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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

or

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

For the transition period from _____ to _____

Commission File Number: **001-38207**

Celcuity Inc.
(Exact name of registrant as specified in its charter)

Delaware	**82-2863566**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
16305 36th Avenue North, Suite 100 Minneapolis, MN	**55446**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(763) 392-0767**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	CELC	The Nasdaq Stock Market LLC

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

None

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on $6.93, the closing price of the shares of common stock on June 30, 2020 (the last business day of the registrant's most recently completed second fiscal quarter) as reported by The Nasdaq Capital Market on such date, was approximately $40,900,174.

As of February 5, 2021, there were 10,304,089 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED IN PART BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2021 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

2020 Annual Report on Form 10-K

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Special Note Regarding Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements regarding us, our business prospects and our results of operations that are subject to certain risks and uncertainties that could cause our actual business, prospects and results of operations to differ materially from those that may be anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described in Part I, Item 1A, "Risk Factors" and elsewhere in this Annual Report. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report. We expressly disclaim any intent or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Readers are urged to carefully review and consider the various disclosures made by us in this Annual Report and in our other reports filed with the Securities and Exchange Commission (the "SEC") that advise interested parties of the risks and uncertainties that may affect our business.

All statements, other than statements of historical facts, contained in this Annual Report, including statements regarding our plans, objectives and expectations for our business, operations and financial performance and condition, are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "target," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our results, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this Annual Report. Additionally, our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Forward-looking statements may include, among other things, statements relating to:

- our plans to develop and commercialize our CELsignia platform and CELsignia tests for patients with cancer and our expectations regarding the various cancer sub-types our CELsignia tests will identify;
- any perceived advantage of our CELsignia platform and CELsignia tests as compared to traditional molecular or other diagnostic tests, including, without limitation, the ability of our platform and tests to help physicians treat their patients' cancers or to identify new patient populations not diagnosable with currently available diagnostic tests;
- our expected first-mover advantage in providing products to culture living tumor cells on a commercial scale, or the sustainability of our competitive advantages;
- the size and growth potential of the markets for our CELsignia platform, and our ability to serve those markets;
- the rate and degree of market acceptance, both in the United States and internationally, and clinical utility of our diagnostic platform and tests;
- our ability to partner with and generate revenue from pharmaceutical partners and physicians, and the market opportunity for HER2 and c-Met therapies and other CELsignia programs for our pharmaceutical partners as a result of our CELsignia platform;
- the success of competing tests that are or may become available;
- expectations with respect to our CELsignia Multi-Pathway Test, which combines our CELsignia HER2 Pathway Activity Test with additional tests to analyze c-Met and PI3K signaling function and the expected capabilities of such test;
- the ability of our CELsignia platform and tests to impact clinical trials by our pharmaceutical partners, such as streamlining approval from the U.S. Food and Drug Administration (the "FDA") of targeted therapeutics;
- the success, cost and timing of our CELsignia platform development activities and planned clinical trials, as well as our reliance on collaboration with third parties to conduct our clinical trials;
- expectations with respect to clinical trials and collaborations with third parties, including anticipated outcomes and timing of interim and final results;
- our commercialization, marketing and manufacturing capabilities and strategy;
- expectations regarding federal, state, and foreign regulatory requirements and developments, such as potential FDA regulation of our CELsignia platform and CELsignia tests, our operations and our laboratory;
- our plans with respect to pricing in the United States and internationally, and our ability to obtain reimbursement for CELsignia tests, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement from third-party payors, such as commercial insurance companies and health maintenance organizations, and from government insurance programs, such as Medicare and Medicaid;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our CELsignia platform and CELsignia tests;
- our expectations with respect to our facility needs;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- future agreements with third parties about the commercialization of our CELsignia diagnostic platform and tests;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our CELsignia platform and approach;
- our ability to attract and retain key scientific or management personnel;
- our expectations regarding the period during which we qualify as an emerging growth company defined under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act");
- the impact on our business of the requirements of being a public company;
- our anticipated use of the net proceeds from our initial public offering ("IPO"); and
- our expectations regarding the impact that the COVID-19 pandemic and related economic effects will have on our business and results of operations.

