data cut- off date, March 16, 2023, for** treatment- naïve patients ~~(~~**in Escalation** Arm A **and Expansion Arm A (n = 41** ), **median progression free survival (mPFS) was 48. 6 months, median duration of response (mDOR) was 46. 9 months, and** ORR was ~~85~~ **79** % **. respectively. This data compares favorably to published data for current first- line standard- of- care treatments for patients with HR / HER2- advanced breast cancer** . In patients who received prior hormonal therapy alone or in combination with a CDK4 / 6 inhibitor (Arms B, C, and D), ORR **(including unconfirmed partial responses)** ranged from 36 % to 77 %. Each arm achieved its primary endpoint target, which was reporting higher ORR in the study arm than ORR from either the PALOMA- 2 (ORR = 55 %) study that evaluated palbociclib plus letrozole for Arm A or the PALOMA- 3 study (ORR = 25 %) that evaluated palbociclib plus fulvestrant for Arms B, C, and D. For all enrolled patients, a clinical benefit rate (CBR) of ≥ 79 % was observed. Median progression- free survival (PFS) was 12. 9 months for patients who received a prior CDK4 / 6 inhibitor and were treated **in the study** with the Phase 3 dosing schedule (Arm D) ~~. For the Arm A patients that were treatment naive in the advanced setting, median PFS had not yet been reached~~ . Gedatolisib combined with palbociclib and endocrine therapy demonstrated a favorable safety profile with manageable toxicity. The majority of treatment emergent adverse events were Grade 1 and 2. The most frequently observed adverse events included stomatitis / mucosal inflammation, the majority of which were Grade 1 and 2. The most common Grade 4 AEs were neutropenia and neutrophil count decrease, which were assessed as related to treatment with palbociclib. No grade 5 events were reported in this study. We ~~activated VIKTORIA- 1,~~ **are currently enrolling patients in** a Phase 3, open- label, randomized clinical trial **(VIKTORIA- 1)** to evaluate the efficacy and safety of two regimens in adults with HR / HER2- advanced breast cancer whose disease has progressed after prior CDK4 / 6 therapy in combination with an aromatase inhibitor: 1) gedatolisib in combination with palbociclib and fulvestrant ~~:~~ **;** and 2) gedatolisib in combination with fulvestrant. ~~Two~~ **Approximately two** hundred clinical sites in North America, Europe, South America, Asia, and Australia have been selected to participate in the study. The first clinical site was activated in the third quarter ~~. The~~ **of 2022, and the** first ~~dosage of a~~ patient **was dosed** ~~in the trial occurred~~ in December 2022. The **VIKTORIA- 1 Phase 3** clinical trial will enable separate evaluation of subjects according to their PIK3CA status. Subjects who meet eligibility criteria and are PIK3CA WT will be randomly assigned (1: 1: 1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm A), gedatolisib and fulvestrant (Arm B), or fulvestrant (Arm C). Subjects who meet eligibility criteria and are PIK3CA MT will be randomly assigned (3: 3: 1) to receive a regimen of either gedatolisib, palbociclib, and fulvestrant (Arm D), **or** alpelisib and fulvestrant (Arm E), or gedatolisib and fulvestrant (Arm F) **. We received approval from the US FDA in mid- 2023 to proceed with the clinical development of gedatolisib in combination with Nubeqa ® (darolutamide), an approved**

**androgen receptor inhibitor, for the treatment of patients with mCRPC. We have since initiated a Phase 1b / 2 study (CELC- G- 201) that will enroll up to 54 participants with mCRPC who progressed after treatment with an androgen receptor inhibitor. We dosed our first patient in this trial in February 2024. In the Phase 1b portion of the study, Celcuity expects that 36 participants will be randomly assigned to receive 600 mg darolutamide combined with either 120 mg gedatolisib in Arm 1 or 180 mg gedatolisib in Arm 2. An additional 12 participants will then be enrolled in the Phase 2 portion of the study at the recommended phase 2 dose (RP2D) level to enable evaluation of 30 participants treated with the RP2D of gedatolisib. The primary objectives of the Phase 1b portion of the trial include assessment of the safety and tolerability of gedatolisib in combination with darolutamide and determination of the recommended Phase 2 dose of gedatolisib. The primary objective of the Phase 2 portion of the trial is to assess the radiographic progression-free survival (rPFS) at six months of patients who received the RP2D** . Our proprietary CELsignia diagnostic platform is the only commercially ready technology we are aware of that uses a patient' s living tumor cells to identify the specific abnormal cellular process driving a patient' s cancer and the targeted therapy that best treats it. This enables us to identify patients whose tumors may respond to a targeted therapy, even though they lack a previously associated molecular mutation. By identifying cancer patients whose tumors lack an associated genetic mutation but have abnormal cellular activity a matching targeted therapeutic is designed to inhibit, CELsignia CDx can expand the markets for a number of already approved targeted therapies. Our current CDx identifies breast and ovarian cancer patients whose tumors have cancer drivers potentially responsive to treatment with human epidermal growth factor receptor 2- negative (HER2), mesenchymal- epithelial transition factor (c- MET), or phosphatidylinositol 3- kinases (PI3K) targeted therapeutics. While U. S. Food and Drug Administration (" FDA ") approval or clearance is not currently required for CELsignia tests offered as a stand- alone laboratory developed test, if we are partnered with a drug company to launch a CELsignia test as a companion diagnostic for a new drug indication, we would be required to obtain premarket approval, or PMA, in conjunction with the pharmaceutical company seeking a new drug approval for the matching therapy. We are supporting the advancement of new potential indications for ~~four~~ **three** different targeted therapies, controlled by other pharmaceutical companies, that would rely on a CELsignia CDx to select patients. ~~Four~~ **Three** Phase 2 trials are underway to evaluate the efficacy and safety of these therapies in CELsignia selected patients. These patients are not currently eligible to receive these drugs and are not identifiable with a molecular test. Supporting the development of a potential first- in- class targeted therapy for breast cancer, like gedatolisib, with our CELsignia platform is a natural extension of our strategy to use our CELsignia CDx to enable new indications for other companies' targeted therapies. By combining companion diagnostics designed to enable proprietary new drug indications with targeted therapies that treat signaling dysregulation our CDx identifies, we believe we are uniquely positioned to improve the standard- of- care for many early and late- stage breast cancer patients. Our goal is to play a key role in the multiple treatment approaches required to treat breast cancer patients at various stages of their disease. With each program, we are: ● Leveraging the proprietary insights CELsignia provides into live patient tumor cell function ● Using a CELsignia CDx to identify new patients likely to respond to the paired targeted therapy ● Developing a new targeted therapeutic option for breast cancer patients ● Maximizing the probability of getting regulatory approval to market the targeted therapy indicationRecent Developments On **February 22, 2024, the Company announced that the first patient has been dosed in its Phase 1b / 2 study (CELC- G- 201) evaluating gedatolisib in combination with Nubeqa ® (darolutamide), an approved androgen receptor inhibitor, for the treatment of patients with mCRPC. In** December ~~22, 2022~~ **2023** , Celcuity ~~closed~~ **presented data from nonclinical studies evaluating gedatolisib and other PI3K / AKT / mTOR (PAM) inhibitors in breast cancer cell lines during a poster session at the 2023 San Antonio Breast Cancer Symposium (SABCS). In a panel of breast cancer cell lines, gedatolisib was found to be more cytotoxic and at least 300-fold more potent,** on **average, compared to the single node PAM inhibitors. On December 1, 2023, pursuant to an Open Market Sale AgreementSM with Jefferies LLC, as agent, the Company sold 1, 034, 500 shares of common stock in** a **single transaction at a price of** $ ~~20~~ **14** . **50 per share** ~~0 million term loan (the " Term B Loan ") with an affiliate of Innovatus Capital Partners~~ , **generating gross proceeds** ~~LLC (" Innovatus "), pursuant to a Loan and Security Agreement, dated April 8, 2021 (the " Loan Agreement "), as amended by that First Amendment to Loan and Security Agreement, dated August 9, 2022 (the " Amendment and collectively with the Loan Agreement, the " Amended Loan Agreement "). The Company became eligible to draw down the Term B Loan upon the closing~~ of ~~the Company' s previously disclosed $ 100 million private placement on December 9, 2022. As previously disclosed, the Amended Loan Agreement may provide the Company with up to $ 75. 0 million through funding of up to five term loans. Funding of the first~~ $ 15 ~~.~~ **million before deducting commissions and other offering expenses of $** 0 ~~million term loan occurred on April 8, 2021 in connection with entering into the original Loan Agreement. As of December 31, 2022, term loans totaling $ 35 million are outstanding under the Amended Loan Agreement. Celcuity will be able to draw on two additional tranches of $ 10 million each and one additional tranche of $ 20 million upon achievement of certain clinical trial milestones and satisfaction of certain financial covenants determined on a pro forma as-funded basis. Funding of these additional tranches is also subject to other customary conditions and limits on when the Company can request funding for such tranches. Celcuity is entitled to make interest only payments for the 48- month period from the original agreement date or for the 60- month period from the original agreement date if certain conditions are met. The loans will mature on April 8, 2027, the sixth anniversary of the initial funding date. Innovatus has the right to convert outstanding principal into shares of Celcuity common stock until the third anniversary of the loan amendment date, with such amount limited to an aggregate of up to $ 6~~~~ . 6 million ~~assuming all tranches are funded. The loan is secured by all of Celcuity' s assets~~ . On **October** ~~December 9, 2022, Celcuity closed on a private placement of common stock and preferred stock, resulting in gross proceeds of approximately $ 100 million, before deducting placement agent fees and other expenses. Celcuity issued 6, 182~~ **18** , **2023** ~~574 shares of common stock , 1, 120, 873 shares of Series A Preferred Stock and warrants exercisable for 6, 956, 450 shares of common stock to certain institutional and other~~ -- **the Company entered into** ~~accredited investors pursuant to~~ a securities purchase agreement ~~entered into on May 15, 2022. Pursuant~~ to **sell pre** ~~the securities purchase agreement, the closing~~

~~(funding) of the private placement followed dosage of the first patient in Celcuity' s Phase 3 clinical trial, VIKTORIA -~~ **funded warrants** ~~1, evaluating gedatolisib, Celcuity' s lead therapeutic candidate. Investors purchased shares of common stock and Series A Preferred Stock~~ at a price of $ **8. 70 per warrant, to purchase up to** 5 **, 747, 787 shares of the Company' s common stock in a private placement** . ~~75~~ **The closing of the private placement occurred on October 20, 2023 and resulted in gross proceeds of approximately $ 50 million, before deducting offering expenses of approximately $ 0. 1 million. Each Warrant to purchase one share has a purchase price of $ 8. 699** per share **,** ~~(on an~~ **and** ~~as converted to common stock basis), with forty percent (40 %) warrant coverage (on an as converted to common stock basis) and customary resale registration rights. The warrants have~~ an exercise price of $ ~~8~~ **0** . ~~05~~ **001** per share **for** ~~. On December 7, 2022, Celcuity announced that~~ the ~~first patient was dosed~~ **Common Stock issuable upon exercise of the Warrant (for aggregate consideration equating to $ 8. 70 per share). The Company expects to use the net proceeds to advance clinical development of gedatolisib and for general corporate purposes. The Company has entered into a Registration Rights Agreement** in **connection with the private placement, pursuant to which** it ~~Phase --~~ **has agreed** ~~3 VIKTORIA- 1 clinical trial. Operational activities continue~~ to **register** ~~focus on facilitating activation of sites and enrolling patients. The clinical trial protocol was updated to include an additional study arm (Arm F) to evaluate gedatolisib plus fulvestrant in 50 patients who have PIK3CA mutations. This update was made in response to a recommendation from the European Medicines Agency (EMA) that the study arms~~ for **resale** ~~PIK3CA mutated patients mirror~~ the ~~same study arms~~ **shares issuable upon exercise** ~~for -~~ **or** ~~PIK3CA non- mutated patients. No changes -~~ **exchange** ~~were made to the primary endpoints. VIKTORIA- 1 will evaluate the safety and efficacy~~ of ~~gedatolisib in combination with fulvestrant with or without palbociclib in adults with HR / HER2- advanced breast cancer whose disease progressed while receiving prior CDK4 / 6 therapy. Further details about~~ the **Warrants** ~~study are available at ClinicalTrials. gov~~ . We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since we began operations in 2012. For the years ended December 31, **2023 and** 2022 ~~and 2021~~ , we reported a net loss of approximately $ **63. 8 million and $** 40. 4 million ~~and $ 29. 6 million~~ , respectively. As of December 31, ~~2022~~ **2023** , our cash and cash equivalents and short- term investments were approximately $ ~~168~~ **180** . 6 million, and we had an accumulated deficit of approximately $ ~~96~~ **160** . ~~3~~ **1** million ~~. Impact of COVID- 19 on our Business Although we have largely returned to normal operations in our facility, the COVID- 19 pandemic continues and its effect on our operations and financial condition will depend in large part on future developments which cannot be reasonably estimated at this time. Future developments include the duration, scope and severity of the pandemic, the emergence of new virus variants that are more contagious or harmful than prior variants, actions taken by governmental authorities, suppliers, clinical trial sites, and other business partners to contain or mitigate the pandemic' s impact, and the potential adverse effects on the suppliers, labor market and general economic activity. As we continue to advance our clinical trial collaborations, we remain in close contact with our current clinical sponsors, and principal investigators, as well as prospective pharmaceutical company and clinical collaborators, to monitor the impact of COVID- 19 on our trial enrollment timelines and collaboration discussions. We experienced delays in the enrollment of patients in our ongoing CELsignia Phase 2 clinical trials and now expect interim results from FACT- 1 and FACT- 2 to be delayed until the second half of 2023. We could experience further delays in clinical trials and collaborations with pharmaceutical companies and sponsors if new variants emerge or if the spread of COVID- 19 once again accelerates. Due to the inherent uncertainty associated with the COVID- 19 pandemic, we are unable to predict the impact the pandemic may have on our clinical trial work and overall financial condition~~ . RESULTS OF OPERATIONS Components of Operating Results Revenue To date, we have not generated any revenue. With the execution of the Pfizer license agreement in April 2021, whereby we acquired exclusive world- wide licensing rights to develop and commercialize gedatolisib, we initiated a Phase 3 clinical trial, VIKTORIA- 1, in 2022 to support potential regulatory approval to market gedatolisib **. In August 2023, we announced plans to proceed with the clinical development of gedatolisib in combination with Nubeqa ® (darolutamide), an approved androgen receptor inhibitor, for the treatment of patients with mCRPC** . If we obtain regulatory approvals to market gedatolisib, we expect to generate revenue from sales of the drug for the treatment of breast cancer patients. Additionally, we will seek to generate revenue from partnership agreements with pharmaceutical companies to provide companion diagnostics for such pharmaceutical partners' existing or investigational targeted therapies. If a new drug indication is received that requires use of our companion diagnostic to identify eligible patients, we expect to generate revenues from sales of tests to treating physicians. Research and Development Since our inception, we have primarily focused on research and development of gedatolisib, a PI3K / mTOR targeted therapy **,** and our CELsignia platform and corresponding tests. Research and development expenses primarily include: ● employee- related expenses related to our research and development activities, including salaries, benefits, recruiting, travel and stock- based compensation expenses; ● laboratory supplies; ● consulting fees paid to third parties; ● clinical trial costs; ● validation costs for gedatolisib; ● facilities expenses; and ● legal costs associated with patent applications. Internal and external research and development costs are expensed as they are incurred. As we continue **to** ~~development ----~~ **develop** ~~of~~ gedatolisib **, and** manage **studies and clinical trials, including** the VIKTORIA- 1 Phase 3 trial **, the CELC- G- 201 Phase 1b / 2 trial,** and other clinical trials to evaluate the efficacy of targeted therapies in cancer patients selected with one of our CELsignia tests, the proportion of research and development expenses allocated to external spending will grow at a faster rate than expenses allocated to internal expenses. General and Administrative General and administrative expenses consist primarily of salaries, benefits and stock- based compensation related to our executive, finance and support functions. Other general and administrative expenses include professional fees for auditing, tax, and legal services associated with being a public company, director and officer insurance, investor relations and travel expenses for our general and administrative personnel. Sales and Marketing Sales and marketing expenses consist primarily of professional and consulting fees related to these functions. To date, we have incurred immaterial sales and marketing expenses as we continue to focus primarily on ~~the development~~ **developing** ~~of~~ our first drug, gedatolisib, managing the VIKTORIA- 1 Phase 3 **and CELC-**