PART I

ITEM 1. Business

Overview

Unless otherwise provided in this Annual Report, references to the "Company," "we," "us," and "our" and similar references refer to Celcuity Inc., a Delaware corporation. We own various unregistered trademarks and service marks, including our corporate logo. Solely for convenience, the trademarks, trade names and service marks in this Annual Report, including those owned by third parties, may be referred to without the ®,™ or ℠ symbols, but such references should not be construed as any indicator that the owner of such trademarks, trade names and service marks will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies' trademarks, trade names and service marks to imply an endorsement or sponsorship of us by any other companies.

We are developing companion diagnostic tests designed to expand the eligible patient populations for targeted therapies by discovering new cancer sub-types molecular-based approaches cannot detect. 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. We believe our CELsignia platform provides two important improvements over traditional molecular diagnostics. First, molecular diagnostics can only provide a snapshot of the genetic mutations present in a patient's tumor because they analyze cell fragments. Using cell fragments prevents molecular diagnostics from analyzing the dynamic cellular activities, known as cell signaling, that regulate cell proliferation or survival. Cancer can develop when certain cell signaling activity becomes abnormal, or dysregulated. Since genetic mutations are often only weakly correlated to the dysregulated cell signaling activity driving a patient's cancer, a molecular diagnostic is prone to providing an incomplete diagnosis. CELsignia tests overcome this limitation by measuring dynamic cell signaling activity in a cancer patient's living tumor cells. When a CELsignia test detects abnormal signaling activity, a more accurate diagnosis of the patient's cancer driver is obtained. Second, molecular diagnostics can only estimate the probability of a patient's potential drug response based on a statistical analysis of the drug's clinical trial results. Instead of this indirect estimate of drug response, CELsignia tests confirm that a targeted therapeutic matches the patient's cancer driver, which significantly increases the likelihood of a positive clinical outcome.

Our first analytically validated and commercially ready test using our CELsignia platform is our CELsignia HER2 Pathway Activity Test for breast cancer, which diagnoses two new sub-types of HER2-negative breast cancer that traditional molecular diagnostics cannot detect. Our internal studies show that approximately 15%-20% of HER2-negative breast cancer patients have abnormal HER2 signaling activity similar to levels found in HER2-positive breast cancer cells. As a result, these HER2-negative patients have undiagnosed HER2-driven breast cancer and would be likely to respond to the same anti-HER2 targeted therapies only HER2-positive patients receive today. Our CELsignia HER2 Pathway Activity Test is targeting HER2-negative breast cancer patients receiving drug treatment.

Our second CELsignia test for breast cancer evaluates independent c-Met signaling activity and its involvement with HER family signaling in HER2-negative breast cancer tumor cells. Our internal studies have found that approximately 20%-25% of HER2-negative breast cancer patients have abnormal c-Met signaling activity that is co-activated with abnormal HER family signaling. These studies suggest that this sub-group of HER2-negative breast cancer patients may best respond to treatment with a combination of HER family and c-Met inhibitors.

Our third CELsignia test for breast cancer evaluates PI3K signaling in HER2-negative breast cancer tumor cells. Our internal studies demonstrate how measurement of PI3K-involved signaling may provide a more sensitive and specific method of identifying patients most likely to benefit from PI3K inhibitors than current genetic tests that measure PI3K mutations.

We intend to combine these three tests to create the CELsignia Multi-Pathway Activity Test, or CELsignia MP Test. With this next generation CELsignia test, we plan to provide an analysis of EGFR/HER1, HER2, HER3, c-MET, and PI3K-node involved signaling activity for each patient tumor specimen received.

We completed development of our first CELsignia test for ovarian cancer in 2020. This test identifies a new sub-group of ovarian cancer patients with tumors that have abnormal c-Met and HER2 signaling activity. These findings suggest that a significant sub-group of ovarian cancer patients may respond to treatment with a combination of ErbB and c-Met inhibitors. Nearly 15,000 women a year die from ovarian cancer, a disease that has less than a 50% five-year survival rate and a limited range of targeted therapy options. There is thus a significant unmet need for additional therapeutic options for ovarian cancer patients. As a companion diagnostic, our CELsignia test for ovarian cancer will be intended to help pharmaceutical companies obtain new drug indications and expand treatment options for this challenging tumor type. We initiated discussions with pharmaceutical companies about collaborating on clinical trials in late 2020.

We also made significant progress in 2020 developing a new CELsignia test intended to diagnose breast and ovarian cancers driven by dysregulated RAS signaling. Dysregulation of RAS signaling, which includes the RAF/MEK/ERK and PI3K/AKT/mTOR pathways, is estimated to drive 30%-40% of all cancers. Pharmaceutical companies have developed numerous drugs that target RAS-involved pathways. However, the number of interactions amongst RAS-regulated pathways has made it extremely difficult to use molecular tests to identify patients with dysregulated RAS signaling tumors. The challenge of diagnosing a cancer driven by a dysregulated RAS signaling network is magnified because two or more different pathways are typically involved. Recent research has also found that RAS mutations play a much less important role in dysregulated RAS signaling than previously thought. Our CELsignia platform is uniquely suited to untangle the complexity of dysregulated RAS signaling tumors and identify the targeted therapy combination capable of treating it.

Once development of the new RAS test is completed, we intend to add it to our current CELsignia Multi-Pathway Activity tests for breast and ovarian cancer. This next generation CELsignia test would provide an analysis of EGFR/HER1, HER2, HER3, c-MET, PI3K, and RAS-involved signaling activity for each patient tumor specimen received. Our current CELsignia tests have the potential to diagnose oncogenic signaling activity undetectable by molecular tests in up to one in three HER2-negative breast cancer patients and one in five ovarian cancer patients. If our efforts to develop a RAS dynamic signaling test are successful, the percentage of cancer patients who could benefit from a CELsignia test would further increase.

In addition to the new breast cancer sub-types our CELsignia test diagnoses, we discovered eight new potential cancer sub-types in lung, ovarian, kidney, and bladder cancers. Approved or investigational drugs are currently available to treat each of these new potential cancer sub-types. CELsignia tests for these additional cancer sub-types are in various stages of development, and we expect them to become commercially ready on a staggered basis over the next few years. The development process for these additional CELsignia tests includes completion of internal animal, verification, training set, and validation studies. As new CELsignia tests become commercially ready, we expect to initiate collaborations with pharmaceutical companies to help them obtain new drug indications for the new cancer sub-types our tests identify. In addition, we will continue our research to identify additional new cancer sub-types and to develop the corresponding CELsignia tests to diagnose them.

Our overall commercialization strategy is to develop companion diagnostics that expand the patient population eligible for targeted therapies. We expect to collaborate with pharmaceutical companies to advance the clinical development of their targeted therapies with the eventual goal of obtaining FDA approval of a new drug indication. Collaborations are expected to involve initially Phase I or Phase II interventional clinical trials to evaluate the efficacy of our collaboration partners' targeted therapies patients selected with one of our CELsignia tests. We are currently evaluating, or expect to evaluate, a variety of targeted therapies in combination with other targeted therapies, hormonal therapies, of chemotherapies, including: i) pan-HER and c-Met inhibitors; ii) pan-HER inhibitors and endocrine therapy; iii) pan-HER inhibitors and chemotherapies; and iv) PI3K inhibitors and endocrine therapy. The FDA has approved three c-Met inhibitors, six HER-family inhibitors, and four PI3K inhibitors for cancer treatment. Additional c-Met, HER-family, and PI3K inhibitors are being evaluated in on-going clinical trials.

We have four collaborations underway that rely on a CELsignia Pathway Activity Test to select breast cancer patients for treatment with targeted therapies. For the first one of these collaborations, we are fielding a prospective open-label Phase II clinical trial with Genentech, Inc. ("Genentech") and NSABP Foundation, Inc. ("NSABP") to evaluate the efficacy and safety of Genentech's HER2 targeted therapies, Herceptin and Perjeta, in early-stage HER2-negative breast cancer patients with hyperactive HER2 signaling tumors. We expect interim results from this trial in either the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later. For the second of these collaborations, we are fielding a prospective open-label Phase II clinical trial with Puma Biotechnology, Inc. ("Puma") and West Cancer Center to evaluate the efficacy and safety of Puma's drug, Nerlynx, and chemotherapy in early-stage triple-negative breast cancer patients selected with our CELsignia HER2 Pathway Activity Test. We expect to obtain interim results in either the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later.