**G- 201 Phase 1b / 2** ~~trial~~ **trials** , and ~~development~~ **developing** ~~of~~ our CELsignia platform and corresponding CELsignia tests. We would expect to begin to incur increased sales and marketing expenses in anticipation of the commercialization of our first drug, gedatolisib, and CELsignia tests. These increased expenses are expected to include ~~payroll~~ **employee** - related ~~costs as we add employees in the commercial departments, costs related to the initiation~~ and **consulting** ~~operation of our sales and distribution network and marketing related~~ costs. Interest Expense Interest expense is primarily due to a Loan Agreement and finance lease obligations. Interest Income Interest income consists of interest income earned on our cash, cash equivalents and investment balances. Results of Operations Comparison of the Years Ended December 31, **2023 and** 2022 ~~and 2021~~ Years Ended December 31, Increase (Decrease) **2023** 2022 ~~2021~~ $ Percent Change Statements of Operations Data: Operating expenses: Research and development $ **60, 594, 005 $** 35, 289, 548 $ 25, ~~758~~ **304** , **457 72** ~~006 $ 9, 531, 542 37~~ % General and administrative **5, 636, 326** 4, 101, 543 ~~2, 597, 909~~ 1, ~~503~~ **534** , ~~634 58~~ **783 37** Total operating expenses **66, 230, 331** 39, 391, 091 ~~28~~ **26** , ~~355, 915 11, 035, 176 39~~ **839 , 240 68** Loss from operations ( **66, 230, 331) (** 39, 391, 091) ( ~~28~~ **26** , ~~355~~ **839** , ~~915~~ **240** ) **68** ~~(11, 035, 176) 39~~ Other income (expense) Interest expense ( **5, 326, 387) (** 2, 106, 111) ( ~~1~~ **3** , ~~262~~ **220** , ~~350~~ **276** ) **153** ~~(843, 761) 67~~ Interest income **7, 777, 602** 1, 127, 162 ~~13 6~~ , **650** ~~262 1~~ , **440 590** ~~113, 900 8, 399 Loss on sale of fixed assets~~ ~~(263) 263 n / a~~ Other income (expense), net **2, 451, 215** (978, 949) **3, 430, 164** ( **350** ~~1, 249, 351) 270, 402 (22~~ ) Net loss before income taxes ( **63, 779, 116) (** 40, 370, 040) ( ~~29~~ **23** , ~~605~~ **409** , ~~266~~ **076** ) **58** ~~(10, 764, 774) 36~~ Income tax benefits---- Net loss $ ( **63, 779, 116) $ (** 40, 370, 040) $ ( ~~29~~ **23** , ~~605~~ **409** , ~~266~~ **076** ) **58** ~~$ (10, 764, 774) 36~~ % For the year ended December 31, ~~2022~~ **2023** , our research and development expenses were approximately $ ~~35~~ **60** . ~~3~~ **6** million, representing an increase of approximately $ ~~9~~ **25** . ~~5~~ **3** million, or ~~37~~ **72** %, compared to the same period in ~~2021~~ **2022** . **Of** ~~Included in~~ the $ ~~9~~ **25** . ~~5~~ **3** million increase ~~is a $ 10 million reduction in gedatolisib licensing related expenses offset by increases of $ 19. 5 million in other research and development expenses. In the 2021 period, research and development expenses included a $ 10. 0 million upfront license fee related to the execution of the Pfizer license agreement while there were no licensing agreement expenses for gedatolisib in 2022. Of the $ 19. 5 million increase~~ in research and development expense, $ **2.** 4 ~~. 9~~ million was related to increased employee and consulting expenses ~~, of which $ 0. 9 million was in the form of non- cash stock- based compensation~~ . The remaining $ ~~14~~ **22** . ~~6~~ **9** million increase of research and development costs ~~is~~ **are primarily** related to costs **supporting activities** for ~~existing clinical trials and for activities supporting the initiation of~~ the VIKTORIA- 1 pivotal trial. Conducting a significant amount of research and development is central to our business model. We plan to increase our research and development expenses for the foreseeable future as we seek to develop gedatolisib, manage the VIKTORIA- 1 Phase 3 **and the CELC- G- 201 Phase 1b / 2** ~~trial~~ **trials** , discover new cancer sub- types, and develop and validate additional CELsignia tests to diagnose such sub- types. We also expect to incur increased expenses to support companion diagnostic business development activities with pharmaceutical companies as we develop additional CELsignia tests and manage ~~a~~ **the** clinical ~~trial~~ **trials** for gedatolisib. For the year ended December 31, ~~2022~~ **2023** , our total general and administrative expenses were $ ~~4~~ **5** . ~~1~~ **6** million, representing an increase of approximately $ 1. 5 million, or ~~58~~ **37** %, compared to the same period in ~~2021~~ **2022** . The increase primarily resulted from a $ 1. ~~3~~ **1** million increase in ~~compensation related~~ **employee and consulting** expenses ~~, including approximately $ 1. 1 million of non- cash stock- based compensation~~ . In addition, other general and administrative expenses increased $ 0. ~~2~~ **4** million primarily due to professional fees **and other expenses** associated with being a public company ~~and director and officer insurance~~ . We anticipate that our general and administrative expenses will increase in future periods, reflecting both increased costs in connection with the potential future commercialization of gedatolisib and CELsignia tests, an expanding infrastructure, and increased professional fees associated with ~~being a~~ public company **regulatory developments and other compliance matters** . For the year ended December 31, ~~2022~~ **2023** , interest expense was $ ~~2~~ **5** . ~~1~~ **3** million and represents an increase of $ ~~0~~ **3** . ~~8~~ **2** million compared to the same period in ~~2021~~ **2022** . The **increase is due to the** Loan Agreement that was executed in April 2021 **,** amended in August 2022, and includes $ ~~0~~ **2** . ~~9~~ **1** million of non- cash interest expense. The increase **in interest expense is** primarily ~~reflects~~ **due to** the **incremental $ 20 million funding of Term** ~~loan~~ **Loan** ~~being~~ **B** in **December** ~~place for the full year in~~ 2022 ~~, while only a portion of the year in 2021~~ . For the year ended December 31, ~~2022~~ **2023** , interest income **was** ~~increased approximately~~ $ ~~1~~ **7** . ~~1~~ **8 million and represents an increase of $ 6. 7** million compared to the same period in ~~2021~~ **2022** . The increase was primarily the result of higher market interest rates and the closing of additional financing activities, leading to higher cash, cash equivalents and short- term investment balances. LIQUIDITY AND CAPITAL RESOURCES Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through December 31, ~~2022~~ **2023** , we have funded our operations primarily through private placements and registered offerings of our equity securities and unsecured convertible notes, and borrowings under loan agreements. From inception through December 31, ~~2022~~ **2023** , we raised an aggregate of approximately $ ~~223~~ **288** . ~~7~~ **0** million of net proceeds through sales of our securities, and as of December 31, ~~2022~~ **2023** had $ 35. 0 million of borrowings under loan agreements. **In March 2024, an investor exercised 1, 739, 080 warrants at an exercise price of $ 8. 05, which generated approximately $ 14 million in cash. The warrants were issued pursuant to a private placement that closed and was funded on December 9, 2022.** As of December 31, ~~2022~~ **2023** , our cash and cash equivalents and short- term investments were approximately $ ~~24~~ **30** . ~~6~~ **7** million and $ ~~144~~ **149** . ~~0~~ **9** million, respectively, and we had an accumulated deficit of approximately $ ~~96~~ **160** . ~~3~~ **1 million. Open Market Sale OfferingSM. On February 4, 2022, we entered into an Open Market Sale AgreementSM with Jefferies LLC, as agent, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $ 50, 000, 000. Pursuant to the Open Market Sale AgreementSM with Jefferies LLC, as agent, on December 1, 2023, the Company sold 1, 034, 500 shares of common stock in a single transaction at a price of $ 14. 50 per share, generating gross proceeds of $ 15 million ($ 14. 4 million net of commissions and offering expenses). At December 31, 2023, $ 29. 8 million of common stock remains available for sale under the Jefferies agreement. Pre- funded Warrants On October 18, 2023, the Company entered into a securities purchase agreement to sell pre- funded warrants at a price of $ 8. 70 per warrant, to purchase up to 5, 747, 787 shares of**

**the Company' s common stock in a private placement. The closing of the private placement occurred on October 20, 2023, and resulted in gross proceeds of approximately $ 50 million, before deducting offering expenses of approximately $ 0. 1** million. Private Placement. On December 9, 2022, we issued 6, 182, 574 shares of common stock, 1, 120, 873 shares of Series A Preferred Stock and warrants exercisable for 6, 956, 450 shares of common stock to certain institutional and other accredited investors pursuant to a securities purchase agreement entered into on May 15, 2022. Pursuant to the securities purchase agreement, the closing (funding) of the private placement occurred following dosage of the first patient in the Company' s Phase 3 study, VIKTORIA- 1. Investors purchased shares of common stock and Series A Preferred Stock at a price of $ 5. 75 per share (on an as converted to common stock basis), with forty percent (40 %) warrant coverage (on an as converted to common stock basis) and customary resale registration rights. The warrants have an exercise price of $ 8. 05 per share. The private placement generated gross proceeds of approximately $ 100 million before deducting placement agent fees and other offering expenses of $ 4. 3 million. Open Market Sale AgreementSM. On ~~February 4~~ **October 12** , 2022, **pursuant to our** ~~we entered into an~~ Open Market Sale AgreementSM with Jefferies LLC ~~,~~ as agent ~~, pursuant to which we may offer and sell, from time to time, through Jefferies, shares of our common stock having an aggregate offering price of up to $ 50, 000, 000. On October 12, 2022, pursuant to this agreement~~ , the Company sold 500, 000 shares of common stock in a single transaction at a price of $ 10. 35 per share, generating gross proceeds of $ 5. 2 million ($ 4. 8 million net of commissions and offering expenses) ~~. At December 31, 2022, $ 44. 8 million of common stock remains available for sale under the Jefferies agreement~~ . Innovatus Loan Agreement. On April 8, 2021, we entered into a Loan Agreement with Innovatus Life Sciences Lending Fund I, LP (" Innovatus "), under which Innovatus agreed to loan up to $ 25 million in three tranches consisting of (i) a $ 15. 0 million non- contingent Term A loan that was funded on April 8, 2021, (ii) a $ 5 million Term B loan with a deadline of March 31, 2022, and (iii) a $ 5 million Term C loan to be funded upon our request, subject to our ability to achieve certain milestones, no later than March 31, 2023. On August 9, 2022, the Company amended the Loan Agreement with Innovatus to provide for up to $ 75 million in term loans. As of December 31, ~~2022~~ **2023** , term loans totaling $ 35 million are outstanding under the Loan Agreement, including the initial Term A loan of $ 15 million which was funded on April 8, 2021, and a $ 20 million Term B loan which was funded on December 22, 2022 following the closing of the $ 100 million private placement described above. Additionally, the Company will be able to draw on two additional tranches of $ 10 million and one additional tranche of $ 20 million upon achievement of certain clinical trial milestones and satisfaction of certain financial covenants determined on a pro forma as- funded basis. Funding of these additional tranches is also subject to other customary conditions and limits on when the Company can request funding for such tranches. We expect that our research and development and general and administrative expenses will increase as we continue to develop gedatolisib, manage the VIKTORIA- 1 Phase 3 **and CELC- G- 201 Phase 1b / 2** ~~trial~~ **trials** , conduct research related to the discovery of new cancer sub- types, conduct **other studies and** clinical trials, and pursue other business development activities. We would also expect to incur sales and marketing expenses as we commercialize gedatolisib and our CELsignia tests. We expect to use cash on hand **, which includes funds received under the debt and equity financings described above,** to fund our research and development expenses, clinical trial costs, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses. Based on our current business plan, we believe that our current cash, cash equivalents and short- term investments together with available borrowings under the Innovatus Loan Agreement will provide sufficient cash to finance our operations and pay obligations when due through at least 2025. Our expectations as to how long our current capital resources will be sufficient to fund our operations are based on assumptions that may not be accurate, and we could use our current capital resources sooner than we currently expect. In addition, we may seek to raise additional capital to finance capital expenditures and operating expenses over the next several years as we launch our integrated therapeutic and companion diagnostic strategy and expand our infrastructure, commercial operations and research and development activities, and to take advantage of financing or other opportunities that we believe to be in the best interests of the Company and our stockholders. Additional capital may be raised through the sale of common or preferred equity or convertible debt securities, entry into debt facilities or other third- party funding arrangements. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. Agreements entered into in connection with such capital raising activities could contain covenants that would restrict our operations or require us to relinquish certain rights. Additional capital may not be available on reasonable terms, or not at all. Cash Flows The following table sets forth the primary sources and uses of cash for the years ended December 31: December 31, **2023** 2022 ~~2021~~ Net cash provided by (used in): Operating activities $ ( ~~36~~ **53** , ~~008~~ **812** , ~~171~~ **253** ) $ ( ~~20~~ **36** , ~~311~~ **008** , ~~940~~ **171** ) Investing activities ( ~~144~~ **5** , ~~031~~ **008** , ~~794~~ **207** ) ( ~~81~~ **144** , ~~398~~ **031, 794** ) Financing activities **64, 911, 677** 120, 325, 141 ~~93, 041, 808~~ Net increase (decrease) in cash and cash equivalents $ **6, 091, 217 $** (59, 714, 824) ~~$ 72, 648, 470~~ Operating Activities ~~.~~ Net cash used in operating activities was approximately $ ~~20~~ **53** . ~~3~~ **8** million for the year ended December 31, ~~2021~~ **2023** and consisted primarily of a net loss of approximately $ ~~29~~ **63** . ~~6~~ **8** million, ~~adjusted for~~ **offset by working capital changes of $ 3.9 million and** non- cash **expense** items of approximately $ ~~8~~ **6** . **1** ~~5 million and working capital changes of approximately $ 0.8~~ million.Non- cash expense items of approximately $ ~~8~~ **6** . ~~5~~ **1** million **primarily** consisted of $ ~~5~~ **4** . ~~0~~ **9** million ~~for issuance~~ of ~~common stock related to a license agreement,~~ stock- based compensation expense ~~of approximately $ 2.6 million~~ ,non- cash interest expense of $ ~~0~~ **2** . ~~6~~ **1** million and depreciation **expense** of ~~approximately~~ $ 0. ~~3~~ **1** million **,offset by $ 1.0 accrued interest income** .The **approximately $ 3.9 million of** working capital ~~change~~ **changes** ~~of approximately $ 0.8 million~~ was primarily due to **increases in accounts payable and accrued expenses,offset by** an increase in **other current assets.** ~~accounts payable,slightly offset by an~~ Net cash used in operating activities was approximately $ 36. 0 million for the year ended December 31, 2022 and consisted primarily of a net loss of approximately $ 40. 4 million and working capital changes of $ 1. 2 million, offset by non- cash expense items of approximately $ 5. 6 million. Non- cash expense items of approximately $ 5. 6 million primarily consisted of $ 4. 6 million of stock- based compensation expense, non- cash interest expense of $ 0. 9 million and depreciation expense of $ 0. 2 million. The approximately $ 1. 2 million of working capital changes was primarily

due to an increase in ~~prepaid~~ **other current** assets, somewhat offset by increases in accounts payable and accrued expenses . Net cash used in operating activities..... offset by an increase in prepaid assets . Investing Activities Net cash used in investing activities for the year ended December 31, **2023 was approximately $ 5. 0 million and consisted of approximately $ 4. 9 million of net purchases of short- term investments in government securities (U. S. Treasury Bills and U. S. government agency securities) and approximately $ 0. 1 million in purchases of property and equipment. Net cash used in investing activities for the year ended December 31,** 2022 was approximately $ 144. 0 million and consisted of approximately $ 143. 9 million of short- term investments in government securities (U. S. Treasury Bills and U. S. government agency securities) and approximately $ 0. 1 million in ~~purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2021 was approximately $ 0. 1 million and consisted of~~ purchases of property and equipment. Financing Activities Net cash provided by financing activities for the year ended December 31, **2023 was approximately $ 64. 9 million. The $ 64. 9 million primarily consisted of net proceeds from a pre- funded warrants offering and ATM offering, collectively totaling $ 64. 4 million. The remaining $ 0. 5 million was the result of proceeds from the exercise of employee stock options, the exercise of warrants, and proceeds from employee stock purchases, slightly offset by payments for secondary registration and debt issuance costs. Net cash provided by financing activities for the year ended December 31,** 2022 was approximately $ 120. 3 million. The $ 120. 3 million primarily consisted of net proceeds from a private placement offering and ATM offering **, collectively** totaling $ 100. 5 million **,** and $ 19. 5 million from net proceeds related to the closing of a Loan Agreement. The remaining $ 0. 3 million was the result of proceeds from the exercise of ~~employee stock options and proceeds from employee stock purchases. Net cash provided by financing activities for the year ended December 31, 2021 was approximately $ 93. 0 million. The $ 93. 0 million primarily consisted of net proceeds from the sale of shares of our common stock through two follow- on offerings totaling $ 78. 5 million and $ 14. 4 million from net proceeds related to the closing of a Loan Agreement. The remaining $ 0. 1 million was the result of proceeds from the exercise of common stock warrants and~~ employee stock options and proceeds from employee stock purchases. RECENT ACCOUNTING PRONOUNCEMENTS From time- to- time new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed in Note 2 to our financial statements included elsewhere in this Annual Report, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our financial position or results of operations upon adoption. CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES Our management' s discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or Generally Accepted Accounted Principles (" U. S. GAAP "). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances; the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates. Our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report. Of our significant accounting policies, we believe that the following are the most critical: Stock- Based Compensation Our stock- based compensation consists of common stock options and restricted stock issued to certain employees and nonemployees and our Employee Stock Purchase Plan (" ESPP "). We recognize compensation expense based on an estimated grant date fair value using the Black- Scholes option- pricing method. We have elected to account for forfeitures as they occur. The inputs for the Black- Scholes valuation model require management' s significant assumptions. Prior to our IPO, the price per share of common stock was determined by our board based on recent prices of common stock sold in private offerings. Subsequent to the IPO, the price per share of common stock is determined by using the closing market price on the Nasdaq Capital Market on the grant date. The risk- free interest rates are based on the rate for U. S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life was based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility was estimated based on historical volatility information of peer companies that are publicly available in combination with our calculated volatility since being publicly traded. All assumptions used to calculate the grant date fair value of nonemployee options are generally consistent with the assumptions used for options granted to employees. In the event we terminate any of our consulting agreements, the unvested options issued in connection with such agreements would also be cancelled. For grants of restricted stock, we record compensation expense based on the quoted fair value of the shares on the grant date over the requisite service period. Compensation expense for ESPP rights is recorded in line with each respective offering period. Clinical Trial Costs The Company records prepaid assets or accrued expenses for prepaid or estimated clinical trial costs conducted by third- party service providers, which includes the conduct of preclinical studies and clinical trials. These costs can be a significant component of the Company' s research and development expenses. The Company primarily relies on a compilation of progress reports from third- party service providers, including the respective invoicing, to record actual expenses, along with determining changes to prepaid assets and accrued liabilities. To date, the ~~company~~ **Company** believes utilization of third- party reports most accurately reflects expenses **incurred** . As the current VIKTORIA- 1 Phase 3 **and CELC- G- 201 Phase 1b / 2** ~~trial~~ **trials** ~~ramps~~ **ramp** up site activation and patient enrollment, the Company **' s** ~~may need to estimate~~ **estimated** expenses in future periods and **the** actual services performed may vary from these estimates **, and these estimates may become more significant** . Changes in these estimates that result in material changes to the Company' s prepaid assets or accrued expenses could materially affect the Company' s results of operations. ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk As a

smaller reporting company, we are not required to provide disclosure pursuant to this item. ITEM 8. Financial Statements and Supplementary Data REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM To the Board of Directors and Stockholders of Celcuity Inc. Opinion on the Financial Statements We have audited the accompanying balance sheets of Celcuity Inc. (the Company) as of December 31, **2023 and** 2022 ~~and 2021~~, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years in the two- year period ended December 31, ~~2022~~ **2023**, and the related notes (collectively referred to as the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, **2023 and** 2022 ~~and 2021~~, and the results of its operations and its cash flows for each of the years in the two- year period ended December 31, ~~2022~~ **2023**, in conformity with accounting principles generally accepted in the United States of America. Basis for Opinion These financial statements are the responsibility of the Company' s management. Our responsibility is to express an opinion on the Company' s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U. S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion. Critical Audit Matters Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there were no critical audit matters. / s / Boulay ~~PLLP~~ **LLP** We have served as the Company' s auditor since 2017. Minneapolis, Minnesota March ~~23~~ **27**, ~~2023~~ **2024** PCAOB ID: 542 PART I. FINANCIAL INFORMATION ITEM 1. Financial Statements Celcuity Inc. Balance Sheets December 31, ~~2022~~ **2023** December 31, ~~2021~~ **2022** Assets Current Assets: Cash and cash equivalents $ **30, 662, 774 $** 24, 571, 557 ~~$ 84, 286, 381~~ Investments **149, 919, 974** 144, 015, 954 **Other current** ~~- Deposits 22, 009 22, 009 Deferred transaction costs 33, 195 22, 144 Payroll tax receivable 203, 665 298, 764 Prepaid~~ assets **10, 007, 849** 6, ~~344~~ **603**, **026** ~~157 722, 677~~ Total current assets **190, 590, 597** 175, 190, 537 ~~85, 351, 975~~ Property and equipment, net **228, 782** 260, 294 ~~312, 444~~ Operating lease right- of- use assets **400, 019** 246, 266 ~~241, 901~~ Total Assets $ **191, 219, 398 $** 175, 697, 097 ~~$ 85, 906, 320~~ Liabilities and Stockholders' Equity: Current Liabilities: Accounts payable $ **5, 076, 699 $** 2, 627, 076 ~~$ 1, 507, 099 Finance lease liabilities 2, 449 5, 850 Operating lease liabilities 191, 749 189, 858 Accrued expenses 4, 060, 280 802, 893 Total current liabilities 6, 881, 554 2, 505, 700~~ Finance lease liabilities- 2, 449 Operating lease liabilities **184, 950 191, 749 Accrued expenses 8, 927, 094 4, 060, 280 Total current liabilities 14, 188, 743 6, 881, 554 Operating lease liabilities 225, 922** 61, 002 ~~61, 771~~ Note payable, non- current **37, 035, 411** 34, 983, 074 ~~14, 625, 923~~ Total Liabilities **51, 450, 076** 41, 925, 630 ~~17, 195, 843~~ Commitments and Contingencies (Note ~~10~~ **9**) ~~--~~ Stockholders' Equity: Preferred stock, $ 0. 001 par value: 2, 500, 000 shares authorized; **854, 134 and** 1, 120, 873 ~~and 0~~ shares issued and outstanding as of December 31, **2023 and** 2022 ~~and December 31~~, ~~2021~~ **respectively 854** 1, 121 ~~--~~ Common stock, $ 0. 001 par value: 65, 000, 000 ~~and 25, 000, 000~~ shares authorized **as of December 31, 2023 and 2022, respectively**; **25, 506, 012 and** 21, 667, 250 ~~and 14, 918, 887~~ shares issued and outstanding as of December 31, **2023 and** 2022 ~~and December 31, 2021~~, respectively **25, 506** 21, 667 ~~14, 919~~ Additional paid- in capital **299, 818, 965** 230, 045, 566 ~~124, 622, 405~~ Accumulated deficit ( ~~96~~ **160**, ~~296~~ **076**, ~~887~~ **003**) ( ~~55, 926~~ - **96**, ~~847~~ **296, 887**) Total Stockholders' Equity **139, 769, 322** 133, 771, 467 ~~68, 710, 477~~ Total Liabilities and Stockholders' Equity $ **191, 219, 398 $** 175, 697, 097 ~~$ 85, 906, 320~~ See accompanying notes to the financial statements Statements of Operations **2023 2022** Years Ended December 31, **2023** 2022 ~~2021~~ Operating expenses: Research and development $ **60, 594, 005 $** 35, 289, 548 ~~$ 25, 758, 006~~ General and administrative **5, 636, 326** 4, 101, 543 ~~2, 597, 909~~ Total operating expenses **66, 230, 331** 39, 391, 091 ~~28, 355, 915~~ Loss from operations ( ~~39~~ **66**, ~~391~~ **230**, ~~091~~ **331**) ( ~~28~~ **39**, ~~355~~ **391**, ~~915~~ **091**) Other income (expense) Interest expense ( ~~2~~ **5**, ~~106~~ **326**, ~~111~~ **387**) ( ~~1~~ **2**, ~~262~~ **106**, ~~350~~ **111**) Interest income **7, 777, 602** 1, 127, 162 ~~13, 262 Loss on sale of fixed assets- (263)~~ Other income (expense), net **2, 451, 215** (978, 949 ~~) (1, 249, 351~~) Net loss before income taxes ( ~~40~~ **63**, ~~370~~ **779**, ~~040~~ **116**) ( ~~29~~ **40**, ~~605~~ **370**, ~~266~~ **040**) Income tax benefits-- Net loss $ ( ~~40~~ **63**, ~~370~~ **779**, ~~040~~ **116**) $ ( ~~29~~ **40**, ~~605~~ **370**, ~~266~~ **040**) Net loss per share, basic and diluted $ (2. ~~64~~ **69**) $ (2. ~~21~~ **64**) Weighted average common shares outstanding, basic and diluted **23, 679, 472** 15, 418, 543 ~~13, 382, 553~~ Statements of Changes in Stockholders' Equity **Shares Amount Shares Amount Capital Deficit Total** Common Stock Preferred Stock Additional Paid- In Accumulated Shares Amount Shares Amount Capital Deficit Total Balance at December 31, ~~2020~~ **2021** ~~10~~ **14**, ~~299~~ **918**, ~~822~~ **887** $ ~~10~~ **14**, ~~300~~ **919**- - $ **124** ~~- $ 38~~, ~~013~~ **622**, ~~551~~ **405** $ ( **55,** ~~26~~ **926**, **847** ~~321, 581~~) $ ~~11, 702, 270 Stock- based compensation 2, 964 3-- 2, 609, 932- 2, 609, 935 Employee stock purchases 13, 487 14-- 65, 825- 65, 839 Exercise of common stock warrants 1, 975 2-- 18, 760- 18, 762 Exercise of common stock options, net of shares withheld for exercise price 27, 051 27-- 63, 393- 63, 420 Issuance of common stock upon closing of follow- on offerings, net of underwriting discounts and offering costs 4, 221, 100 4, 221-- 78, 526, 363- 78, 530, 584 Issuance of common stock in an at- the- market (" ATM ") offering 3, 082 3-- 38, 959- 38, 962 Issuance costs associated with ATM offering---- (3, 868)- (3, 868) Issuance of common stock warrants, note payable---- 289, 839- 289, 839 Issuance of common stock, licensing agreement 349, 406 349-- 4, 999, 651- 5, 000, 000 Net loss----- (29, 605, 266) (29, 605, 266) Balance at December 31, 2021 14, 918, 887 14, 919-- 124, 622, 405 (55, 926, 847) 68, 710, 477 Balance~~ 14, 918, 887 14, 919-- 124, 622, 405 (55, 926, 847) 68, 710, 477 Stock- based compensation 3, 523 2-- 4, 638, 203- 4, 638, 205 Employee stock purchases 32, 669 33-- 171, 677- 171, 710 Exercise of common stock options, net of shares withheld for exercise price 29, 597 30-- 152, 382- 152, 412 Issuance of common and