For our third collaboration, we are fielding a prospective open-label Phase II clinical trial with Puma Biotechnology, Inc. ("Puma"), Massachusetts General Hospital, the UCLA Jonsson Comprehensive Cancer Center and the Vanderbilt-Ingram Cancer Center to evaluate the efficacy and safety of Puma's drug, Nerlynx, and Faslodex, an AstraZeneca drug, in previously treated metastatic HR-positive, HER2-negative breast cancer patients selected with our CELsignia HER2 Pathway Activity Test. For our fourth collaboration, we are fielding a prospective open-label Phase II clinical trial with Pfizer Inc. and Sarah Cannon Research Institute to evaluate the efficacy and safety of two Pfizer targeted therapies, Vizimpro, a pan-HER inhibitor, and Xalkori, a c-Met inhibitor, in previously treated metastatic HER2-negative breast cancer patients selected with our CELsignia Multi-Pathway Activity Test.

An additional collaboration to evaluate tissue samples from a Phase II study evaluating Puma's pan-HER inhibitor, Nerlynx, Genentech's HER2 antibody, Herceptin, and Bristol-Myers Squibb's EGFR inhibitor, Erbitux, in metastatic colorectal cancer patients is expected to be completed in late 2022. Unlike the four clinical trial collaborations, our CELsignia test will be used solely to evaluate tissue samples after they have been enrolled in this trial. We will not receive payment for the testing we perform. We expect our CELsignia test will provide critical insight after the trial is completed about the patient characteristics most correlative to drug response.

While molecular tests identify increasing numbers of genetic variants in tumor tissue, determining the dysfunction driving most patient's cancer using molecular tests remains elusive. Less than 20% of Americans who died of cancer in 2018 were eligible for a molecular targeted therapy because they lacked what are currently considered actionable genetic or proteomic mutations. This reflects the limitations of using static measurements of proteins or genetic mutations in cell fragments to characterize the dynamic and complex cell signaling activity that may be driving a patient's cancer.

Directly measuring dynamic cell signaling activity is an alternative diagnostic approach to identify the cancer driver in patient tumors lacking actionable genomic or proteomic mutations. This approach requires the use of living patient tumor cells as well as technology to quantify signaling activity levels. Efforts to obtain patient tumor cells have previously been limited by the lack of reliable methods to extract and culture cancer cells from patient tumors. Lack of access to living patient tumor cells, in turn, hampered development of technology to analyze dynamic signaling activity.

Our CELsignia platform addresses the need for better cancer diagnostic tests using two complementary technologies that represent a significant departure from molecular-based analyses. Unlike molecular tests that use cell fragments and can only measure the static composition of a cell, our CELsignia platform measures real-time signaling activity in a patient's live tumor cells. This enables us to (1) identify the cellular signaling dysfunction driving a patient's cancer; and (2) identify the targeted therapy that matches the dysfunction in the patient's cells. Our CELsignia tests are performed in our laboratory in Minneapolis, Minnesota that is certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and accredited by the College of American Pathologies, or CAP.

Our platform, comprised of our internally developed cell microenvironment and cell signaling quantification technologies, allows for more accurate diagnoses and the discovery of new cancer sub-types. We believe our CELsignia platform will fundamentally change the standard-of-care many cancer patients receive. Patients with the newly identified cancer sub-types we have discovered have oncogenic pathways that are signaling abnormally, and, we believe, may respond positively to a matching targeted therapy. By identifying patients with a new cancer sub-type, each CELsignia test will create, in effect, a proprietary patient population that molecular diagnostics cannot identify.

Our initial commercial strategy is to partner with pharmaceutical companies to provide companion diagnostics for the pharmaceutical partners' existing or investigational targeted therapies. We expect such partnerships to involve collaboration on clinical trials, regulatory submissions, and commercialization activities. We will initiate activities to pursue partnerships as our CELsignia tests become commercially ready and can be matched with a potential partner's targeted therapies. Our commercial-related efforts to date have focused on seeking partnerships for our CELsignia tests, the first of which became commercially ready as a laboratory developed test ("LDT") in 2016. We expect to seek pharmaceutical partnerships for a variety of different targeted therapies in other solid tumor types as we are conducting our initial clinical trials with Genentech's, Pfizer's, and Puma's targeted therapies.

We believe our CELsignia tests will expand the matching drug's market size because they can facilitate approval of new drug indications that a pharmaceutical company would not otherwise be able to obtain. We expect that successful pharmaceutical company partnerships will generate significant revenue from the sale of tests to identify patients eligible for clinical trials, from milestone payments, and, potentially, from royalties on the incremental drug revenues our tests enable. A key requirement for success of these partnerships will be clinical trial results that demonstrate the advantages of using a CELsignia test as a companion diagnostic. Once a new drug indication is received that requires use of the CELsignia test to identify eligible patients, we will offer our tests directly to treating physicians and coordinate go-to-market strategies with our partner. This coordination of commercialization strategies will allow us to significantly leverage the sales, marketing and reimbursement resources of our pharmaceutical partner, unlike traditional molecular diagnostic companies.

Our Value Proposition

We believe we offer a clear and compelling value proposition to the key healthcare stakeholders:

- **Patients & Providers-Improved patient outcomes.** Our CELsignia tests provide a more accurate diagnosis of a patient's cancer driver. This will enable physicians to match more precisely the targeted therapy they use to treat their patients, which we believe will increase the percentage of patients responding to the drug, improving overall patient outcomes significantly.

- **Pharma-Increased revenue & optimized clinical trials.** CELsignia tests can significantly increase the revenue potential for many existing targeted therapies by identifying entirely new pools of patients potentially responsive to their therapy. For some targeted therapies, we estimate a CELsignia test could double the number of patients approved to receive treatment, thus driving billions of dollars in incremental sales. Also, by providing more precise selection of patients, our CELsignia tests can increase the odds a clinical trial meets its trial endpoint, greatly enhancing the likelihood the drug will obtain FDA approval for a new indication. In addition, according to an ARK Invest publication dated August 2016, companion diagnostics that increase the response rates of a drug can reduce Phase 3 clinical trial size as much as ten-fold and costs as much as 60%.

- **Payors-Lower costs per responsive patient.** By providing more precise cancer diagnoses and driving higher drug response rates, we will significantly reduce the money spent on drugs that do not benefit patients. Many targeted therapies cost more than $50,000 per treatment and only benefit a small fraction of patients receiving them. Calculating drug costs on a cost-per-responsive patient, and not just cost-per-treated patient, highlights the true cost of targeted therapies and the expense associated with low drug response rates. For instance, a $50,000 targeted therapy with a 30% response rate costs $167,000 per responsive patient; however, that same drug would only cost $83,000 per responsive patient if the response rate was 60%.

Our Competitive Strengths

We have a number of key strengths that enhance our ability to achieve our mission and build a successful company:

- **First mover.** We are the first company that we are aware of to launch diagnostic tests that measure the signaling pathway activity in a patient's live tumor cells, which we believe gives us a significant first mover advantage.

- **High barriers to entry.** Our issued and pending patents, as well as our proprietary information and trade secrets, give us a strong intellectual property position that we believe creates a significant barrier to entry for potential competitors.

- **Broad range of applications for our platform.** We can develop tests for a wide range of signaling pathways and a wide range of cancer types. This allows us to build a deep new product pipeline that creates multiple paths to build a large and profitable business.

- **Diverse revenue streams including pharma partnerships.** We anticipate generating significant revenue from companion diagnostic pharmaceutical partners, including revenue from the sale of tests to identify patients eligible for clinical trials, milestone payments, and potentially, from royalties on the incremental drug revenues our tests enable. Our most significant revenue opportunity comes from ongoing sales of CELsignia tests to physicians during the commercialization stage of the companion diagnostic.

- **Strong senior leadership team.** Our founders and senior leaders have a proven track record of success building, operating and selling several successful companies. We have deep and highly relevant and complementary diagnostic, scientific, product development, and commercialization experience that has enabled us to establish market leadership positions for the companies we previously led.

Our Platform Advantages

Our unique and proprietary CELsignia functional cellular analysis technology represents a major shift from the diagnostic industry's reliance on molecular profiling to characterize a patient's cancer sub-type. Our goal is to leverage our technology to build a durable competitive advantage that enables us to improve outcomes for a significant percentage of cancer patients.