preferred stock upon closing of private placement offering 6, 182, 574 6, 183 1, 120, 873 1, 121 99, 992, 696- 100, 000, 000 Issuance costs associated with private placement offering---- (4, 316, 534)- (4, 316, 534) Issuance of common stock in an ATM offering 500, 000 500-- 5, 174, 500- 5, 175, 000 Issuance costs associated with an ATM offering---- (389, 763)- (389, 763) Net loss----- (40, 370, 040) (40, 370, 040) Balance at December 31, 2022 21, 667, 250 $ 21, 667 1, 120, 873 $ 1, 121 $ 230, 045, 566 $ (96, 296, 887) $ 133, 771, 467 Balance 21, 667, 250 $ 21, 667 1, 120, 873 $ 1, 121 $ 230, 045, 566 $ (96, 296, 887) $ 133, 771, 467 ~~See accompanying notes~~ **Stock- based compensation 1, 958 2-- 4, 901, 432- 4, 901, 434 Conversion of preferred** to ~~the financial statements~~ **common stock 2, 667, 390 2, 668 (266, 739) (267) (2, 401)-- Employee stock purchases 33, 850 33-- 202, 812- 202, 845 Exercise of common stock options, net of shares withheld for exercise price 98, 695 99-- 388, 423- 388, 522 Exercise of common stock warrants 2, 369 2-- 22, 503- 22, 505 Issuance costs associated with private placement offering---- (7, 486)- (7, 486) Issuance of common stock in an ATM offering 1, 034, 500 1, 035-- 14, 999, 216- 15, 000, 251 Issuance costs associated with an ATM offering---- (614, 205)- (614, 205) Issuance of pre- funded warrants---- 50, 000, 000- 50, 000, 000 Issuance costs associated with pre- funded warrants---- (116, 895)- (116, 895) Net loss----- (63, 779, 116) (63, 779, 116) Balance at December 31, 2023 25, 506, 012 $ 25, 506 854, 134 $ 854 $ 299, 818, 965 $ (160, 076, 003) $ 139, 769, 322 Balance 25, 506, 012 $ 25, 506 854, 134 $ 854 $ 299, 818, 965 $ (160, 076, 003) $ 139, 769, 322** Statements of Cash Flows **2023 2022** Years Ended December 31, **2023** 2022 ~~2021~~ Cash flows from operating activities: Net loss $ ( ~~40~~ **63** , ~~370~~ **779** , ~~040~~ **116** ) $ ( ~~29~~ **40** , ~~605~~ **370** , ~~266~~ **040** ) Adjustments to reconcile net loss to net cash used for operations: Depreciation **142, 772** 210, 918 ~~303, 235~~ Stock- based compensation 4, **901, 434 4,** 638, 205 ~~2, 609, 935 Issuance of common stock, licensing agreement- 5, 000, 000~~ Amortization of debt issuance costs and discount **241, 752** 395, 757 ~~267, 821~~ PIK interest **1, 810, 584** 455, 074 ~~300, 001~~ Non- cash operating lease, net **4, 368** (3, 243) ~~(7, 740) Loss on sale of fixed assets- 263~~ Change in accrued interest income ( **993, 457) (** 142, 928) ~~-~~ Changes in operating assets and liabilities: **Other current assets** ~~Payroll tax receivable 95, 099~~ ( ~~108~~ **3** , ~~764~~ **438, 018** ) ~~Prepaid assets and deposits~~ (5, ~~621~~ **526** , **381** ~~480) (405, 637~~ ) Accounts payable **2, 430, 614** 1, 077, 080 ~~1, 305, 932~~ Accrued expenses **4, 866, 814** 3, 257, 387 ~~28, 280~~ Net cash used for operating activities ( ~~36~~ **53** , ~~008~~ **812** , ~~171~~ **253** ) ( ~~20~~ **36** , ~~311~~ **008** , ~~940~~ **171** ) Cash flows from investing activities: **Proceeds from maturities of investments 309, 614, 521-** Purchases of investments ( **314, 525, 084) (** 143, 873, 026) ~~-~~ Purchases of property and equipment ( **97, 644) (** 158, 768) ~~(81, 898) Proceeds from sale of property and equipment- 500~~ Net cash used for investing activities ( ~~144~~ **5** , ~~031~~ **008** , ~~794~~ **207** ) ( ~~81~~ **144** , ~~398~~ **031, 794** ) Cash flows from financing activities: Proceeds from exercise of common stock warrants **22** ~~-~~ ~~18~~ , ~~762~~ **505-** Proceeds from exercise of employee stock options **388, 522** 152, 412 ~~63, 420~~ Proceeds from employee stock purchases **202, 845** 171, 710 ~~65, 839 Proceeds from follow- on offering, net of underwriting discounts and offering costs- 78, 530, 585 Proceeds from an ATM offering, net of commission fees and offering costs 4, 776, 046 21, 073 Proceeds from note payable, net of debt issuance and discount costs 19, 509, 037 14, 347, 939~~ Proceeds from a private placement offering, net of discounts and offering costs **-** 95, 721, 786 **Proceeds from note payable, net of debt issuance and discount costs- 19, 509, 037 Proceeds from an ATM offering, net of commission fees and offering costs 14, 431, 186 4, 776, 046 Proceeds from pre- funded warrants, net of offering costs 49, 917, 589- Payments for secondary registration statement costs (45, 805)- Payments for debt issuance costs (2, 716)** - Payments for finance leases ( ~~5~~ **2** , ~~850~~ **449** ) (5, ~~810~~ **850** ) Net cash provided by financing activities **64, 911, 677** 120, 325, 141 ~~93, 041, 808~~ Net change in cash and cash equivalents **6, 091, 217** (59, 714, 824) ~~72, 648, 470~~ Cash and cash equivalents: Beginning of period **24, 571, 557** 84, 286, 381 ~~11, 637, 911~~ End of period $ **30, 662, 774 $** 24, 571, 557 ~~$ 84, 286, 381~~ Supplemental disclosure of cash flow information: Interest paid $ **3, 274, 051 $** 1, 255, 280 ~~$ 694, 528~~ Supplemental disclosures of non- cash investing and financing activities: Deferred financing costs and offering and registration statement costs included in accounts payable $ **56, 414 $** 51, 020 **Property** ~~$ 8, 123 Issuance of common stock warrants~~ and **equipment included in accounts** ~~final fee recognized as discount to note~~ payable **13** ~~- 964~~ , ~~839~~ **615-** CELCUITY INC. NOTES TO FINANCIAL STATEMENTS 1. Organization Nature of Business Celcuity Inc., a Delaware corporation (the " Company "), is a clinical- stage biotechnology company **pursuing** ~~focused on~~ development ~~of targeted therapies~~ for **oncology** ~~multiple solid tumor indications~~ . The Company' s lead therapeutic candidate is gedatolisib, a potent pan- PI3K and mTOR inhibitor. Its mechanism of action and pharmacokinetic properties are highly differentiated from other currently approved and investigational therapies that target PI3K or mTOR alone or together. A Phase 3 clinical trial, VIKTORIA- 1, evaluating gedatolisib in combination with fulvestrant with or without palbociclib in patients with HR / HER2- advanced breast cancer is currently enrolling patients. ~~Its~~ **A Phase 1b / 2 clinical trial, CELC- G- 201, evaluating gedatolisib in combination with darolutamide in patients with metastatic castration resistant prostate cancer, was initiated in the first quarter of 2024 and is currently enrolling patients. The Company' s** CELsignia companion diagnostic platform is uniquely able to analyze live patient tumor cells to identify new groups of cancer patients likely to benefit from already approved targeted therapies. The Company was co- founded in 2012 by Brian F. Sullivan and Dr. Lance G. Laing and is based in Minnesota. The Company has not generated any revenues to date ~~. Private Placement Offering On December 9, 2022, the Company completed the closing (funding) of its private placement offering with certain institutional and other accredited investors for the sale of Company common stock, preferred stock that may be convertible into common stock and warrants exercisable for common stock for $ 100 million in the aggregate, before deducting placement agent fees and other offering expenses of $ 4. 3 million. The closing followed dosage of the first patient in Celcuity' s Phase 3 clinical trial, VIKTORIA- 1~~ . 2. Basis of Presentation, Summary of Significant Accounting Policies and Recent Accounting Pronouncements Basis of Presentation The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States (" U. S. GAAP ") and pursuant to the rules and regulations of the Securities and Exchange Commission (the " SEC "). Operating results for the year ended December 31, ~~2022~~ **2023** are not necessarily indicative of results to be expected for any future year. Accounting Estimates Management uses estimates and assumptions in preparing these financial statements in accordance with U. S. GAAP. Those estimates and assumptions affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported revenues and expenses. Actual results could differ from those estimates and the difference could be

significant. Significant items subject to such estimates and assumptions include the valuation of stock- based compensation and prepaid or accrued clinical trial costs. Cash and Cash Equivalents The Company maintains its accounts at ~~one~~ **two** financial ~~institution~~ **institutions** . At times throughout the year, the Company' s cash balances may exceed amounts insured by the Federal Deposit Insurance Corporation. At December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , the Company had $ **30, 662, 774 and $** 24, 571, 557 ~~and $ 84, 286, 381~~ , respectively, in business checking accounts and money market funds that are considered cash equivalents and not insured by the Federal Deposit Insurance Corporation. The Company maintains its investments in U. S. governmental agency securities and U. S. treasury bills and has classified them as held- to- maturity at the time of purchase. Held- to- maturity purchases are those securities in which the Company has the ability and intent to hold until maturity. Held- to- maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums and discounts. Premiums and discounts are amortized or accreted over the life of the related held- to- maturity security using a straight- line method. The difference between the carrying value, which is based on cost, and the aggregate fair value of the held- to- maturity securities, was immaterial as of December 31, ~~2022~~ **2023** . At December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , the Company had $ **149, 919, 974 and $** 144, 015, 954 ~~and $ 0~~ , respectively, of short- term investments. Property and Equipment Property and equipment are stated at cost. Depreciation is provided over estimated useful lives using the straight- line method. Maintenance and repairs are expensed as incurred; major improvements and betterments are capitalized. Estimated useful lives of property and equipment are as follows for the major classes of assets: Schedule of Estimated Useful Lives of Property and ~~Equipment~~ **EquipmentAsset Description** Estimated ~~Asset Description~~ Lives Furniture and Equipment 4- 5 Leasehold Improvements 2- 3Long- Lived Assets Long- lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long- lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying value. If the carrying value of the long- lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying value exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values, and third- party independent appraisals, as considered necessary. Deferred Transaction Costs Deferred transaction costs **in** ~~for the year ended December 31,~~ 2022 ~~,~~ primarily consist of legal fees that ~~were~~ **are** capitalized as incurred and will be offset against the proceeds from future ATM offerings. The deferred transaction costs will be reviewed periodically to assess the probability that future securities will be offered. In the event that no future offering will occur, any deferred transaction costs will be expensed. Total costs incurred, but not accounted for as a reduction in equity, were $ **0 and $** 33, 195 ~~and $ 22, 144~~ as of December 31, **2023 and** 2022 ~~and 2021~~ , respectively. Comprehensive Loss Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For all periods presented, there was no difference between net loss and comprehensive loss. Risks and Uncertainties The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its initial drug product, gedatolisib, the clinical and commercial success of its diagnostic tests, ability to obtain regulatory approval for gedatolisib and its diagnostic tests, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, and significant competition. Fair Value of Financial Instruments The Company' s accounting for fair value measurements of assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring or nonrecurring basis adheres to the Financial Accounting Standards Board (" FASB ") fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to measurements involving significant unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are as follows: ● Level 1 Inputs: Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the Company at the measurement date. ● Level 2 Inputs: Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability. ● Level 3 Inputs: Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date. The level in the fair value hierarchy within which a fair value measurement in its entirety falls, is based on the lowest level input that is significant to the fair value measurement in its entirety. The carrying values of cash equivalents, accounts payable, accrued expenses and other financial working capital items approximate fair value at December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , due to the short maturity nature of these items. Income Taxes The Company accounts for income taxes using the asset and liability method, as required by the accounting standard for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, as well as net operating loss and tax credit carryforwards. Deferred taxes are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred taxes of a change in tax rates is recognized in results of operations in the period that includes the enactment date. The effects of any future changes in tax laws or rates have not been considered. The Company regularly reviews deferred tax assets to assess their potential realization and establish a valuation allowance for portions of such assets to reduce the carrying value if the Company does not consider it to be more likely than not that the deferred tax assets will be realized. The Company recognizes the impact of an uncertain tax position in its financial statements if, in management' s judgment, the position is more- likely- than- not sustainable upon audit based on the position' s technical merits. This involves the identification of potential uncertain tax positions, the evaluation of applicable tax laws and an assessment of whether a liability for an uncertain tax position is necessary. The Company' s stock- based compensation consists of stock options and restricted stock issued to certain employees and nonemployees of the Company and the Company' s 2017

Employee Stock Purchase Plan. The Company recognizes compensation expense based on an estimated grant date fair value using the Black- Scholes option- pricing method. If the factors change and different assumptions are used, the Company' s stock- based compensation expense could be materially different in the future. The Company recognizes stock- based compensation expense for these options on a straight- line basis over the requisite service period. The Company has elected to account for forfeitures as they occur. Research and development costs are expensed as incurred. Research and development costs amounted to $ ~~35~~ **60** , ~~289~~ **594** , ~~548~~ **005** , for the year ended December 31, ~~2022~~ **2023** and $ ~~25~~ **35** , ~~758~~ **289** , ~~006~~ **548** , for the year ended December 31, ~~2021~~ **2022** . The Company records prepaid assets or accrued expenses for prepaid or estimated clinical trial costs conducted by third- party service providers, which includes the conduct of preclinical studies and clinical trials. These costs can be a significant component of the Company' s research and development expenses. The Company primarily relies on a compilation of progress reports from third- party service providers, including the respective invoicing, to record actual expenses, along with determining changes to prepaid assets and accrued liabilities. To date, the Company believes utilization of third- party reports most accurately reflects expenses incurred. As the current VIKTORIA- 1 Phase 3 **and CELC-G- 201 Phase 1b / 2** ~~trial~~ **trials** ~~ramps~~ **ramp** up site activation and patient enrollment, the Company' s estimated expenses in future periods and actual services performed may vary from these estimates, and these estimates may become more significant. Changes in these estimates that result in material changes to the Company' s prepaid assets or accrued expenses could materially affect the Company' s results of operations. Segment Data The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. ~~Recently Adopted Accounting Pronouncements In May 2021, the FASB issued Accounting Standards Update (ASU) No. 2021- 04, Issuer' s Accounting for Certain Modifications or Exchanges of Freestanding Equity- Classified Written Call Options, which provides guidance on how an issuer should account for modifications made to equity- classified written call options. The guidance in the ASU requires the issuer to treat the modification of an equity- classified warrant that does not cause the warrant to become liability- classified as an exchange of the original warrant for a new warrant. The issuer should measure the effect of a modification as the difference between the fair value of the modified warrant and the fair value of that warrant immediately before modification. The standard is effective for all entities for all fiscal years beginning after December 15, 2021. The Company adopted this accounting standard effective January 1, 2022, and based on the standard, determined that the Representative' s Warrant amendment was equity- classified, treated as a deemed dividend within Additional Paid- in Capital, and the estimated incremental fair value of the modification for the Representative' s Warrant at the date of amendment was $ 271, 988.~~ 3. Liquidity Based on the Company' s cash and cash equivalents and short- term investments on hand at December 31, ~~2022~~ **2023** of $ ~~24~~ **30** , ~~571~~ **662** , ~~557~~ **774** and $ ~~144~~ **149** , ~~015~~ **919** , ~~954~~ **974** , respectively, the Company believes that its cash and short- term investments will be sufficient to fund the Company' s current operating plan through at least the next 12 months from the issuance date of this Annual Report. 4. Net Loss Per Common Share Basic and diluted net loss per common share is determined by dividing net loss attributable to common stockholders by the weighted- average common shares outstanding during the period. For all periods presented, the common shares underlying the preferred stock, options, ~~and~~ warrants **, and restricted stock** have been excluded from the calculation because their effect would be anti- dilutive. Therefore, the weighted- average shares outstanding used to calculate both basic and diluted loss per common share are the same. ~~For~~ **The following table summarizes** the ~~years ended December 31, 2022 and 2021,~~ potentially **-** dilutive ~~securities~~ **shares** excluded from the ~~computations of~~ diluted weighted- average shares outstanding ~~were~~ **: Schedule of Potentially- Dilutive Shares Excluded from the Diluted Weighted- Average Shares Outstanding 2023 2022 December 31, 2023 2022 Potentially- dilutive shares excluded from diluted weighted- average shares outstanding:** ~~preferred~~ **Preferred** stock on an as- if- converted to common stock ~~basis of~~ **8, 541, 340** 11, 208, 730 **Options to purchase** ~~and zero shares of~~ common stock **2** , ~~respectively~~ **815** , ~~options~~ **392 1, 976, 586 Warrants** to purchase ~~1, 976, 586 and 1, 315, 321 shares of~~ common stock ~~, respectively, warrants to purchase~~ 7, **263, 733 7,** 266, 102 **Restricted** ~~and 377, 652 shares of~~ common stock **1** , **958** ~~respectively, and~~ 3, 273 ~~and 2~~ **Total 18** , ~~964~~ **622, 423 20, 454, 691 Pre- funded warrant** shares of **5** ~~restricted common stock~~ , ~~respectively~~ **747, 787 are included in the computation of basic and diluted net loss per share for the year ended December 31, 2023, as the pre- funded warrants are issuable for nominal consideration** . In accordance with ASU 2021- 04, for purposes of calculating basic and diluted net loss per share for the year ended December 31, 2022, the reported net loss was increased by approximately $ 272, 000 related to the deemed dividend resulting from the amendment to the warrant agreement as further discussed in Note ~~11~~ **10** . This adjustment increased the basic and diluted net loss per share by $ 0. 02 for the year ending December 31, 2022. 5. Investments The following table summarizes the Company' s held- to- maturity investment securities at amortized cost as of December 31, **2023 and** 2022: Schedule of ~~Investments~~ **Investment Amortized Cost, as Adjusted Gross Unrealized Holding Gains Gross Unrealized Holding Losses Estimated Fair Value December 31, 2023 Amortized Cost, as Adjusted Gross Unrealized Holding Gains Gross Unrealized Holding Losses Estimated Fair Value U. S. Treasury Bills $ 149, 919, 974 $ 30, 995 $- $ 149, 950, 969 Total $ 149, 919, 974 $ 30, 995 $- $ 149, 950, 969** Amortized Cost, as Adjusted Gross Unrealized Holding Gains Gross Unrealized Holding Losses Estimated Fair Value December 31, 2022 Amortized Cost, as Adjusted Gross Unrealized Holding Gains Gross Unrealized Holding Losses Estimated Fair Value Governmental Agency Securities $ 46, 230, 893 $ 29, 517 $- $ 46, 260, 410 U. S. Treasury Notes 97, 785, 061 41, 639- 97, 826, 700 Total $ 144, 015, 954 $ 71, 156 $- $ 144, 087, 110 The ~~Company had no investments as of December 31, 2021. The~~ fair value of the Company' s held- to- maturity debt securities are determined based upon inputs, other than the quoted prices in active markets, that are observable either directly or indirectly **,** and are classified as level 2 fair value instruments. 6. ~~Payroll Tax Receivable The payroll tax receivable is the~~ **Other Current** ~~result of the Company' s utilization of research and development tax credits as authorized by the Path Act. The balance at December 31, 2022 was $ 203, 665 and December 31, 2021 was $ 298, 764. 7. Prepaid~~ Assets ~~Prepaid~~ **Other current** assets consisted of the following at December 31: Schedule of ~~Prepaid~~ **Other Current** Assets **2023** 2022 ~~2021~~ Current: **Prepaid clinical trial $ 8, 763, 150 $ 5, 656, 737 Miscellaneous receivable 805, 882- Other 281, 364 351, 073 Prepaid** ~~Directors~~ **directors** & officers' insurance ~~$~~ **157, 453**