Our CELsignia platform advantages include:

- **Powerful cancer sub-type discovery tool.** We have already discovered 16 new potential cancer sub-types that are not currently diagnosed and treated with a matching targeted therapy. These sub-types are characterized by the dysregulated signaling pathway activity our CELsignia tests identify. By identifying new cancer sub-types, we are creating new patient populations to which pharmaceutical companies can offer new and existing drug therapies.

- **Direct patient-specific assessment of disease status.** Even though the response rates for many targeted therapeutics are low, for those patients who do respond, their outcomes can be improved significantly. The problem is matching the patient to the right drug. Our platform overcomes this problem by directly identifying whether an oncogenic signaling pathway is abnormally active in a patient's cells. This provides the most complete assessment available today of the intracellular activity driving a patient's cancer. Existing genomic tests typically can only provide a determination whether cancer is present and an assessment of molecular mutations that may or may not be associated with the patient's cancer driver.

- **Direct measurement of matching drug effectiveness.** An important advantage of the CELsignia platform is its ability to quantify the amount of signaling dysfunction that a matching targeted therapy can inhibit in an individual patient's cancer cells. This allows us to evaluate whether there are inherent drug resistance mechanisms that would prevent the therapy from functioning in the patient's tumor cells. Molecular tests cannot provide this evaluation.

- **Improved response rates.** We believe a patient population will have a higher response rate to a matching targeted therapy when it is diagnosed with a CELsignia test than with a molecular biomarker. By first identifying whether dysregulated signaling is present and then confirming that a matching targeted therapy can inhibit the dysfunction, a CELsignia test eliminates the two primary variables that confound patient response to targeted therapy signaling: the presence or absence of the disease and the drug not functioning as intended. A molecular test provides insight on neither of these variables in most cases.

- **Identified drug responsive proprietary patient cohorts.** Approximately 80% of cancer patients lack a genetic biomarker to guide treatment. For these patients, the cellular dysfunction driving the cancer goes undiagnosed, thus excluding such patients from receiving a potentially beneficial targeted therapy. We believe our CELsignia tests will enable us to identify new proprietary patient populations not currently diagnosable with molecular tests and increase the number of patients likely to respond to a matching targeted therapy. Moreover, we will be the only partner a pharmaceutical company can work with to develop a companion diagnostic for a new indication of a targeted therapy addressing these new patient populations. By contrast, most molecular diagnostic tests are undifferentiated and have little proprietary value, which gives pharmaceutical companies a wide range of companies to select from when choosing a molecular-based companion diagnostic partner.

- **Streamlined FDA approval of targeted therapeutics.** CELsignia tests will enable our pharmaceutical partners to enroll patients in their clinical trial with the same cellular dysfunction their targeted therapy is designed to inhibit. We believe this will improve patient response rates, increasing the likelihood the trial meets its endpoint target and thus the likelihood the drug receives FDA approval. Improved patient response rates would also help reduce the size, cost, and length of our partner's clinical trials.

Our Industry

According to the Centers for Disease Control and Prevention, cancer was the second-leading cause of death in the United States in 2019, responsible for nearly one of every four deaths. There are many types of cancer treatment options, including surgery, radiation therapy, chemotherapy, immunotherapy, hormone therapy, stem cell transplant, and targeted therapy. Targeted therapies are drugs or other substances that block the growth and spread of cancer by interfering with specific molecular targets involved in the progression of cancer. Targeted therapies differ from standard chemotherapy drugs in that they are often cytostatic (block tumor cell proliferation) rather than cytotoxic (kill tumor cells). According to the National Cancer Institute, there are currently more than 90 approved targeted oncology therapies, some of which cost more than $100,000 per treatment course.

Diagnostic tests to detect single biomarkers are now widely used by pathologists to determine the molecular sub-type of a cancer. When a molecular biomarker test is used to support the choice of therapy to prescribe, it is often referred to as a "companion diagnostic." Increasing numbers of targeted therapeutics are prescribed based on the results from a companion diagnostic test to detect the presence of a molecular biomarker. Only patients testing positive for the biomarker are eligible to receive the associated therapy.