173, 416 ~~$ 313, 958~~ Prepaid research & development ~~-~~ 421, 800 ~~338, 760 Clinical trial 5, 656, 737- Other 92, 204 69, 959~~ Total $ **10, 007, 849 $** 6, ~~344~~ **603** , **026 7** ~~157 $ 722, 677 8~~ . Property and Equipment Property and equipment consisted of the following at December 31: Summary of Property and Equipment **2023** 2022 ~~2021~~ **Furniture and equipment $ 1, 788, 195 $ 1, 676, 935** Leasehold improvements ~~$~~ 302, 577 ~~$~~ 302, ~~848 Furniture~~ **577 Property** and equipment **, Gross 2, 090, 772** 1, ~~676, 935 1, 517, 896 Property and equipment, Gross 1,~~ 979, 512 ~~1, 820, 744~~ Less: Accumulated depreciation (1, ~~719~~ **861** , ~~218~~ **990** ) (1, ~~508~~ **719** , ~~300~~ **218** ) Total $ **228, 782 $** 260, 294 ~~$ 312, 444~~ Depreciation expense was $ **142, 772 and $** 210, 918 ~~and $ 303, 235~~ for the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. ~~9~~ **8** . Accrued Expenses Accrued expenses consisted of the following at December 31: Schedule of Accrued Expenses **2023** 2022 ~~2021 Accrued compensation $ 929, 216 $ 438, 477 Employee Stock Purchase Plan 38, 967 34, 455~~ Clinical trial costs **$ 6, 464, 772 $** 2, 246, 573 ~~138~~ **Accrued compensation 1** , ~~788~~ **763, 316 929, 216** Other **641, 512** 845, 524 ~~191~~ **Employee stock purchase plan 57** , ~~173~~ **494 38, 967** Total $ **8, 927, 094 $** 4, 060, 280 **9** ~~$ 802, 893 10~~ . Commitments Operating and Finance Leases The Company leases its corporate space in Minneapolis, Minnesota ~~. In September 2017~~ , **with an** ~~the Company entered into a non- cancelable~~ operating lease ~~agreement~~ **in place through April 30, 2026. The lease provides** for **monthly rent** ~~building space. The new lease commenced~~ , **real estate taxes** ~~and the Company moved to the facility in May 2018~~ , **and operating expenses** ~~in conjunction with the termination of its then existing lease~~ . Rent expense is recorded on a straight- line basis over the lease term. In ~~July~~ **March** ~~2020~~ **2023 ,** the Company signed ~~an~~ **the fourth** amendment to extend this lease through April 30, ~~2022~~ **2026** ~~. The lease amendment provides for monthly rent, real estate taxes and operating expenses. As a result of the lease amendment, the Company recorded an incremental $ 197, 211 in the operating right- of- use (" ROU ") asset and lease liability. In July 2021, the Company signed the second amendment to extend this lease through April 30, 2023~~ . This amendment provides for monthly rent, real estate taxes and operating expenses. The Company recorded an incremental $ ~~193~~ **355** , **578** ~~517 in the operating right- of- use (" ROU ") asset and lease liability pertaining to this amendment. In July 2022, the Company signed the third amendment to extend this lease through April 30, 2024. This amendment provides for monthly rent, real estate taxes and operating expenses. The Company recorded an incremental $ 195, 437~~ in the operating right- of- use (" ROU ") asset and lease liability pertaining to this amendment. In May 2018, the Company entered into a non- cancelable finance lease agreement for office equipment with a five- year term. The underlying assets are included in furniture and equipment. The lease contains a bargain purchase option at the end of the lease. **The finance lease expired in May 2023 and the equipment was acquired for the bargain purchase option price.** When an implicit rate is not provided, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments. Supplemental balance sheet information consisted of the following at December 31, ~~2022~~ **2023** : Schedule of Supplemental Balance Sheet Information Related to ~~Leases Operating~~ **LeasesOperating** Lease Right- of- use assets $ ~~246~~ **400** , ~~266~~ **019** Operating lease liability $ ~~252~~ **410** , ~~751~~ **872** Less: short term portion ( ~~191~~ **184** , ~~749~~ **950** ) Long term portion $ ~~61~~ **225** , **922** ~~002 Finance Lease Furniture and equipment $ 28, 932 Less: Accumulated depreciation (26, 521) Net book value of property and equipment under finance lease $ 2, 411 Finance lease liability $ 2, 449 Less: short term portion (2, 449) Long term portion $-~~ Maturity analysis under lease agreements consisted of the following as of December 31, ~~2022~~ **2023** : Schedule of Maturity Analysis Under Lease Agreements Operating Leases ~~Finance Leases 2023~~ **2024** $ **213, 537 2025 220, 389** ~~206~~ **2026 74** , **170** ~~957 $ 3, 023 2024 69, 439~~ Total minimum lease payments ~~276~~ **508** , **096** ~~396 3, 023~~ Less: Present value discount ( ~~23~~ **97** , **224** ~~645) (5) Less amount representing services- (569~~ ) Present value of net minimum lease payments $ ~~252~~ **410** , **872** ~~751 $ 2, 449~~ Weighted Average Remaining Lease Term Discount Rate Operating lease ~~1~~ **2** . 3 years ~~8~~ **10** . **5** ~~0 % Finance lease 0. 3 years 1. 0~~ % Lease costs for the ~~years~~ **period** ended December 31: Schedule of Lease Costs **2023** 2022 ~~2021~~ Operating lease cost $ **212, 238 $** 197, 767 ~~$ 185, 379~~ Finance lease cost: Amortization ~~5~~ **2** , ~~786~~ **411** 5, 786 Interest **4** 39 ~~79~~ Variable lease cost **101, 957** 81, 077 ~~79, 477 Total lease~~ **Lease cost costs $ 316, 610** $ 284, 669 ~~$ 270, 721~~ Supplemental cash flow information related to leases **period** ~~for the years~~ ended December 31: Schedule of Supplemental Cash Flow Information Related to Leases **2023** 2022 ~~2021~~ Cash paid for amounts included in operating and finance leases: Operating cash outflow from operating leases $ **308, 914 $** 282, 086 ~~$ 274, 297~~ Operating cash outflow from finance leases **4** 39 ~~79~~ Financing cash outflow from finance leases **2, 449** 5, 850 ~~5, 810~~ Total cash paid for amounts included in operating and finance leases $ **311, 367 $** 287, 975 ~~$ 280, 186~~ Clinical Research Studies The Company enters into contracts in the normal course of business to conduct research and development programs internally and through third parties that include, among others, arrangements with vendors, consultants, CMO' s, and CRO' s. The Company currently has ~~four~~ **three** Phase 2 clinical trial agreements in place to evaluate targeted therapies selected with one of our CELsignia tests. Timing of milestone payments related to the Phase 2 clinical trials are uncertain and the contracts generally provide for termination following a certain period after notice, therefore the Company believes that non- cancelable obligations under the agreements are not material. The Company also has a license agreement in place with Pfizer to research, develop, manufacture and commercialize gedatolisib. In conjunction with the license agreement, the Company continued a Phase 1b study – B2151009 related to gedatolisib. These patients subsequently transitioned to an Expanded Access study – CELC- G- 001. Contracts related to the Phase 1B study and the Expanded Access study, are generally based on time and material. In addition, contracts related to the Company' s Phase 3 clinical study (VIKTORIA- 1 **) and Phase 1b / 2 clinical study (CELC- G- 201** ) are generally cancelable with reasonable notice within 120 days and the Company' s obligations under these contracts are primarily based on services performed through termination dates plus certain cancelation charges, if any, as defined in each of the respective agreements. In addition, these agreements may, from time to time, be subjected to amendments as a result of any change orders executed by the parties. As of December 31, ~~2022~~ **2023** , the Company had **two** ~~only one~~ material non- cancelable contractual commitment with respect to these arrangements, which totaled approximately $ 2. ~~3~~ **1** million. ~~11~~ **10** . Stockholders' Equity Capital Stock At December 31, ~~2021~~ **2022** , the Company' s authorized capital stock consisted of ~~25~~ **65** , 000, 000 shares of ~~$. 001 par value~~ common stock, of which ~~14~~ **21** , ~~918~~ **667** , ~~887~~ **250** shares were outstanding, and 2, 500, 000 shares of ~~$. 001 par value~~ preferred stock, **including 1, 850, 000 shares designated as Series A Preferred Stock,** of which ~~0~~ **1,**

**120, 873 shares** were outstanding ~~. The authorized number of shares of common stock was increased to 30, 000, 000 shares on May 12, 2022 and to 65, 000, 000 shares on September 1, 2022~~ . On May 16, 2022, the Company designated 1, 850, 000 shares of the authorized preferred stock as Series A Convertible Preferred Stock (" Series A Preferred Stock "). The Series A Preferred Stock is non- voting, and each share is convertible at the option of the holder, subject to certain limitations, into 10 shares of common stock. Holders of Series A Preferred Stock are entitled to receive dividends, on an as- if- converted- to- common stock basis, when, as and if, and in the same form as, dividends are actually paid on the common stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or in the event of a Deemed Liquidation Event (as defined in the Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock), the holders of Series A Preferred Stock are entitled to be paid from assets of the Company available for distribution to its stockholders, before any payment is made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the original issue price ($ 5. 75 on an as- converted- to- common stock basis), plus all accrued and unpaid dividends and (ii) the amount that the holder would have been entitled to receive at such time if the Series A Preferred Stock were converted into common stock. The Company may not, without the consent of holders of a majority of the outstanding shares of Series A Preferred Stock, amend its charter in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock or issue or obligate itself to issue shares of any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company and the payment of dividends. **On March 31, 2023, one of the Company' s preferred shareholders elected to convert 25, 000 shares of Series A Convertible Preferred Stock into 250, 000 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $ 5. 75. On June 29, 2023, one of the Company' s preferred shareholders elected to convert 10, 000 shares of Series A Convertible Preferred Stock into 100, 000 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $ 5. 75. On September 21, 2023, one of the Company' s preferred shareholders elected to convert 25, 000 shares of Series A Convertible Preferred Stock into 250, 000 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $ 5. 75. On October 16, 2023, one of the Company' s preferred shareholders elected to convert 181, 739 shares of Series A Convertible Preferred Stock into 1, 817, 390 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $ 5. 75. On December 12, 2023, one of the Company' s preferred shareholders elected to convert 25, 000 shares of Series A Convertible Preferred Stock into 250, 000 shares of Common Stock, in accordance with the Securities Purchase Agreement dated May 15, 2022. The cost basis of the shares transferred is $ 5. 75.** At December 31, ~~2022~~ **2023** , the Company' s authorized capital stock consisted of 65, 000, 000 shares of common stock, of which ~~21, 667, 250~~ **25, 506, 012** shares were outstanding, and 2, 500, 000 shares of preferred stock, including 1, 850, 000 shares designated as Series A Preferred Stock, of which ~~1~~ **854** , **134** ~~120, 873~~ shares were outstanding. As of December 31, ~~2022~~ **2023** , no dividends have been declared on the Company' s capital stock. Sale and Issuance of Stock **On February 4, 2022, the Company entered into an Open Market Sale AgreementSM with Jefferies LLC, as agent (" Jefferies "), pursuant to which the Company may offer and sell, from time to time, through Jefferies, shares of common stock having an aggregate offering price of up to $ 50, 000, 000. The Company will pay Jefferies a commission equal to 3. 0 % of the aggregate gross proceeds from each sale of such shares. On October 12, 2022, pursuant to the above agreement, the Company sold 500, 000 shares of common stock in a single transaction at a price of $ 10. 35 per share, generating gross proceeds of $ 5. 2 million before deducting commissions and other offering expenses of $ 0. 4 million.** On December 9, 2022, the Company issued 6, 182, 574 shares of common stock, 1, 120, 873 shares of Series A Preferred Stock and warrants exercisable for 6, 956, 450 shares of common stock to certain institutional and other accredited investors pursuant to a securities purchase agreement entered into on May 15, 2022. Pursuant to the securities purchase agreement, the closing (funding) of the private placement occurred following dosage of the first patient in the Company' s Phase 3 study, VIKTORIA- 1. Investors purchased shares of common stock and Series A Preferred Stock at a price of $ 5. 75 per share (on an as converted to common stock basis), with forty percent (40 %) warrant coverage (on an as converted to common stock basis) and customary resale registration rights. The private placement generated gross proceeds of approximately $ 100 million before deducting placement agent fees and other offering expenses of $ 4. 3 million. **Pre- Funded Warrants** On ~~February 4~~ **October 18** , ~~2022~~ **2023** , the Company entered into **a securities purchase** ~~an Open Market Sale AgreementSM~~ **agreement** ~~with Jefferies LLC, as agent~~ ( **the** " ~~Jefferies~~ **Securities Purchase Agreement** ") ~~,~~ **with certain investors (the " Investors ")** pursuant to which the Company **agreed to** ~~may offer and~~ sell ~~, from time~~ to **the Investors in a private placement** ~~time, through Jefferies, shares of common stock having an aggregate offering price~~ -- **pre** ~~of~~ **- funded warrants to purchase** up to ~~$ 50, 000, 000. The Company will pay Jefferies a commission equal to 3. 0 % of the aggregate gross proceeds from each sale of such shares. On October 12, 2022, pursuant to the above agreement, the Company sold 500, 000 shares of common stock in a single transaction at a price of $ 10. 35 per share, generating gross proceeds of $~~ 5 ~~. 2 million before deducting commissions and other offering expenses of $ 0. 4 million. On February 26~~ , ~~2021~~ **747** , **787** ~~the Company completed a follow- on offering in which it sold 1, 971, 100 shares of common stock (including 257, 100 shares of common stock in connection with the full exercise of the underwriters' option to purchase additional shares) at a public offering price of $ 14. 00 per share. The offering generated gross proceeds of approximately $ 27. 6 million before deducting underwriting discounts and other offering expenses of approximately $ 1. 8 million. On April 8, 2021, in conjunction with entering into a license agreement with Pfizer to research, develop, manufacture and commercialize gedatolisib, the Company issued to Pfizer 349, 406~~ shares of the Company' s common stock **, par value** ~~at a price of~~ $ ~~14~~ **0** . ~~31~~ **001** per share ~~, for an aggregate~~ **. Each Warrant to purchase one share has a purchase** price of $ ~~5~~ **8** . **699** ~~0 million. On July 1, 2021, the Company completed a follow- on offering in which it sold 2, 250, 000 shares of common stock at a public offering price of $ 25. 00~~ per

share **, and an exercise price of $ 0. 001 per share for the Common Stock issuable upon exercise of the Warrant** . The ~~offering generated~~ **closing of the Private Placement occurred on October 20, 2023, and resulted in** gross proceeds **to the Company** of approximately $ **50** ~~56. 3~~ million **,** before deducting ~~underwriting discounts and other~~ offering expenses of approximately $ ~~3~~ **0** . ~~5~~ **1** million. **Each Warrant is immediately exercisable and will not expire. Under the terms of the** Warrants **, the Company may not effect the exercise of any such Warrant, and a holder will not be entitled to exercise any portion of any Warrant, if, upon giving effect to such exercise, the aggregate number of shares of Common Stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder' s affiliates, and any other persons whose beneficial ownership of Common Stock would or could be aggregated with the holder' s or any of the holder' s affiliates for purposes of Section 13 (d) or Section 16 of the Securities Exchange Act of 1934, as amended (the " Exchange Act ")) would exceed 4. 99 % of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is calculated in accordance with Section 13 (d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission (the " Maximum Percentage "). A holder may reset the Maximum Percentage to a higher percentage (not to exceed 19. 99 %), effective 61 days after written notice to the Company, or a lower percentage, effective immediately upon written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of Warrants. The Securities Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions.** Schedule of ~~WarrantsAt~~ -- **Warrants At** December 31, ~~2022~~ **2023** : Issue Date Expiration Date # of Warrants Outstanding Exercise Price Offering 1 / 21 / 2016 1 / 14 / 2026 33, 719 $ 7. 56 private placement offering- issued to placement agent 5 / 2 / 2016 5 / 2 / 2026 21, 530 $ 7. 56 private placement offering- issued to placement agent 4 / 28 / 2017 4 / 28 / 2027 33, 250 $ 8. 42 private placement offering- issued to placement agent 5 / 17 / 2017 5 / 17 / 2027 15, 365 $ 8. 42 private placement offering- issued to placement agent 9 / 22 / 2017 9 / 22 / 2024 ~~109~~ **107** , ~~746~~ **377** $ 9. 50 purchasers of convertible notes 9 / 22 / 2017 9 / 19 / 2025 70, 000 $ 10. 45 IPO- issued to underwriter 4 / 8 / 2021 4 / 8 / 2031 26, 042 $ 14. 40 debt financing- issued to lender 12 / 9 / 2022 see below 6, 956, 450 $ 8. 05 securities purchase agreement- issued to institutional and other accredited investors **10 / 18 / 2023 see above 5, 747, 787 $ 0. 001 private placement offering- issued to investors** Total Warrants Outstanding ~~7~~ **13** , ~~266~~ **011** , ~~102~~ **520** On December 9, 2022, in connection with entering into a securities purchase agreement on May 15, 2022, the Company issued warrants to certain institutional and other accredited investors to purchase 6, 956, 450 shares of the Company' s common stock at a price of $ 8. 05. The warrants may be exercised at any time or from time to time on or after the date of issuance and on or before the earlier of (i) 5: 00 p. m. (New York City time) on December 9, 2027 or (ii) seventy- five (75) days after the Company publicly announces (x) whether the progression- free survival (PFS) of gedatolisib in combination with palbociclib and fulvestrant (Arm A) to fulvestrant (Arm C) in the Phase 3 study met its primary endpoint target, (y) whether the PFS of gedatolisib in combination with fulvestrant (Arm B) to fulvestrant (Arm C) in the Phase 3 study met its primary endpoint target, and (z) the associated hazard ratios and median PFS values for each of Arm A, Arm B, and Arm C. The warrants are equity classified and the $ 21. 8 million of fair value allocated to the warrants is reflected as Additional Paid- in Capital. On September 13, 2022, the Company entered into a First Amendment to Representative' s Warrant (the " Warrant Amendment ") with Craig- Hallum Capital Group LLC (" Craig- Hallum "), amending the terms of that certain Representative' s Warrant, dated September 22, 2017 (the " Representative' s Warrant ") issued by the Company to Craig- Hallum in connection with the Company' s initial public offering. Under the terms of the Warrant Amendment, (i) the number of shares of the Company' s common stock issuable upon exercise of the Representative' s Warrant was reduced from 138, 000 shares to 70, 000 shares, and (ii) the exercise period of the Representative' s Warrant was extended three years to September 19, 2025. There were no other material amendments or modifications to the Representative' s Warrant. The estimated incremental fair value of the Representative' s Warrant at the date of amendment was $ 271, 988. As the Company has an accumulated deficit balance in Retained Earnings, the incremental impact will be recorded as a deemed dividend, classified within Additional Paid- in Capital. ~~On April 8, 2021, in connection with entering into a loan and security agreement with Innovatus Life Sciences Lending Fund I, LP, the Company issued a warrant to Innovatus to purchase 26, 042 shares of the Company' s common stock at an exercise price of $ 14. 40 per share. This warrant is equity classified and the $ 289, 839 fair value of the warrant was reflected as additional debt discount.~~ At December 31, **2023 and** 2022 ~~and 2021~~ , the Company had warrants to purchase **13, 011, 520 and** 7, 266, 102 ~~and 377, 652~~ shares of common stock outstanding, at a weighted average exercise price of $ **4. 53 and $** 8. 12 ~~and $ 9. 76~~ , respectively. A total of **2** ~~0 and 1~~ , ~~975~~ **369 and zero** warrants were exercised in the years ended December 31, **2023 and** 2022 ~~and 2021~~ , respectively. ~~12~~ **11** . Stock- Based Compensation ~~Equity Incentive Plan~~ The 2012 Equity Incentive Plan, as amended, was adopted by the Company' s board and approved by the members of Celcuity LLC on August 10, 2012. The Company reserved a maximum of 625, 000 shares of common stock for issuance under the 2012 Equity Incentive Plan. The 2012 Equity Incentive Plan provides for options, restricted stock awards, performance stock awards or stock bonuses. The exercise price of each option granted under the 2012 Equity Incentive Plan is not less than 100 % of the fair market value of one share on the date of grant. The maximum permitted term of options granted under the 2012 Equity Incentive Plan is ten years. The Company' s board administers the 2012 Equity Incentive Plan and determines the provisions of incentive awards, including eligible recipients, number of shares subject to an incentive award, exercise price, vesting schedule, duration of an incentive award and other restrictions an incentive award may be subject to. The 2012 Equity Incentive Plan was frozen on September 6, 2017 and any new awards will be issued under the terms of the 2017 Amended and Restated Stock Incentive Plan. Stock Incentive Plan The 2017 Amended and Restated Stock Incentive Plan (the " 2017 Plan ") was adopted by the Company' s board on September 6, 2017, became effective following the corporate conversion on September 15, 2017, and was approved by stockholders at the Company' s annual stockholder meeting on May 10, 2018. The 2017 Plan was amended and approved by stockholders at the Company' s annual

stockholder meeting on May 14, 2020. The Company initially reserved a maximum of 750, 000 shares of common stock for issuance under the 2017 Plan. The number of shares reserved for issuance was automatically increased by **216, 673 and** 149, 189 ~~and 102, 998~~ shares on January 1, **2023 and** 2022 ~~and 2021~~, respectively and will increase automatically on January 1 of each of ~~2023~~ **2024** through 2027 by the number of shares equal to 1. 0 % of the aggregate number of outstanding shares of Company common stock as of the immediately preceding December 31. However, the Company' s board may reduce the amount of the increase in any particular year. At the Annual Meeting held on May 12, 2021 and May 12, 2022, the stockholders approved a one- time, 500, 000 increase each year for a total of 1, 000, 000 increase, **to the number of shares reserved for issuance under the 2017 Plan. At the Annual Meeting held on May 11, 2023, the stockholders approved a one- time, 1, 500, 000 increase** to the number of shares reserved for issuance under the 2017 Plan. The 2017 Plan provides for options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards and stock bonuses. The exercise price of each option granted under the 2017 Plan is not less than 100 % of the fair market value of one share on the date of grant. The maximum permitted term of options granted under the 2017 Plan is ten years. The 2017 Plan is generally administered by the compensation committee of the Company' s board, which has the authority to interpret the 2017 Plan, grant awards and make all other determinations necessary for the administration of the 2017 Plan. The following table summarizes the activity for all stock options outstanding for the years ended December 31: Schedule of Stock Options Activity **2023** 2022 ~~2021~~ Shares Weighted Average Exercise Price Shares Weighted Average Exercise Price Options outstanding at beginning of year 1, **976, 586 $ 6. 34 1,** 315, 321 $ 11. 97 ~~849, 949 $ 9. 33~~ Granted **1, 003, 298 10. 69** 843, 797 7. 64 ~~538, 567 16. 09~~ Exercised **(98, 695) 3. 94** (29, 597) 5. 15 **Forfeited** ( ~~44~~ **65** , ~~828~~ **797** ) 7. **45** ~~06 Forfeited~~ (152, 935) 9. 70 ~~(28, 367) 18. 72~~ Balance at December 31: **2, 815, 392 $ 7. 95** 1, 976, 586 $ 6. 34 ~~1, 315, 321 $ 11. 97~~ Options exercisable at December 31: **1, 524, 731 $ 6. 44** 995, 629 $ 5. 91 ~~592, 141 $ 9. 53~~ Weighted Average Grant Date Fair Value for options granted during the period: $ **7. 48 $** 5. 22 ~~$ 14. 93~~ The following table summarizes additional information about stock options outstanding and exercisable at December 31, ~~2022~~ **2023** : Schedule of Stock Options Outstanding and ExercisableOptions Outstanding Options Exercisable Options Outstanding Weighted Average Remaining Contractual Life Weighted Average Exercise Price Aggregate Intrinsic Value Options Exercisable Weighted Average Exercise Price Aggregate Intrinsic Value **2, 815, 392 7. 95 $ 7. 95 $ 18, 740, 216** 1, ~~976~~ **524** , **731** ~~586 7. 86~~ $ 6. ~~34~~ **44** $ ~~15~~ **12** , ~~246~~ **478** , **244** ~~085 995, 629 $ 5. 91 8, 157, 756~~ The Company recognized stock- based compensation expense for stock options of $ 4, **716, 475 and $ 4,** 415, 415 ~~and $ 2, 448, 742~~ for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. In May 2022, the Company modified the exercise price on 776, 324 stock option awards to $ 5. 50, the closing market price on the Nasdaq Capital Market on May 17, 2022. The effect of this modification on stock- based compensation was $ **134, 000 and $** 517, 000 for the ~~year~~ **years** ended December 31, **2023 and** 2022 **, respectively** . The effect of this modification on stock- based compensation over the remaining service period will be approximately $ ~~317~~ **163** , 000. In December 2021, the Company modified the exercise price on 311, 000 stock option awards to $ 13. 44, the closing market price on the Nasdaq Capital Market on December 15, 2021. No director or officer awards were modified. The effect on stock- based compensation was $ **65, 000 and $** 92 ~~, 000 and $ 53~~ , 000 for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. The effect on stock- based compensation over the remaining service period will be approximately $ ~~173~~ **98** , 000. In May 2020, the Company modified the exercise price on 203, 750 stock option awards to $ 5. 10, the closing market price on the Nasdaq Capital Market on May 14, 2020. No director or officer awards were modified. The effect on stock- based compensation was $ **19, 000 and $** 38 ~~, 000 and $ 46~~ , 000 for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. The effect on stock- based compensation over the remaining service period **is not material** ~~will be approximately $ 20, 000~~ . The Black- Scholes option- pricing model was used to estimate the fair value of equity- based awards with the following weighted- average assumptions for the years ended December 31: Schedule of Assumptions for Fair Value of Equity- based Awards **2023** 2022 ~~2021~~ Risk- free interest rate **3. 41 %- 4. 86 %** 1. 68 %- 4. 22 ~~% 0. 63 %- 1. 39~~ % Expected volatility **77. 1 %- 79. 8 %** 76. 2 %- 79. 6 ~~% 76. 6 %- 76. 9~~ % Expected life (years) 5. **25 to 6. 08 5.** 29 to 6. 25 ~~5. 0 to 6. 11~~ Expected dividend yield 0 % 0 % The inputs for the Black- Scholes valuation model require management' s significant assumptions. Prior to the Company' s initial public offering, the price per share of common stock was determined by the Company' s board based on recent prices of common stock sold in private offerings. Subsequent to the initial public offering, the price per share of common stock is determined by using the closing market price on the Nasdaq Capital Market on the grant date. The risk- free interest rates are based on the rate for U. S. Treasury securities at the date of grant with maturity dates approximately equal to the expected life at the grant date. The expected life is based on the simplified method in accordance with the SEC Staff Accounting Bulletin Nos. 107 and 110. The expected volatility is estimated based on historical volatility information of peer companies that are publicly available in combination with the Company' s calculated volatility since being publicly traded. All assumptions used to calculate the grant date fair value of non- employee options are generally consistent with the assumptions used for options granted to employees. In the event the Company terminates any of its consulting agreements, the unvested options issued in connection with the agreements would also be cancelled. The Company had **1, 958 and** 3, 273 ~~and 2, 964~~ shares of restricted stock outstanding ~~for~~ **at December 31, 2023 and 2022, respectively, and 3, 273 and 3, 214 shares of restricted stock vested during** the years ended December 31, **2023 and** 2022 ~~and 2021, respectively, and 3, 214 and 15, 686 shares of restricted stock vested during the years ended December 31, 2022 and 2021~~ , respectively. The Company recognized stock- based compensation expense for restricted stock of $ **18, 499 and $** 41, 431 ~~and $ 80, 150~~ for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. The total remaining shares available for grant under the Company' s 2017 Plan as of December 31, ~~2022~~ **2023** was ~~242~~ **1** , ~~435~~ **019, 149** . Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized ~~as follows~~ **at December 31** : Schedule of Unrecognized Compensation Cost ~~2023~~ **2024** $ ~~3~~ **4** , ~~347~~ **075** , ~~255~~ **020** ~~2024~~ **2025** 2, ~~161~~ **770** , ~~383~~ **901** ~~2025~~ **2026** 1, ~~405~~ **819** , ~~076~~ **779** ~~2026~~ **2027** ~~365~~ **906** , ~~245~~ **379** Total estimated compensation cost to be recognized $ ~~7~~ **9** , ~~278~~ **572** , ~~959~~ **079** Employee Stock Purchase Plan The Company' s 2017 Employee Stock Purchase Plan (the " ESPP ") was adopted by the Company' s board on September 6, 2017 and approved

by stockholders at the Company' s annual stockholder meeting on May 10, 2018. The Company initially reserved a total of 100, 000 shares for issuance under the ESPP. The number of shares reserved for issuance was automatically increased by **108, 337 and** 74, 595 ~~and 51, 499~~ shares on January 1, **2023 and** 2022 ~~and 2021~~, respectively and will increase automatically on each subsequent January 1 by the number of shares equal to 0. 5 % of the total outstanding number of shares of Company common stock as of the immediately preceding December 31. However, the Company' s board may reduce the amount of the increase in any particular year. The total remaining shares available for issuance under the employee stock purchase plan as of December 31, ~~2022~~ **2023** is ~~192~~ **266**, ~~148~~ **635**. The ESPP provides participating employees with an opportunity to purchase shares of the Company' s common stock at a discount through payroll deductions. The ESPP is available to all employees unless they are employed for less than 20 hours per week or own 5 % or more of the total combined voting power or value of the Company' s common stock. The ESPP is administered using overlapping 24 month offering periods, referred to as an Offering Period. Each Offering Period has four six- month purchase periods. A new Offering Period and purchase period begin every six months on May 1 and November 1 of each year. Participating employees may purchase common stock, on a voluntary after tax- basis, at a price equal to 85 % of the fair market value of a share of common stock on either the offering date or the purchase date, whichever is lower. If the purchase date has a lower price, the employee will automatically be placed in the Offering Period beginning immediately after the purchase date. The Company recognized stock- based compensation expense related to the ESPP of $ **166, 460 and $** 181, 359 ~~and $ 41, 043~~ for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. The Company recognized total stock- based compensation expense as follows for the years ended December 31: Schedule of Stock- based Compensation Expense **2023** 2022 ~~2021 Year~~ **Years** Ended December 31 **~~,~~ : 2023** 2022 ~~2021~~ Stock- based compensation expense in operating expenses: Research and development $ 2, **700, 318 $ 2,** 563, 291 ~~$ 1, 645, 353~~ General and administrative 2, **201, 116 2,** 074, 914 ~~964, 582~~ Total $ 4, **901, 434 $ 4,** 638, 205 **12** ~~$ 2, 609, 935 13~~. Debt On April 8, 2021, the Company entered into a loan and security agreement (the " Loan Agreement ") with Innovatus Life Sciences Lending Fund I, LP, a Delaware limited partnership (" Innovatus ") in its capacity as Collateral Agent and sole Lender. The Lender agreed to loan up to $ 25 million in three tranches consisting of (i) a $ 15. 0 million non- contingent term A loan that was funded on April 8, 2021, (ii) a $ 5 million term B loan with a deadline of March 31, 2022 and (iii) a $ 5 million term C loan to be funded upon request, subject to our ability to achieve certain milestones, no later than March 31, 2023 (collectively the " Term Loans "). The Loan Agreement also contains certain events of default, warranties and covenants of the Company. In connection with each funding of the Term Loans, the Company is required to issue Innovatus a warrant (the " Warrants ") to purchase a number of shares of the Company' s stock equal to 2. 5 % of the principal amount of the relevant Term Loan funded divided by the exercise price, which will be based on the lower of (i) $ 14. 40 per share or (ii) the volume weighted price per share of the Company' s stock for the five- trading day period ending on the last trading day immediately preceding the funding date of the Term B or Term C Loan, as applicable. The warrants may be exercised on a cashless basis and are immediately exercisable through the tenth anniversary of the applicable funding date. In connection with the first tranche of the Term Loans, the Company issued a warrant to Innovatus to purchase 26, 042 shares of the Company' s common stock at an exercise price of $ 14. 40 per share. The Company evaluated the warrant under ASC 470, debt, and recognized an additional debt discount of approximately $ 0. 3 million based on the relative fair value of the base instruments and warrants. The Company calculated the fair value of the warrant using the Black- Scholes model. In connection with the funding of the first tranche of the Term Loans, a final fee of approximately $ 0. 7 million was recorded as additional principal as a debt discount, and a facility fee of approximately $ 0. 1 million was recorded as additional debt discount. The Company is also required to maintain a minimum cash balance in agreement with the term loans' default terms. On August 9, 2022, the Company amended the Loan Agreement. Under the amended Loan Agreement, Innovatus, as Lender, has agreed to loan up to $ 75 million, a $ 50 million increase from the original Loan Amount, in five tranches consisting of: (i) a $ 15 million term A loan that was funded on April 8, 2021 upon entering into the original Loan Agreement, (ii) a $ 20 million term B loan to be funded upon request of the Company no later than December 31, ~~2022~~ **2023**, with such funding conditioned upon the closing of the Company' s $ 100 million private placement announced on May 16, 2022, (iii) a $ 10 million term C loan to be funded upon request of the Company no later than April 1, 2024, (iv) a $ 20 million term D loan to be funded upon request of the Company no later than November 1, 2024, and (v) a $ 10 million term E loan to be funded upon request of the Company no later than February 28, 2025. As of December 31, ~~2022~~ **2023**, term loans totaling $ 35 million are outstanding under the Loan Agreement, including the initial Term A loan of $ 15 million which was funded on April 8, 2021, and a $ 20 million Term B loan which was funded on December 22, 2022 following the closing of the $ 100 million private placement described above. Funding of the term C, D, and E loans are conditioned upon satisfaction of certain clinical trial milestones and certain financial covenants determined on a pro forma as- funded basis. In connection with the original and amended Loan Agreement and the funding of the first and second tranche of the Term Loans, the Company incurred debt issuance costs of approximately $ 1. 1 million. The debt issuance costs and the debt discount are amortized to interest expense using the effective interest method over the life of the Term Loans. The carrying value of the debt approximates fair value as of December 31, ~~2022~~ **2023**. Under the amended Loan Agreement, Innovatus has the right, at its election and until August 9, 2025, the third anniversary of the loan amendment date, to convert into Common Stock up to (1) 20 % of the outstanding principal amount of term A loan, and (ii) an additional 7 % of the amount by which the aggregate principal amount of the funded term B, C, D, and E loans exceed $ 35 million, provided that the aggregate outstanding principal amount of all term loans is at least $ 35 million, which such conversion based upon a price per share equal to $ 10. 00. No additional warrants are required to be issued under the funding of term B, C, D, and E. The Company is entitled to make interest- only payments for forty- eight months, or up to sixty months from the original Loan Agreement date if certain conditions are met. The Term Loans will mature on April 8, 2027, the sixth anniversary of the initial funding date, and will bear interest at a rate equal to the sum of (a) the greater of (i) Prime Rate (as defined in the amended Loan Agreement) or (ii) 3. 25 %, plus 5. 7 %. Additionally, the Company elected to make 4. 95 % of the interest rate as payable in- kind, which shall accrue as