Companion diagnostics are becoming increasingly important to the pharmaceutical industry. The use of companion diagnostics to better match patients to effective treatments positively impacts clinical outcomes and lowers expenditures on drugs that do not benefit patients. Stratifying the eligible patient population to include only likely responders is particularly important when the percentage of likely responders is only a fraction of the total cancer population. In these circumstances, narrowing the eligible patient population is often necessary to meet the clinical endpoint targets required to receive FDA drug approval.

Our Market Opportunities

Companion Diagnostic Development Opportunities

We believe there at least 50 different potential opportunities for our company to collaborate on companion diagnostic programs with pharmaceutical companies. Our ability to develop partnering relationships with these pharmaceutical companies will be predicated on a number of factors, including the size of the patient population our CELsignia test identifies, the remaining patent life of the matching targeted therapy, and the success or failure of clinical trials we have conducted with other pharmaceutical companies. Completing clinical trials requires, among other things, successful enrollment of patients, meeting trial endpoint goals, and completing the trial in a timely manner. The time to complete a clinical trial can vary widely depending on a number of factors, many of which will be specific to any particular clinical trial.

We believe the revenue opportunity per companion diagnostic program will be consistent with other development programs pharmaceutical companies support. In addition, the revenue for an individual companion diagnostic program would represent only a small fraction of the potential value that the new drug indication could create for our pharmaceutical company partner. For some drugs, our tests could double the number of patients eligible for a targeted therapy.

CELsignia Testing Opportunities

We expect to generate recurring companion diagnostic testing revenues once a CELsignia companion diagnostic-linked drug therapy is approved for patient use. On average, we believe that the lifetime value of providing the companion diagnostic test will significantly exceed the revenue generated from the companion diagnostic development program. We expect to offer each CELsignia test to patients at prices ranging from $4,000-$7,000, depending on the number of pathways evaluated. No tests directly comparable to the CELsignia tests are available today to offer reference points for pricing purposes. Pricing for several proprietary complex genomic tests, however, fall within this range and we believe this provides guidance on the amount insurance companies are willing to pay for highly informative tests that guide patient care.

CELsignia Technology Background

The Role of Cellular Signaling Pathways in Cancer

Cancer is a class of exceedingly complex and diverse diseases characterized by the development of abnormal cells that divide uncontrollably and can infiltrate and destroy normal body tissue and disrupt normal organ function. In normal cells, a series of biochemical activities, known as signal transduction, transmit biochemical signals through an interconnected network of signaling pathways to control cell proliferation and survival. Cancer arises when alterations occur in one or more of these signaling pathways and normal cell processes are disrupted, resulting in uncontrolled cell proliferation. These alterations are driven by a variety of cellular aberrations, including genetic mutations and dysregulated signaling pathway mechanisms. Identifying the alteration driving an individual's cancer is complicated by the immense complexity of these signal transduction processes and the practically unquantifiable number of pathway variables.

As recently as 20 years ago, most cancers were classified and subsequently treated solely on the basis of the anatomical location of the tumor in the body. Chemotherapies that kill rapidly dividing cells were widely used, but they had only limited efficacy for many patients and caused a wide range of dangerous side effects due to lack of discrimination for tumor tissue. As tools to identify molecular mutations became available, scientists began to uncover correlations between certain molecular mutations, cancer tissue type, and a patient's prognosis. This fostered the development of molecularly targeted therapeutics that were designed to disrupt the specific cellular function of the drug target, typically abnormal signaling pathway activity, associated with the molecular mutation. These targeted therapies greatly improved outcomes for some cancer patients and are a testament to the efficacy of targeted therapies when effectively prescribed. According to information published by the Journal of Clinical Oncology in July 2017, targeted therapies are oftentimes 10 to 20 times more expensive than chemotherapies.

In conjunction with the advent of targeted therapies, new molecular diagnostics were developed to help physicians refine the classification of a patient's cancer into sub-types based on the presence of specific molecular anomalies, such as genetic mutations or over-expressed proteins. Such mutations or over-expressed proteins are commonly referred to as "biomarkers" when they are used to diagnose a disease and evaluate treatment options. For instance, breast cancer diagnostic tests are performed to determine whether two protein biomarkers, human epidermal growth factor receptor 2 (HER2) or estrogen receptors (ER), are overexpressed in the cancer cells. The results of these tests are used to classify the patient's cancer molecular sub-type and to guide selection of a corresponding targeted drug therapy.