principal monthly. The Amended Loan Agreement includes certain other fees, such as a final fee of 4. 5 % of the funded loan amounts not converted into equity by the lender, which apply if prepayment, an event of default, or change of control occurs prior to August 9, 2025, the third anniversary of the Amendment date. Subject to certain other conditions, no final fee will be payable after August 9, 2025. The Company has the option to prepay the loan at any time following the first anniversary of the amended loan agreement date, with tiered prepayment fees ranging from 0 to 1 % based on when the prepayment occurs. Upon a change in control or event of default, mandatory prepayment will be required, and if such an event occurs prior to the first anniversary of the Amendment date, an additional prepayment fee of 3. 0 % applies. The amended Loan Agreement remains secured by all assets of the Company. Proceeds will be used for working capital purposes and to fund the Company' s general business requirements. The amended Loan Agreement contains customary representations and warranties and covenants, subject to customary carve outs, and includes financial covenants related to or based upon liquidity, trailing twelve months revenue and the funded loan amounts. Long- term debt consisted of the following at December 31, **2023 and** 2022 ~~and 2021~~ : Schedule of Long- term Debt **2023** 2022 ~~2021~~ Note payable $ 35, 000, 000 $ ~~15~~ **35** , 000, 000 Add: PIK interest (added to principal) **2, 565, 660** 755, 075 ~~300, 001 Add: final fee- 675, 000~~ Less: unamortized debt issuance costs ( ~~707~~ **480** , ~~001~~ **810** ) ( ~~386~~ **707** , ~~578~~ **001** ) Less: unamortized debt discount ( ~~65~~ **49** , ~~000~~ **439** ) ( ~~962~~ **65** , ~~500~~ **000** ) Total long- term debt $ **37, 035, 411 $** 34, 983, 074 ~~$ 14, 625, 923~~ Future principal payments are as follows: Schedule of Long Term Debt Future Principal Payments Years Ending December 31, 2025 $ ~~13~~ **14** , ~~408~~ **087** , ~~153~~ **122** 2026 ~~17~~ **18** , ~~877~~ **782** , ~~538~~ **830** 2027 4, ~~469~~ **695** , ~~384~~ **708** Total $ ~~35~~ **37** , ~~755~~ **565** , **660 13** ~~075 14. License Agreement On April 8, 2021 the Company entered into a license agreement with Pfizer to research, develop, manufacture and commercialize gedatolisib, a potent, well- tolerated, reversible dual inhibitor that targets PI3K and mTOR, for the treatment, diagnosis and prevention of all diseases. The Company paid Pfizer $ 5. 0 million in upfront fees and issued to Pfizer $ 5. 0 million of shares of the Company' s common stock pursuant to an Equity Grant Agreement. The upfront payment and the issuance of shares were expensed to research & development in full for the three months ending June 30, 2021. The Company is also required to make milestone payments to Pfizer upon achievement of certain development and commercial milestone events, up to an aggregate of $ 335. 0 million. Additionally, the Company will pay Pfizer tiered royalties on sales of gedatolisib at percentages ranging from the low to mid- teens, which may be subject to deductions for expiration of valid claims, amounts due under third- party licenses and generic competition. Unless earlier terminated, the license agreement will expire upon the expiration of all royalty obligations. The royalty period will expire on a country- by- country basis upon the later of (a) 12 years following the date of first commercial sale of such product in such country, (b) the expiration of all regulatory or data exclusivity in such country for such product or (c) the date upon which the manufacture, use, sale, offer for sale or importation of such product in such country would no longer infringe, but for the license granted in the license agreement, a valid claim of a licensed patent right. The Company has the right to terminate the license agreement for convenience upon 90 days' prior written notice. Pfizer may not terminate the agreement for convenience. Either the Company or Pfizer may terminate the license agreement if the other party is in material breach and such breach is not cured within the specified cure period. In addition, either the Company or Pfizer may terminate the license agreement in the event of specified insolvency events involving the other party. 15~~ . Income Taxes Following the conversion of Celcuity LLC to Celcuity Inc. on September 15, 2017, Celcuity Inc. began filing federal and state returns where required. No income tax benefit was recorded for the years **2023 and** 2022 ~~and 2021~~ , due to net losses and recognition of a valuation allowance. The following table presents a reconciliation of the tax expense computed at the statutory federal rate and the Company' s tax expense for the years ending December 31: Schedule of Effective Income Tax Rate Reconciliation **2023** 2022 ~~2021~~ Tax benefit at statutory federal rate $ ( ~~8~~ **13** , ~~478~~ **394** , 000) $ ( ~~6~~ **8** , ~~217~~ **478** , 000) State income tax benefit, net of federal tax effect ( ~~64~~ **82** , 000) ( ~~49~~ **64** , 000) Change in valuation allowance on deferred tax assets **13, 542, 000** 9, 543 ~~, 000 6, 330~~ , 000 Research & Development Credits ( **550** ~~1, 347~~ , 000) ( ~~222~~ **1, 347** , 000) Other permanent items **484, 000** 346 ~~, 000 158~~ , 000 Income tax benefits $- $- ~~On December 22, 2017 H. R. 1, commonly referred to as the Tax Cuts and Jobs Act, (the " Tax Act ") was enacted. As part of Tax Act, for tax years beginning on or after January 1, 2022, Congress requires taxpayers to capitalize research and experimental expenditures that qualify as section 174 costs and recover them over 5 years for domestic expenditures, and 15 years for expenditures attributed for foreign research. The Inflation Reduction Act of 2022 (the " IRA ") was signed into law on August 16, 2022. Among other things, the IRA contained three key changes for corporations — a corporate minimum tax, a one percent excise tax on certain stock buybacks and certain clean energy incentives and initiatives. The enactment of the IRA did not result in any material impact to the Company' s income tax provision. On August 9, 2022, President Biden signed the CHIPS and Science Act of 2022 into law, which provides certain financial incentives with the intention of increasing American semi- conductor research, development and production and promoting domestic scientific and technological advances. The enactment of the CHIPS did not result in any material impact to the Company' s income tax provision.~~ Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company' s deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. In accordance with ASC 740, " Income Taxes, " the Company recorded a valuation allowance to fully offset the net deferred tax asset, because it is more likely than not that the Company will not realize future benefits associated with these deferred tax assets at December 31, ~~2022~~ **2023** . The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are ~~as follows~~ **at December 31** : Schedule of Deferred Tax Assets and Liabilities **2023** 2022 ~~2021~~ Deferred tax assets (liabilities): Accrued expenses $ ~~103~~ **207** , 000 $ ~~50~~ **103** , 000 Share- based compensation **2, 141, 000** 1, 419 ~~, 000 796~~ , 000 Property and equipment **393, 000** 364 ~~, 000 319~~ , 000 Right- of- use assets ( ~~52~~ **85** , 000) ( ~~51~~ **52** , 000) Lease liability ~~53~~ **87** , 000 53, 000 IRC 174 Expenditures **13, 900, 000** 3, 326, 000 ~~–~~ Start- up expenditures **11, 029, 000** 10, 333 ~~, 000 6, 966~~ , 000 Net operating losses and tax credits **8, 461, 000** 7, 045 ~~, 000 4, 915~~ , 000 Valuation allowance ( ~~22~~ **36** , ~~591~~ **133** , 000) ( ~~13~~ **22** , ~~048~~ **591** , 000) Net deferred tax assets $- $- At December 31, ~~2022~~ **2023** , the Company had federal and state net operating loss carryforwards of approximately $ ~~19~~ **25** . ~~3~~ **9**

million and $ 0. ~~5~~ **7** million, respectively. The federal and state net operating loss carryforwards for 2017 will begin to expire in the year ending December 31, 2037. The federal net operating loss carryforwards starting in 2018 have no expiration. These deferred tax assets were subject to a full valuation allowance as of December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** . At December 31, ~~2022~~ **2023** , the Company had federal and state research and development tax credit carryforwards resulting in deferred tax assets of approximately $ 2. ~~2~~ **0** million and $ 1. ~~0~~ **3** million, respectively. The federal and state credit carryforwards will begin to expire in the years ending December 31, 2038 and December 31, 2033, respectively. These deferred tax assets were subject to a full valuation allowance as of December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** . Under the provisions of Section 382 of the Internal Revenue Code of 1986, certain substantial changes in the Company' s ownership, including a sale of the Company, or significant changes in ownership due to sales of equity, may limit in the future the amount of net operating loss carryforwards available to offset future taxable income. The Company recognizes uncertain tax positions in accordance with ASC 740 on the basis of evaluating whether it is more- likely- than not that the tax positions will be sustained upon examination by tax authorities. For those tax positions that meet the more- likely- than not recognition threshold, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement. As of December 31, **2023, and** 2022 ~~, and 2021~~ , the Company has no significant uncertain tax positions. There are no unrecognized tax benefits included on the balance sheet that would, if recognized, impact the effective tax rate. The Company does not anticipate there will be a significant change in unrecognized tax benefits within the next 12 months. Prior to the conversion, Celcuity was a limited liability company and therefore was taxed as a partnership for income tax purposes. Accordingly, no benefit for income taxes was recorded prior to the conversion. For years prior to ~~2018~~ **2020** , the Company is no longer subject to U. S. federal or state income tax examinations **and remains open for the unutilized tax attributes as of December 31, 2023, carried forward from these years** . The Company' s policy is to recognize interest and penalties related to uncertain tax positions as a component of general and administrative expenses. ~~16~~ **14** . Subsequent Event ~~On~~ **In** March ~~13, 2023~~ **2024** , ~~the Company signed~~ an ~~amendment~~ **investor exercised 1, 739, 080 warrants at an exercise price of $ 8. 05, which generated approximately $ 14 million in cash. The warrants were issued pursuant** to ~~extend its operating lease for~~ a **private placement that closed** ~~period of two years. The commencement of the extended period is May 1, 2024~~ and ~~will terminate~~ **was funded** on ~~April 30~~ **December 9** , ~~2026~~ **2022** ~~. This amendment provides for monthly rent, real estate taxes and operating expenses~~ . ITEM 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures ITEM 9A. Controls and Procedures Evaluation of Disclosure Controls and Procedures Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, ~~2022~~ **2023** . The term " disclosure controls and procedures, " as defined in Rules 13a- 15 (e) and 15d- 15 (e) under the Securities Exchange Act of 1934, as amended (the " Exchange Act "), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC' s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company' s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost- benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, ~~2022~~ **2023** , our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective. Management Report on Internal Control over Financial Reporting Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a- 15 (f) under the Securities Exchange Act of 1934. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, ~~2022~~ **2023** based on criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (" COSO – 2013 ") in Internal Control- Integrated Framework. Based on this assessment, our Chief Executive Officer and Chief Financial Officer concluded that our system of internal control over financial reporting was effective as of such date. This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management' s report was not subject to attestation by our registered public accounting firm pursuant to our designation as a small reporting company or SRC and Non- Accelerated filer. Changes in Internal Control over Financial Reporting There were no changes to our system of internal control over financial reporting during the three months ended December 31, ~~2022~~ **2023** and during the subsequent time period through the filing of this Annual Report that have materially affected, or are reasonably likely to materially affect, our system of controls over financial reporting. ITEM 9B. Other Information **During the three months ended December 31, 2023, none of our directors or officers adopted or terminated a " Rule 10b5- 1 trading arrangement " or " non- Rule 10b5- 1 trading arrangement, " as each term is defined in Item 408 of Regulation S- K. ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections Not Applicable.** PART III ITEM 10. Directors, Executive Officers and Corporate Governance Brian F. Sullivan, age ~~61~~ **62** , is our co- Founder and has served as Chairman of the Board and Chief Executive Officer since we commenced operations in 2012. Mr. Sullivan has over 30 years of experience founding and building successful, high growth technology companies. He was Chairman and CEO of SterilMed, a medical device reprocessing company, from 2003, when he led an investment group to acquire a majority interest, until its sale to Ethicon Endo- Surgery Inc., a Johnson & Johnson company, for $ 330 million in 2011. Previously, he was co- founder and Chief Executive Officer of Recovery Engineering, a filtration company, which he took public and subsequently sold to Procter & Gamble for $ 265 million in 1999. Mr. Sullivan **previously** served on the board of directors of **two publicly- held companies,** Entegris, Inc. **and Virtual Radiologic Inc** ~~, a publicly- held company from 2003- 2021~~ . Mr. Sullivan has received nine U. S. patents and has several

pending. He graduated magna cum laude with distinction from Harvard College with an A. B. in economics. Among other attributes, skills, and qualifications, the board of directors believes Mr. Sullivan is uniquely qualified to serve as a director based on his extensive operational and business development experience, and his knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Lance G. Laing, Ph. D., age ~~61~~ **62** , is our co- Founder and has served as Chief Science Officer, Vice President, Secretary and Director since we commenced operations in 2012. Dr. Laing' s career spans more than 20 years in drug discovery research and technology development. He received his doctorate in biophysics and biochemistry from The Johns Hopkins University and completed a National Institutes of Health post- doctoral fellowship at Washington University Medical School. He has received 24 U. S. patents and has several U. S. patents pending. His drug discovery research career began at Scriptgen / Anadys Pharmaceuticals (purchased by Novartis), where he worked under Professor Peter Kim, who became President of Merck Research. He also was Director of Chemistry and Bioapplications and Director of Detection Product Development for two companies that each developed instruments similar to those Celcuity uses to perform the CELsignia tests. His work at these two instrument companies gave him unique expertise and experience in developing a variety of patented applications for these instruments. Most recently, he served as an executive director for an international drug discovery and development company. Among other attributes, skills, and qualifications, the board of directors believes Dr. Laing is uniquely qualified to serve as a director based on his significant research, medical and scientific expertise. Richard E. Buller, M. D., Ph. D., age ~~73~~ **74** , was appointed to Celcuity' s board of directors in December 2019. Dr. Buller has over 15 years of experience leading oncology clinical development and translational medicine departments at major pharmaceutical companies. He has participated in the development of 15 drugs and several companion diagnostics that received U. S. FDA approval. Dr. Buller most recently served as Head Oncology Clinical Development and Vice President of Translational Oncology at Pfizer, Inc, one of the world' s largest pharmaceutical companies, until he retired in 2016. He had previously served as Vice President of Translational Medicine at Exelixis, a leading biopharmaceutical company, where he led efforts to study patients selected by molecular testing for inclusion in their phase 2 and phase 3 clinical trials. He began his pharmaceutical company career at GlaxoSmithKline as Director of the Oncology Medicine Development Center. Prior to his leadership positions in drug development, he was Professor of Gynecologic Oncology at the University of Iowa, where he led laboratory research focused on identifying genomic variants involved in ovarian cancer. He received his M. D. from the Baylor College of Medicine, where he also received his Ph. D. in cell biology. Among other attributes, skills, and qualifications, the board of directors believes Dr. Buller is uniquely qualified to serve as a director based on his oncology drug and diagnostic development expertise. David F. Dalvey, age ~~64~~ **65** , has served as a member of Celcuity' s board of directors since February 2014. Mr. Dalvey has more than 30 years of experience in the fields of corporate finance and venture capital, working primarily with growth- oriented technology and life- science businesses. He has over 10 years of corporate finance advisory experience with two national investment banks, completing over 150 individual transactions. He has been the General Partner of Brightstone Venture Capital, a venture capital management company, since September 2000. Brightstone is a 25- year old venture capital management company that has raised and managed ten venture partnerships. Previously, he held management positions with R. J. Steichen and Company, an investment bank, from 1995 to 2000, The Food Fund LP, a venture capital firm, from 1992 to 1995 and Wessels, Arnold & Henderson, an investment bank, from 1987 to 1992. Mr. Dalvey served on the board of directors for Navarre Corporation (now Speed Commerce, Inc.) from 2009 until November 2012, on the board of managers for Blue Rock Market Neutral Fund, a mutual fund registered under the Investment Company Act of 1940 from 2000 to 2014 and on the board of directors for Digitiliti, Inc. from July 2011 until October 2012. Mr. Dalvey has significant operational exposure as a board director or advisor to many other public and privately held growth businesses and has served on these companies' audit, strategic or governance committees, including companies such as HomeSpotter, Definity Health, AppTec Laboratories, CHF Solutions, BiteSquad, Agiliti, and Nature Vision. Mr. Dalvey received a B. S. in Business / Management Economics from University of Minnesota. Among other attributes, skills, and qualifications, the board of directors believes Mr. Dalvey is uniquely qualified to serve as a director based on his leadership experience in operating both public and private companies and his experience working in the investment community and with investment firms enable him to bring valuable insight and knowledge to our board of directors. Leo T. Furcht, M. D., age ~~76~~ **77** , was appointed to Celcuity' s board of directors in May 2019. Dr. Furcht is currently Allen- Pardee Professor of Cancer Biology and Head of the Department of Laboratory Medicine and Pathology at the University of Minnesota and a member of the Division of Molecular Pathology and Genomics. He served as Chairman of the Board of Directors for University of Minnesota Physicians, the Medical School practice plan with approximately 700 physicians, from 2004- 2014. He was also the founding Director of the Biomedical Engineering Center from 1990- 2001, where he led efforts to establish stem cell and molecular diagnostics expertise at the University of Minnesota. He has published more than 180 scientific papers and holds more than 30 patents in the fields of polypeptides, biomaterials, and adult stem cells. His business experience includes co- founding two medical technology companies, South Bay Medical, a medical device company that was acquired by Mentor Corporation, and Diascreen, a diagnostics company, which was later acquired by Chronimed. Among other attributes, skills, and qualifications, the board of directors believes Dr. Furcht is uniquely qualified to serve as a director based on his research in tumor cell behavior and extracellular matrix proteins, Head of the University of Minnesota' s Department of Laboratory Medicine and Pathology, and his experience in several biotechnology start- ups. Polly A. Murphy, D. V. M., Ph. D., age ~~58~~ **59** , was appointed to Celcuity' s board of directors in September 2022. Dr. Murphy has served as Chief Business Officer at UroGen Pharma, Inc. since August 2020. Prior to that, Dr. Murphy served in various leadership roles at Pfizer, Inc. from September ~~2012~~ **2008** to August 2020, including as Vice President and Head of **Early** Commercial Development **,** Pfizer Oncology Business Unit from January 2019 to August 2020, Vice President and Head of Global Marketing and Commercial Development, Pfizer Oncology Business Unit from June 2017 to December 2018, and as Vice President and Head of Strategy and Business Development for Pfizer China from November 2013 to May 2018. Since August 2020, Dr. Murphy as served on the board of directors of Atea

Pharmaceuticals, Inc., a publicly held company. Dr. Murphy received her D. V. M. and Ph. D. from Iowa State University and her M. B. A. from Nova Southeastern University. Among other attributes, skills, and qualifications, the board of directors believes Dr. Murphy is uniquely qualified to serve as a director based on her significant medical and scientific expertise and experience in the pharmaceutical industry in business development and commercialization. Richard J. Nigon, age ~~75~~ **76**, is currently Senior Vice President of Cedar Point Capital, LLC., a private company that raises capital for early- stage companies, where he has served since 2007. Mr. Nigon has also been a board member for Northern Technologies International Corp. since February 2010, including its non- executive Chairman of the board of directors since November 2012. Mr. Nigon also serves as a director of several private companies. Mr. Nigon previously served as a board member for Tactile Systems Technology from September 2012 to May 2022, Vascular Solutions, Inc. from November 2000 to February 2017, when it was acquired by Teleflex, Incorporated and as a board member for Virtual Radiologic Corporation from May 2007 until it was acquired in July 2010. From February 2001 until December 2006, Mr. Nigon was a Director of Equity Corporate Finance for Miller Johnson Steichen Kinnard, a privately held investment firm, which was acquired in December 2006 by Stifel Nicolaus, a brokerage and investment banking firm. After that acquisition, Mr. Nigon became a Managing Director of Private Placements of Stifel Nicolaus until May 2007. From February 2000 to February 2001, Mr. Nigon served as the Chief Financial Officer of Dantis, Inc., a web hosting company. Prior to joining Dantis, Mr. Nigon was employed by Ernst & Young LLP from 1970 to 2000, where he served as a partner from 1981 to 2000. While at Ernst & Young, Mr. Nigon served as the Director of Ernst & Young' s Twin Cities Entrepreneurial Services Group and was the coordinating partner on several publicly- traded companies in the consumer retailing and manufacturing sectors. Among other attributes, skills, and qualifications, the board of directors believes Mr. Nigon is qualified to serve as a director because of his extensive public accounting and auditing experience, including particular experience with emerging growth companies. The board of directors also believes that Mr. Nigon will bring to the board of directors a strong background in financial controls and reporting, financial management, financial analysis, SEC reporting requirements and mergers and acquisitions. His strategic planning expertise gained through his management and leadership roles at private investment firms also makes him well- suited to serve as a member of the board of directors. Executive Officers Information regarding our Chief Executive Officer, Brian F. Sullivan, and our Chief Science Officer, Lance G. Laing, PhD., is included above under the heading " Directors ". Vicky Hahne, age ~~56~~ **57**, joined as our Chief Financial Officer in July 2017. She has more than 25 years of financial leadership experience, including the most recent 15 years in the healthcare industry. Prior to joining Celcuity, Ms. Hahne served as Controller of Respiratory Technologies Inc., a medical device manufacturer, from 2015 to 2017. While at Respiratory Technologies, she played a key role in the due diligence process to sell the company to Koninklijke Philips. In 2014, she served as Controller for Ability Network Inc., a healthcare information technology company. From 2007 to 2012, Ms. Hahne served as Controller of SterilMed Inc., a medical device reprocessing company, where she was significantly involved in the sale of the company to Johnson & Johnson. Prior to these roles, Ms. Hahne held several senior financial positions at SimonDelivers Inc., including Chief Financial Officer. Ms. Hahne has extensive experience in early stage, high growth companies with responsibilities including financial controls and stewardship, financial analysis, mergers and acquisitions, building infrastructure and systems. She received a B. S. degree in Finance and Accounting from Northern State University and received her CPA certificate in 1990. Corporate Governance Our board of directors has adopted a Code of Business Conduct and Ethics that applies to our directors, officers and employees. ~~This~~ **In addition, our CEO, CFO and other senior financial officers of the company are subject to a** ~~code~~ **Code** ~~is~~ **of Ethical Business Conduct for Senior Financial Officers. These Codes are** available on the corporate governance section of our website (which is a subsection of the investor relations section of our website) at the following address: www. celcuity. com. We intend to disclose on our website any amendments or waivers to ~~the~~ **these** ~~Code~~ **Codes** ~~of Business Conduct and Ethics~~ that are required to be disclosed by SEC **or Nasdaq** rules. Additional information required by this Item 10 will be contained in our definitive proxy statement for our 2023 Annual Meeting of Stockholders (the " Definitive Proxy Statement ") and is incorporated herein by reference. ITEM 11. Executive Compensation The information required by this Item 11 will be contained in the Definitive Proxy Statement and is incorporated herein by reference. ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters The information required by this Item 12 will be contained in the Definitive Proxy Statement and is incorporated herein by reference. ITEM 13. Certain Relationships and Related Transactions, and Director Independence The information required by this Item 13 will be contained in the Definitive Proxy Statement and is incorporated herein by reference. ITEM 14. Principal Accounting Fees and Services The information required by this Item 14 will be contained in the Definitive Proxy Statement and is incorporated herein by reference. PART IV ITEM 15. Exhibits, Financial Statement Schedules. FINANCIAL STATEMENTSItem Page Report of Independent Registered Public Accounting Firm Balance Sheets – December 31, **2023 and** 2022 ~~and 2021~~ Statements of Operations – Years ended December 31, **2023 and** 2022 ~~and 2021~~ Statements of Stockholders' Equity – Years ended December 31, **2023 and** 2022 ~~and 2021~~ Statements of Cash Flows – Years ended December 31, **2023 and** 2022 ~~and 2021~~ Notes to Consolidated Financial Statements FINANCIAL STATEMENT SCHEDULES ~~EXHIBITSSee~~ --- **EXHIBITS See** Exhibit Index immediately following the signature page hereto, which is incorporated herein by reference. ITEM 16. Form 10- K Summary SIGNATURES Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized. Dated: March ~~23~~ **27**, ~~2023~~ **2024** CELCUITY INC. By / s / Brian F. Sullivan Brian F. Sullivan Chairman and Chief Executive Officer (Principal Executive Officer) Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated. Each person whose signature appears below constitutes and appoints Brian F. Sullivan and Vicky Hahne as the undersigned' s true and lawful attorneys- in fact and agents, each acting alone, with full power of substitution and resubstitution, for the undersigned and in the undersigned' s name, place and stead, in any and all amendments to this Annual Report on Form 10- K and to file the same, with all exhibits thereto, and other documents in

connection therewith, with the Securities and Exchange Commission, granted unto said attorneys- in- fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as the undersigned might or could do in person, hereby ratifying and confirming all said attorneys- in- fact and agents, each acting alone, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof. Signature Title Date / s / Brian F. Sullivan Chairman and Chief Executive Officer March ~~23~~ **27** , ~~2023~~ **2024** Brian F. Sullivan (Principal Executive Officer) / s / Vicky Hahne Chief Financial Officer March ~~23~~ **27** , ~~2023~~ **2024** Vicky Hahne (Principal Financial and Accounting Officer) / s / Lance G. Laing Chief Science Officer, Vice President and Secretary, and March ~~23~~ **27** , ~~2023~~ **2024** Lance G. Laing Director / s / Richard E. Buller Director March ~~23~~ **27** , ~~2023~~ **2024** Richard E. Buller / s / Dave F. Dalvey Director March ~~23~~ **27** , ~~2023~~ **2024** Dave F. Dalvey / s / Leo T. Furcht Director March ~~23~~ **27** , ~~2023~~ **2024** Leo T. Furcht / s / Polly A. Murphy Director March ~~23~~ **27** , ~~2023~~ **2024** Polly A. Murphy / s / Richard J. Nigon Director March ~~23~~ **27** , ~~2023~~ **2024** Richard J. Nigon EXHIBIT INDEX FORM 10- KExhibit No. Description 2. 1 Form of Plan of Conversion (incorporated by reference to Exhibit 2. 1 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 3. 1 Certificate of Incorporation of the Company, as amended, including the Certificate of Designations of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3. 1 to the Company' s ~~Quarterly~~ **Annual** Report on Form 10- ~~Q~~ **K / A** filed with the SEC on ~~August 12~~ **April 7** , ~~2022~~ **2023** ). 3. 2 Bylaws of the Company (incorporated by reference to Exhibit 3. 2 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on November 13, 2017). 4. 1 Specimen Certificate representing shares of common stock of Celcuity Inc. (incorporated by reference to Exhibit 4. 1 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 4. 2 ***** Description of Registered Securities ~~(incorporated by reference to Exhibit 4. 2 to the Company' s Annual Report on Form 10- K filed with the SEC on March 13, 2020)~~ . 4. 3 Form of Warrant to Purchase Units of Membership Interest issued by Celcuity LLC to Cedar Point Capital, LLC, as placement agent of membership units and unsecured convertible promissory notes of Celcuity LLC (incorporated by reference to Exhibit 10. 9 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 4. 4 Form of Warrant to Purchase Shares of Common Stock issued by Celcuity Inc. in connection with the conversion of 1. 25 % Unsecured Convertible Promissory Notes (incorporated by reference to Exhibit 10. 2 to the Company' s Current Report on Form 8- K filed with the SEC on September 25, 2017). 4. 5 Representative' s Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on September 25, 2017). 4. 6 First Amendment to Representative' s Warrant, dated September 13, 2022, between Celcuity Inc. and Craig- Hallum Capital Group LLC (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on September 14, 2022). 4. 7 Form of Warrant issued by Celcuity Inc. to Innovatus Life Sciences Lending Fund I, LP in connection with the Loan and Security Agreement dated April 8, 2021 (incorporated by reference from Exhibit 4. 2 to the Company' s Current Report on Form 8- K filed with the SEC on April 8, 2021). 4. 8 Equity Grant Agreement, dated April 8, 2021, between the Company and Pfizer, Inc. (incorporated by reference from Exhibit 4. 1 to the Company' s Current Report on Form 8- K filed with the SEC on April 8, 2021). 4. 9 Form of Warrant issued by Celcuity Inc. in connection with the Securities Purchase Agreement, dated May 15, 2022 (incorporated by reference to Exhibit 4. 1 to the Company' s Current Report on Form 8- K filed with the SEC on May 18, 2022 **). 4. 10 Form of Pre- Funded Warrant issued by Celcuity Inc. in connection with the Securities Purchase Agreement, dated October 18, 2023 (incorporated by reference to Exhibit 4. 1 to the Company' s Current Report on Form 8- K filed with the SEC on October 23, 2023** ). 10. 1 Celcuity Inc. 2017 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10. 1 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 10. 2 Celcuity Inc. Amended and Restated 2017 Stock Incentive Plan (incorporated by reference from Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on May 14, 2020). 10. 3 **Amendment to the Celcuity Inc. Amended and Restated Stock Incentive Plan (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on May 12, 2023). 10. 4** Form of Stock Option Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10. 3 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 10. ~~4~~ **5** Form of Restricted Stock Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10. 4 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 10. ~~5~~ **6** Form of Restricted Stock Unit Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10. 5 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 10. ~~6~~ **7** Form of Stock Appreciation Rights Agreement pursuant to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10. 6 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 10. ~~7~~ **8** Celcuity LLC 2012 Equity Incentive Plan, adopted August 10, 2012, as amended by First Amendment to the Celcuity LLC 2012 Equity Incentive Plan, adopted November 12, 2015 (incorporated by reference to Exhibit 10. 7 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 10. ~~8~~ **9** Form of Incentive Plan Unit Option Agreement pursuant to the Celcuity LLC 2012 Equity Incentive Plan (incorporated by reference to Exhibit 10. 8 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 10. ~~9~~ **10** Commercial Lease, dated September 28, 2017, between West Glen Development I, LLC and Celcuity, LLC (incorporated by reference to Exhibit 10. 11 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on November 13, 2017). 10. ~~10~~ **11** Commercial Lease, First Amendment to Lease, dated July 28, 2020, between West Glen Development I, LLC and Celcuity Inc. (incorporated by reference from Exhibit 10. 3 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on August 10, 2020). 10. ~~11~~ **12** Commercial Lease, Second Amendment to Lease, dated July 19, 2021, between West Glen Development I, LLC and Celcuity Inc. ~~,~~ **(** incorporated by reference from Exhibit 10. 4 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on August 11, 2021 **)** . 10. ~~12~~ **13** Commercial Lease, Third Amendment to Lease, dated July 27, 2022, by and between Celcuity Inc. and West Glen Development I, LLC (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report

on Form 8- K filed with the SEC on July 29, 2022). 10. ~~13~~ **14** Commercial Lease, Fourth Amendment to Lease, dated March 13, 2023, by and between Celcuity Inc. and West Glen Development I, LLC (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on March 15, 2023). 10. ~~14~~ **15** Clinical Trial Agreement, dated May 8, 2017, between NSABP Foundation, Inc. and Celcuity LLC (incorporated by reference to Exhibit 10. 13 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 10. ~~15~~ **16** Clinical Trial Agreement, Amendment No. 1, between NSABP Foundation, Inc and Celcuity Inc., dated October 15, 2020 (incorporated by reference Exhibit 10. 15 to the Company' s Annual Report on Form 10- K filed with the SEC on February 16, 2021). 10. ~~16~~ **17** Confidentiality, Assignment of Inventions and Non- Competition Agreement, dated November 15, 2011, between Celcuity LLC and Brian F. Sullivan (incorporated by reference to Exhibit 10. 14 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 10. ~~17~~ **18** Confidentiality, Assignment of Inventions and Non- Competition Agreement, dated November 15, 2011, between Celcuity LLC and Lance G. Laing (incorporated by reference to Exhibit 10. 15 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 10. ~~18~~ **19** Confidentiality, Non- Compete and Proprietary Rights Agreement, dated May 17, 2017, between Celcuity LLC and Vicky Hahne (incorporated by reference to Exhibit 10. 16 to the Company' s Registration Statement on Form S- 1 filed with the SEC on August 23, 2017). 10. ~~19~~ **20** Form of Indemnification Agreement between Celcuity Inc. and each of its officers and directors (incorporated by reference to Exhibit 10. 17 to the Company' s Registration Statement on Form S- 1 / A filed with the SEC on September 12, 2017). 10. ~~20~~ **21** † License Agreement, dated April 8, 2021, by and between the Company and Pfizer, Inc (incorporated by reference to Exhibit 10. 3 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on August 11, 2021). 10. ~~21~~ **22** † Amendment to License Agreement, dated May 6, 2021, by and between the Company and Pfizer, Inc. (incorporated by reference to Exhibit 10. 5 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on August 11, 2021). 10. ~~22~~ **23** Open Market Sale AgreementSM, dated February 4, 2022, by and between Celcuity Inc., and Jefferies LLC (incorporated by reference to Exhibit 1. 1 to the Company' s Current Report on Form 8- K filed with the SEC on February 4, 2022). 10. ~~23~~ **24** Securities Purchase Agreement, dated May 15, 2022, by and among the Registrant and the Purchasers named therein (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on May 18, 2022). 10. ~~24~~ **25** Registration Rights Agreement, dated May 15, 2022, by and among the Registrant and the Purchasers named therein (incorporated by reference to Exhibit 10. 2 to the Company' s Current Report on Form 8- K filed with the SEC on May 18, 2022). 10. ~~25~~ **26** Loan and Security Agreement, dated as of April 8, 2021, by and between the Company and Innovatus Life Sciences Lending Fund I, LP. (incorporated by reference from Exhibit 10. 2 to the Company' s Quarterly Report on Form 10- Q filed with the SEC on August 11, 2021). 10. ~~26~~ **27** The First Amendment to Loan and Security Agreement, dated August 9, 2022, by and among the Company and Innovatus Life Sciences Lending Fund I, LP (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on August 11, 2022). **10. 28 Securities Purchase Agreement, dated October 18, 2023, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10. 1 to the Company' s Current Report on Form 8- K filed with the SEC on October 23, 2023). 10. 29 Registration Rights Agreement, dated October 18, 2023, by and among the Company and the Investors named therein (incorporated by reference to Exhibit 10. 2 to the Company' s Current Report on Form 8- K filed with the SEC on October 23, 2023).** 23. 1 * Consent of Boulay PLLP. 24. 1 * Power of Attorney (included on the signature page). 31. 1 * Certification of principal executive officer required by Rule 13a- 14 (a). 31. 2 * Certification of principal financial officer required by Rule 13a- 14 (a). 32. 1 * * Section 1350 Certification of principal executive officer. 32. 2 * * Section 1350 Certification of principal financial officer. **97 * Celcuity Inc. Policy for the Recoupment of Erroneously Awarded Compensation.** Financial statements from the Annual Report on Form 10- K of the Company for the year ended December 31, ~~2022~~ **2023** , formatted, in Inline XBRL: (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Changes in Stockholders' Equity, (iv) the Statements of Cash Flows, and (v) the Notes to Financial Statements. Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101). * Filed herewith. * * Furnished herewith. Management contract or compensatory plan. † Certain portions have been omitted from this exhibit **. Exhibit 4. 2 Description of Registrant' s Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934, as amended The following summary of the terms of our capital stock is subject to and qualified in its entirety by reference to our certificate of incorporation, as amended, and bylaws, copies of which are on file with the SEC as exhibits to previous SEC filings. As of December 31, 2023, Celcuity Inc. (" we, " " us, " " our, " and the " Company ") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the " Exchange Act "): common stock, par value $ 0. 001 per share. In addition, we have certain equity interests outstanding that are convertible into common stock, which are described in more detail below. As of December 31, 2023, we were authorized to issue 65, 000, 000 shares of common stock and 2, 500, 000 shares of preferred stock, $ 0. 001 par value per share. Common Stock Fully Paid and Nonassessable The outstanding shares of our common stock are fully paid and nonassessable. Voting Rights Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. Dividend Rights Holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose. Rights and Preferences Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. Right to Liquidation Distributions Upon our liquidation, dissolution or winding- up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock, including the liquidation preference of our Series A Preferred Stock. Transfer Agent and Registrar The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. The transfer agent and**

**registrar' s address is One State Street Plaza, 30th Floor, New York, NY 10004. The Nasdaq Capital Market Our common stock is listed for quotation on The Nasdaq Capital Market under the symbol " CELC ". Our board or directors is authorized, without action by the stockholders, to designate and issue up to an aggregate of 2, 500, 000 shares of preferred stock in one or more series. Our board of directors is authorized to designate the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors is able to authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying, deferring or preventing a change in control of the Company, which might harm the market price of our common stock. See also " Anti- Takeover Effect of Delaware Law and Certain Charter and Bylaw Provisions " below. On May 16, 2022, in connection with a Securities Purchase Agreement, dated May 15, 2022, by and among the Company and the Investors named therein (the " 2022 Securities Purchase Agreement "), the Company filed a Certificate of Designations (the " Certificate of Designations ") with the Secretary of State of the State of Delaware, designating 1, 850, 000 shares out of the authorized but unissued shares of its preferred stock as Series A Convertible Preferred Stock. The following is a summary of the principal terms of the Series A Preferred Stock: Holders of Series A Preferred Stock shall be entitled to receive dividends or distributions on shares of Series A Preferred Stock equal (on an as- if- converted- to- common stock basis) to and in the same form as dividends or distributions actually paid on shares of the common stock when, as and if such dividends or distributions are paid on shares of the common stock. No other dividends or distributions shall be paid on shares of Series A Preferred Stock. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a Deemed Liquidation Event (as defined in the Certificate of Designations) the holders of shares of Series A Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or out of the Available Proceeds (as defined in the Certificate of Designations), as applicable, before any payment shall be made to the holders of common stock by reason of their ownership thereof, an amount per share equal to the greater of (i) the Series A Original Issue Price (as defined in the Certificate of Designations), plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted into common stock pursuant to the Certificate of Designations immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event (the " Series A Liquidation Amount "). The Series A Preferred Stock is non- voting stock and does not entitle the holder thereof to vote on any matter submitted to the stockholders of the Company for their action or consideration, except as otherwise provided by the General Corporation Law of the State of Delaware or the other provisions of the Certificate of Incorporation or the Certificate of Designations. As long as any shares of Series A Preferred Stock are outstanding, the Company may not, without the approval of the holders of a majority of the outstanding shares of Series A Preferred Stock, take the following actions: (i) amend, alter or repeal any provision of the Certificate of Incorporation, the Certificate of Designations or Bylaws of the Company in a manner that adversely affects the powers, preferences or rights of the Series A Preferred Stock; (ii) create, or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock unless the same ranks junior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends and rights of redemption, or increase the authorized number of shares of Series A Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock of the Company unless the same ranks junior to the Series A Preferred Stock with respect to the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends and rights of redemption; (iii) (A) reclassify, alter or amend any existing security of the Company that is pari passu with the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to the Series A Preferred Stock in respect of any such right, preference, or privilege or (B) reclassify, alter or amend any existing security of the Company that is junior to the Series A Preferred Stock in respect of the distribution of assets on the liquidation, dissolution or winding up of the Company, the payment of dividends or rights of redemption, if such reclassification, alteration or amendment would render such other security senior to or pari passu with the Series A Preferred Stock in respect of any such right, preference or privilege; or (iv) purchase or redeem (or permit any subsidiary to purchase or redeem) or pay or declare any dividend or make any distribution on, any shares of capital stock of the Company (with exceptions for dividends on the common stock solely in the form of additional shares of common stock and repurchases from former service providers in connection with the cessation of such services). Conversion Rights Subject to the Beneficial Ownership Limitation described below, each share of Series A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non- assessable shares of common stock as is determined by multiplying one share of Series A Preferred Stock by the Series A Conversion Rate in effect at the time of conversion. The " Series A Conversion Rate " shall initially be ten (10) shares of Common Stock for each share of Series A Preferred Stock. The Series A Conversion Rate shall be subject to adjustment as provided in the Certificate of Designation. Under the terms of the Certificate of Designations, the Company may not effect the conversion of Series A Preferred Stock into common stock, and a holder will not be entitled to request the conversion of shares of Series A Preferred Stock, if, upon giving**

**effect to such conversion, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates, any other persons acting as a group together with the holder or any of the holder' s affiliates, and any other persons whose beneficial ownership of common stock would or could be aggregated with the holder' s for purposes of Section 13 (d) or Section 16 of the Securities Exchange Act of 1934, as amended) would exceed the Beneficial Ownership Limitation, which is 9. 99 % of the number of shares of common stock outstanding immediately after giving effect to the conversion, as such percentage ownership is calculated in accordance with Section 13 (d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission. A holder may reset the Beneficial Ownership Limitation percentage to a higher percentage (not to exceed 19. 9 %), effective 61 days after written notice to the Company, or a lower percentage, effective immediately upon written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of Series A Preferred Stock. The Series A Preferred Stock does not have, or is subject to, any preemptive or similar rights. Pre- Funded Warrants Under the Securities Purchase Agreement, dated October 18, 2023, by and among the Company and the Selling Stockholders (the " 2023 Securities Purchase Agreement "), the Company issued pre- funded warrants (the " 2023 Warrants ") to purchase 5, 747, 787 shares of common stock. Each 2023 Warrant to purchase one share was sold for a purchase price of $ 8. 699 per Warrant and has an exercise price of $ 0. 001 per share (for aggregate consideration equating to $ 8. 70 per share of common stock issuable upon exercise of the 2023 Warrants). Each 2023 Warrant is immediately exercisable and will not expire. Under the terms of the 2023 Warrants, the Company may not effect the exercise of any such 2023 Warrant, and a holder will not be entitled to exercise any portion of any 2023 Warrant, if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates, other persons acting or who could be deemed to be acting as a group together with the holder or any of the holder' s affiliates, and any other persons whose beneficial ownership of common stock would or could be aggregated with the holder' s or any of the holder' s affiliates for purposes of Section 13 (d) or Section 16 of the Exchange Act) would exceed 4. 99 % of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is calculated in accordance with Section 13 (d) of the Exchange Act and the applicable regulations of the Securities and Exchange Commission (the " Maximum Percentage "). A holder may reset the Maximum Percentage to a higher percentage (not to exceed 19. 99 %), effective 61 days after written notice to the Company, or a lower percentage, effective immediately upon written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of 2023 Warrants. Warrants Under the 2022 Securities Purchase Agreement, the Company issued Warrants (the " 2022 Warrants ") to purchase 695, 645 shares of Series A Preferred Stock, each 2022 Warrant having an exercise price of $ 85. 50 per share. The exercise price of the 2022 Warrants is at a 40 % premium to the price (on an as converted to common stock basis) paid by the Investors for the initial shares of common stock purchased under the 2022 Securities Purchase Agreement. On September 1, 2022, the Company amended its Certificate of Incorporation to increase the aggregate authorized number of shares of capital stock and the number of shares of common stock such that the company has available, and has reserved, such number of its duly authorized but unissued shares of common stock as shall be sufficient to effect the conversion of all shares of Series A Preferred Stock then outstanding or available for issuance upon the exercise of the 2022 Warrants. Following this Authorized Share Increase, and notice to the Investors, the 2022 Warrants became exercisable for an aggregate 6, 956, 450 shares of common stock with an exercise price per share adjusted of $ 8. 05. Each 2022 Warrant, when issued, is immediately exercisable and will remain exercisable until the earlier of (i) five years from the date of issuance and (ii) seventy- five (75) days after the Company announces (x) whether the progression- free survival (" PFS ") of gedatolisib in combination with Palbociclib and fulvestrant (Arm A) to fulvestrant (Arm C) in the Phase 3 study met its primary endpoint target, (y) whether the PFS of gedatolisib in combination with fulvestrant (Arm B) to fulvestrant (Arm C) in the Phase 3 study met its primary endpoint target, and (z) the associated hazard ratios and median PFS values for each of Arm A, Arm B, and Arm C. Under the terms of the 2022 Warrants, the Company may not effect the exercise of any such 2022 Warrant, and a holder will not be entitled to request the exercise any portion of any 2022 Warrant, if, upon giving effect to such exercise, the aggregate number of shares of common stock beneficially owned by the holder (together with its affiliates, any other persons acting as a group together with the holder or any of the holder' s affiliates, and any other persons whose beneficial ownership of common stock would or could be aggregated with the holder' s for purposes of Section 13 (d) or Section 16 of the Securities Exchange Act of 1934, as amended) would exceed the Beneficial Ownership Limitation as described in the " Preferred Stock — Conversion Rights " section above. A holder may reset the Beneficial Ownership Limitation percentage to a higher percentage (not to exceed 19. 9 %), effective 61 days after written notice to the Company, or a lower percentage, effective immediately upon written notice to the Company. Any such increase or decrease will apply only to that holder and not to any other holder of 2022 Warrants. Registration Rights Agreement Registration Rights Agreement In connection with the 2023 Securities Purchase Agreement, the Company entered into a Registration Rights Agreement (the " 2023 Registration Rights Agreement ") with the Investors named therein, pursuant to which the Company agreed to register for resale the Registrable Securities (the " 2023 Registrable Securities "), which include: (i) the shares of common stock then issued or issuable upon exercise of the 2023 Warrants (assuming the 2023 Warrants are exercisable in full without regard to any exercise limitation therein) (the " 2023 Warrant Shares "), and (ii) any other securities issued or issuable with respect to, in exchange for or in replacement of, the 2023 Warrant Shares issued and sold pursuant to the 2023 Securities Purchase Agreement. Under the 2023 Registration Rights Agreement, the Company agreed to file a registration statement covering the resale by the Investors of the 2023 Registrable Securities no later than 30 days following the Closing Date (as defined in the 2023 Registration rights Agreement). The Company agreed to use commercially reasonable efforts to cause the registration statement to become effective and to keep such**

**registration statement effective until such time as there are no longer 2023 Registrable Securities held by the Investors. The Company agreed to be responsible for all fees and expenses incurred in connection with the registration of the 2023 Registrable Securities. The Company filed a registration statement on Form S- 3 registering for resale the 2023 Registrable Securities, which was declared effective on November 28, 2023. The Company granted the Investors customary indemnification rights in connection with the registration statement, including for liabilities arising under the Securities Act. The Investors also granted the Company customary indemnification rights in connection with the registration statement. Registration Rights Agreement In connection with the 2022 Securities Purchase Agreement, the Company entered into a Registration Rights Agreement (the " 2022 Registration Rights Agreement ") with the Investors named therein, pursuant to which the Company agreed to register for resale the Registrable Securities (the " 2022 Registrable Securities "), which include: (i) the common stock, (ii) the shares of common stock then issued or issuable upon conversion of the Series A Preferred Stock (assuming on such date the shares of Series A Preferred Stock are convertible in full without regard to any conversion limitations in the Certificate of Designations), and (iii) the common stock then issued or issuable upon exercise of the 2022 Warrants (assuming the 2022 Warrants are exercisable in full without regard to any exercise limitations therein). Under the 2022 Registration Rights Agreement, the Company agreed to file a registration statement covering the resale by the Investors of the 2022 Registrable Securities no later than 30 days following (i) the Closing Date (as defined in the 2022 Registration rights Agreement) and (ii) the date the Company obtained the necessary stockholder approval to effect the Authorized Share Increase. The Company agreed to use commercially reasonable efforts to cause the registration statement to become effective and to keep such registration statement effective until such time as there are no longer 2022 Registrable Securities held by the Investors. The Company agreed to be responsible for all fees and expenses incurred in connection with the registration of the 2022 Registrable Securities. The Company filed a registration statement on Form S- 3 registering for resale the 2022 Registrable Securities, which was declared effective on January 11, 2023. The representations, warranties and covenants contained in each of the 2023 Warrants, the 2022 Warrants, the 2023 Securities Purchase Agreement, the 2022 Securities Purchase Agreement, the 2023 Registration Rights Agreement and the 2022 Registration Rights Agreement were made solely for the benefit of the parties thereto and may be subject to limitations agreed upon by the contracting parties. Anti- Takeover Effect of Delaware Law and Certain Charter and Bylaw Provisions Our certificate of incorporation, as amended, and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our Company. A summary of these provisions is as follows: ● Board of directors vacancies. Our bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors will be permitted to be set only by a resolution adopted by our board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management. ● Advance notice requirements for stockholder proposals and director nominations. Our bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder' s notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer' s own slate of directors or otherwise attempting to obtain control of the Company. ● No cumulative voting. The Delaware General Corporation Law, or DGCL, provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation' s certificate of incorporation provides otherwise. Our certificate of incorporation, as amended, does not provide for cumulative voting. ● Stockholder action; special meetings of stockholders. Our certificate of incorporation, as amended, provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Further, our bylaws provide that special meetings of our stockholders may be called only by a majority of our board of directors, the chairperson of our board of directors, or our Chief Executive Officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors. ● Issuance of undesignated preferred stock. As of the date of this prospectus, we have 650, 000 shares of undesignated preferred stock. Subject to certain limitations and approval requirements with respect to our Series A Preferred Stock as described in " Preferred Stock – Voting Rights " above, our board of directors has the authority, without further action by the stockholders, to issue this preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock would enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or other means. ● Amendment of charter and bylaw provisions. The affirmative vote of stockholders representing at least two- thirds of the voting power of all then- outstanding capital stock, and in certain instances, the vote of the holders of a majority of the then- outstanding Series A Preferred Stock, is required to amend, alter or repeal certain provisions of our certificate of incorporation, as amended, including the provision noted above regarding stockholders not being able to act by written consent. Subject to certain limitations and approval requirements with respect to our Series A Preferred Stock as described in " Preferred Stock –**

**Voting Rights ” above, a majority of our board of directors has authority to adopt, amend or repeal provisions of our bylaws. Stockholders also have the authority to adopt, amend or repeal provisions of our bylaws, but only with the affirmative vote of stockholders representing at least two- thirds of the voting power of all then- outstanding capital stock and in certain instances, the vote of the holders of a majority of the then- outstanding Series A Preferred Stock. We are subject to the provisions of Section 203 of the DGCL, an anti- takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “ business combination ” with an “ interested stockholder ” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a “ business combination ” includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an “ interested stockholder ” is a person who owns 15 % or more of the voting stock of a corporation, or any affiliate or associate of a corporation who, within three years prior, did own 15 % or more of the voting stock of that corporation** . Exhibit 23. 1 CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM We have issued our report dated March ~~23~~ **27** , ~~2023~~ **2024** , with respect to the financial statements included in the Annual Report of Celcuity Inc. on Form 10- K for the year ended December 31, ~~2022~~ **2023** . We hereby consent to the incorporation by reference in the Registration Statements of Celcuity Inc. on Form S- 8 (Reg. Nos. 333- 221117, 333- 238787, 333- 253940, 333- 256500, 333- 265328 ~~and~~ **,** 333- 270238 **and 333- 271976** ) and on Form S- 3 (Reg. No. 333- ~~227466~~ **261155** , 333- **269090** ~~254625,~~ and 333- **275551** ~~261155 and 333- 269090~~ ). / s / Boulay PLLP ~~Minneapolis, Minnesota March 23, 2023~~ Exhibit 31. 1 CERTIFICATION UNDER SECTION 302 OF THE SARBANES- OXLEY ACT OF 2002 I, Brian F. Sullivan, certify that: 1. I have reviewed this annual report on Form 10- K of Celcuity Inc.; 2. Based on my knowledge, this report does not contain any untrue statement of **a** material fact or omit to state a material fact necessary to make the ~~statement~~ **statements** made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report; 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report; 4. The registrant’ s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a- 15 (e) and 15d- 15 (e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a- 15 (f) and 15d- 15 (f)) for the registrant and have: (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; (c) Evaluated the effectiveness of the registrant’ s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and (d) Disclosed in this report any change in the registrant’ s internal control over financial reporting that occurred during the registrant’ s most recent fiscal quarter (the registrant’ s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’ s internal control over financial reporting; and 5. The registrant’ s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’ s auditors and the audit committee of the registrant’ s board of directors (or persons performing the equivalent functions): (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’ s ability to record, process, summarize and report financial information; and (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’ s internal control over financial reporting. Date: March ~~23~~ **27** , ~~2023~~ **2024** By / s / Brian F. Sullivan Brian F. Sullivan Chairman and Chief Executive OfficerExhibit 31. 2 I, Vicky Hahne, certify that: Date: March ~~23~~ **27** , ~~2023~~ **2024** By / s / Vicky Hahne Vicky Hahne Chief Financial OfficerExhibit 32. 1 CERTIFICATION PURSUANT TO 18 U. S. C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES- OXLEY ACT OF 2002 In connection with the filing of the Annual Report on Form 10- K for the year ended December 31, ~~2022~~ **2023** (the “ Report ”) by Celcuity Inc. (“ Registrant ”), I, Brian F. Sullivan, the Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes- Oxley Act of 2002, 18 U. S. C. Section 1350, that to the best of my knowledge: 1. The Report fully complies with the requirements of Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934, as amended; and 2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant. **Exhibit** ~~Date: March 23, 2023 By / s / Brian F. Sullivan Brian F. Sullivan Chairman and Chief Executive OfficerExhibit~~ 32. 2 In connection with the filing of the Annual Report on Form 10- K for the year ended December 31, ~~2022~~ **2023** (the “ Report ”) by Celcuity Inc. (“ Registrant ”), I, Vicky Hahne, the Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes- Oxley Act of 2002, 18 U. S. C. Section 1350, that to the best of my knowledge: **Exhibit Policy for the Recoupment of Erroneously Awarded Compensation Celcuity Inc., a Delaware corporation (the “ Company ”), has adopted this Policy for the Recoupment of Erroneously Awarded Compensation (the “ Policy ”), pursuant to the requirements of Nasdaq Listing Rule 5608 and Securities Exchange Act Rule 10D- 1. The Policy sets forth the circumstances under which the Company will recoup certain incentive compensation paid to the Executive Officers of the Company in connection with certain financial restatements. Each Executive Officer is required to sign and return to the Company the Acknowledgement Form attached hereto as Exhibit A, pursuant to which such Executive Officer will agree to be bound by the terms and comply with this Policy in exchange for adequate and reasonable consideration; provided, however, that any failure by an Executive Officer to return a signed Acknowledgement Form does not affect the validity or**

**enforceability of this Policy. Definitions (A) " Clawback Period " means the three completed fiscal years immediately preceding the earlier of (i) the date the Company' s board of directors concludes, or reasonably should have concluded, that a Covered Accounting Restatement is required to be prepared or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Covered Accounting Restatement, in either case regardless of if or when such Covered Accounting Restatement is filed (such date, the " Clawback Trigger** Date ~~: March 23~~ **"), and any transition period (that results from a change in the Company' s fiscal year) of less than nine months within or immediately following those three completed fiscal years. (B) " Committee " means the Compensation Committee of the Board of Directors of the Company. (C) " Covered Accounting Restatement " means an accounting restatement prepared due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial restatements (i. e., a " Big R " restatement), or that would result in a material misstatement if the error were corrected only in the current period or left uncorrected in the current period (i. e., a " little r " restatement). For the avoidance of doubt, a Covered Accounting Restatement will not include changes to the Company' s financial statements that do not represent error corrections under accounting standards applicable to the Company at the time of the accounting restatement, including as a result of a (i) retrospective application of a change in accounting principle, (ii) retrospective revision to reportable segment information due to a change in the structure of the Company' s internal organization, (iii) retrospective reclassification due to a discontinued operation, (iv) retrospective application of a change in reporting entity, and (v) retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure. (D) " Covered Incentive- Based Compensation " means any Incentive- Based Compensation (i) received by a current or former Executive Officer after beginning service as an Executive Officer, provided that the current or former Executive Officer served as an Executive Officer at any time during the performance period applicable to such Incentive- Based Compensation, (ii) received on or after October 2** , 2023 **(the " Effective Date "), and (iii) received while the Company had a listed class of securities on a national securities exchange. For purposes of this Policy, Incentive- Based Compensation is deemed to be " received " in the fiscal year in which the financial reporting measure included in the Incentive- Based Compensation award is attained or satisfied, regardless of whether the payment or grant occurs before or after such fiscal year, and regardless of whether the Incentive- Based Compensation continues to be subject to a service- based vesting condition. (E) " Executive Officer " has the meaning assigned to it in Nasdaq Listing Rule 5608 (d). (F) " Financial Reporting Measure " means (i) any measure determined in accordance with accounting principles used in the Company' s financial statements, whether presented in or outside of the Company' s financial statements and whether or not included in a filing with the Securities and Exchange Commission, (ii) any measures derived wholly or in part from such measures (including non- GAAP measures), and (iii) other performance measures affected by accounting- related information, including stock price, total shareholder return and relative total shareholder return. (G) " Incentive- Based Compensation " means any compensation that is granted, earned or vested based wholly or in part on the attainment of any Financial Reporting Measure, which may include awards granted under the Company' s annual incentive plan as well as performance- based restricted stock units, and which may include Incentive- Based Compensation contributed to a plan, other than a tax- qualified retirement plan. For the avoidance of doubt, Incentive- Based Compensation shall not include equity awards that vest solely based on continued service and were not granted based on the attainment of any Financial Reporting Measure or any bonus compensation based on discretionary or subjective goals or goals that are not based on any Financial Reporting Measure. (H) " Sarbanes- Oxley Act Section 304 " means Section 304 of the Sarbanes-Oxley Act of 2002. General Rules In the event the Company determines it is required to prepare a Covered Accounting Restatement, the Committee shall review any Covered Incentive- Based Compensation received by a current or former Executive Officer of the Company during the Clawback Period. In the event the Committee determines that the amount of any such Covered Incentive- Based Compensation that was received during the Clawback Period exceeds the amount that otherwise would have been received had it been determined based on the restated results (the " Erroneously Awarded Compensation "), the amount of such Erroneously Awarded Compensation shall be recouped on a pre- tax basis. Recoupment under this Policy with respect to an Executive Officer shall not require the finding of any misconduct by such Executive Officer or such Executive Officer being found responsible for the accounting error leading to the Covered Accounting Restatement. For purposes of this section, Incentive- Based Compensation is deemed to be " received " in the fiscal year in which the financial reporting measure included in the Incentive- Based Compensation award is attained or satisfied, regardless of whether the payment or grant occurs before or after such fiscal year. 2 Calculation of Erroneously Awarded Compensation In the event any applicable Covered Incentive- Based Compensation has been granted in the form of equity or equity- based awards, and such awards remain outstanding as of the Clawback Trigger Date, the Erroneously Awarded Compensation shall be calculated as the number of shares received in excess of the number that should have been received (or the corresponding value of such shares). In the event that any applicable Covered Incentive- Based Compensation is in a nonqualified deferred compensation plan, the Company shall calculate the amount contributed to the notional account based on the Erroneously Awarded Compensation and any earnings accrued to- date on that notional amount, and that sum shall be considered " Erroneously Awarded Compensation " with respect to that plan. For the avoidance of doubt, in the event Covered Incentive- Based Compensation is attained only partially based on the achievement of financial reporting measures, only the portion of such compensation based on or derived from the financial reporting measures shall be subject to recoupment. In the event the Erroneously Awarded Compensation is not able to be calculated directly from information in an accounting restatement (e. g., equity awards subject to total shareholder return (" TSR ") or stock price measures), in order to determine the amount of such**

**Erroneously Awarded Compensation that shall be subject to recoupment, the Committee shall use a reasonable estimate of the effect of the Covered Accounting Restatement on the TSR or stock price upon which the Covered Incentive- Based Compensation was received (in which case the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to The Nasdaq Stock Market). Method for Recoupment The Committee shall, in its discretion, determine the appropriate means for recoupment of any Erroneously Awarded Compensation, including but not limited to the cancellation of outstanding and future annual or long- term incentive compensation or requiring repayment by the applicable Executive Officer, provided that the recoupment occurs reasonably promptly. For the avoidance of doubt, the Committee may, subject to compliance with applicable law, affect recoupment under this Policy from any amount otherwise payable to the applicable Executive Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by such Executive Officer. The Committee may consider all applicable facts and circumstances in determining the appropriate means for recoupment, including pursuing an appropriate balance of cost and speed. Recoupment shall be required in all circumstances unless the Committee determines that it would be impracticable and that one of the conditions set forth in in accordance with Nasdaq Listing Rule 5608 (b) (1) (iv). Non- Exclusive; Conflicts This Policy is in addition to any and all other rights the Company may have to pursue remedies against an employee or former employee in connection with an accounting restatement or for misconduct or similar behavior in the course of employment by the Company, all of which are expressly retained by the Company. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies, including termination of employment and institution of legal proceedings, as well as rights of repayment, forfeiture, offset or recoupment that may be available to the Company pursuant to any other forfeiture policy or similar provisions in any employment agreement, equity award agreement or similar agreement, or any other legal remedies available to the Company. Nothing in this Policy restricts the Company from seeking recoupment under any other compensation recoupment Policy or any applicable provisions in plans, agreements, awards or other arrangements that contemplate the recoupment of compensation from an Executive. 3 The Company' s rights under this Policy are in addition to the reimbursement provisions of Sarbanes- Oxley Act Section 304; provided, that any amounts paid pursuant to Sarbanes-Oxley Act Section 304 will be considered in determining any amounts recovered under this Policy. The Company will not enter into any agreement that exempts any Incentive- Based Compensation from the application of this Policy or that waives the Company' s right to recoupment of any Erroneously Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date). The provisions of this Policy are intended to be applied to the fullest extent of the law. To the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision shall be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law. Indemnification Prohibition The Company is not permitted to indemnify any Executive Officer against (i) the loss of any Erroneously Awarded Compensation that is repaid, returned, recovered or recouped pursuant to the terms of this Policy, or (ii) any claims relating to the Company' s enforcement of its rights under this Policy. The Company is also prohibited from paying or reimbursing an Executive Officer for purchasing insurance to cover any such loss. To the extent of a conflict with any agreement with an Executive Officer that purports to provide indemnification rights to the Executive Officer that conflict with the foregoing, this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date). Reporting and Disclosure The Company shall file all disclosures with respect to this Policy in accordance with the requirements of the federal securities laws, including the disclosure required by applicable Securities and Exchange Commission filings. Amendment or Termination The Committee may amend or terminate this Policy from time to time in its discretion, including as required to comply with any applicable law or regulation. Any such amendment will be binding on employees who continue in the employment after the effective date of such amendment. The Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. The Committee has full and final authority to make all determinations under this Policy, in each case to the extent permitted under applicable rules and regulations and in compliance with (or pursuant to an exemption from the application of) Section 409A of the Internal Revenue Code. All determinations and decisions made by the Committee hereunder shall be final, conclusive and binding on all persons. Any action or inaction by the Committee with respect to an Executive Officer under this Policy in no way limits the Committee' s actions or decisions not to act with respect to any other Executive Officer under this Policy or under any similar policy, agreement or arrangement, nor shall any such action or inaction serve as a waiver of any rights the Company may have against any Executive Officer other than as set forth in this Policy. This Policy is intended to comply with the requirements set forth in Nasdaq Listing Rule 5608 (as such rule may be amended) and shall be construed and interpreted in accordance with such intent. Successors This Policy shall be binding and enforceable against all Executive Officers and, to the extent required by applicable law or guidance from the Securities and Exchange Commission or Nasdaq, their beneficiaries, heirs, executors, administrators, and other legal representatives. Governing Law; Venue The validity, enforceability, construction and interpretation of this Policy shall be governed by and construed exclusively in accordance with the laws of the State of Minnesota, without regard to the conflicts of laws principles of any jurisdictions. 4 Exhibit A Acknowledgement Form By ~~/~~signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Celcuity Inc. Policy for the Recoupment of Erroneously Awarded Compensation (the " Policy "). Capitalized terms used but not otherwise defined in this Acknowledgement Form (this " Acknowledgement Form ") shall have the meanings ascribed to such terms in the Policy. By signing this Acknowledgement Form, the undersigned acknowledges and agrees, in exchange**

**for receipt of adequate and reasonable consideration, that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned'** s ~~/ Vicky Hahne Vicky Hahne Chief Financial Officer~~ **employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation to the Company to the extent required by, and in a manner consistent with, the Policy and the Committee' s determinations thereunder. Signature Printed Name Date**