The launch and on-going development of many new targeted therapies and the increasing use of companion molecular diagnostics to guide selection of the most appropriate therapy for each patient ushered in the era of so-called "precision medicine" in oncology. Advances in genomic and proteomic techniques and drug discovery enabled researchers to identify new drug targets, new molecular diagnostics, and drugs that would specifically bind to the target.

While the increased usage of targeted therapies has improved patient outcomes, there is increasing recognition that the promise of molecularly guided diagnoses and targeted treatment has fallen far short of expectations. This is generally due to the heterogeneous nature of these diseases from patient to patient and the challenge of identifying the specific cellular dysfunction driving a cancer patient's tumor growth. No matter how sophisticated or detailed, a point-in-time molecular profile can only provide a snapshot of a tumor. As a result, the genetic mutations many current tests identify are often only weakly correlated to the abnormal signaling driving a patient's cancer. This is because protein and gene profiling provide an incomplete assessment of the biochemical activity promoting cancer tumor growth. In fact, when dysregulated, the activity of signaling pathway networks are, we believe, not possible to assess using current genetic analyses, despite the impressive investments in mapping the human genome and advancements in techniques to identify molecular mutations.

The combination of the heterogeneous nature of cancer and the weak correlation of abnormal signaling to many genetic mutations helps explain why the response rates for patients treated with many targeted therapies are often less than 50%, and in some cases as low as 20%. For a patient to respond to a targeted therapy designed to disrupt disease-related signaling activity, two factors must be present: (1) the patient's diseased cells must have the same signaling pathway dysfunction the drug is designed to inhibit, and (2) the drug affects its targeted pathway as intended. Current state-of-the-art genomic tests use cell fragments, which limits them to evaluating the presence or concentration of a genetic mutation or protein. These tests cannot evaluate either dynamic signaling activity or whether a drug can affect that activity. When a patient's genomic biomarker status does not represent underlying signaling pathway dysfunction, this can lead to selection of the wrong targeted therapy to treat the patient. Of particular interest to us are those patients with dysregulated signaling who lack a corresponding biomarker; they are not currently eligible to receive any targeted therapy that treats their dysregulated signaling.

To measure dynamic cellular activity, living patient tumor cells are required. Until our advancements, efforts to use living patient tumor cells have been limited by the lack of reliable methods to extract and culture cancer cells from patient tumors. These previously limited efforts reflect the emphasis amongst cancer researchers on creating stable cell lines for use to model cell function or to study and screen millions of test compounds in drug discovery programs. Pharmaceutical companies driving the commercial development of cell technologies work primarily with immortalized cells or cell lines genetically modified to express a target or mutation of interest. These cell lines consist of established cell cultures that proliferate indefinitely and very uniformly. They are used primarily because they provide a highly uniform response when tested with millions of small molecules in the search for potential new drugs, and because techniques to culture these cells are well known, their properties well understood, and other experimental results using them are available for comparison purposes. Conversely, live patient tumor cells are difficult to obtain, are only available in small quantities, and according to several articles published in leading cancer journals between 2017-2019 , the percentage of tumors that yield proliferative cells with conventional culturing methods has until now been well below 50%. For these reasons, researchers prefer paraffin-fixed tissue or cell lines over living tumor cells when studying disease processes or screening drug candidates. This lack of compelling rationale for pharmaceutical companies and academic institutions to work with live tumor cells for research purposes left the field of live tumor cell research in a relatively immature state.

Our CELsignia Platform

We have made significant investments in research and development to build the first commercially-ready cancer diagnostic platform that we are aware of that measures the signaling pathway activity in a patient's living tumor cells. To measure dynamic cellular activity, we internally developed two distinct but complementary technologies, which now comprise our CELsignia platform:

- our proprietary cell microenvironment; and
- our method to quantify dynamic patient cell signaling dysfunction.

We utilize our CELsignia platform to create CELsignia tests that measure specific signaling pathway activity in various tumor types.

Cell microenvironment. Previous research has shown that cancer cells extracted from a patient's tumor share the molecular features of the primary cancers from which they were derived and could provide an *ex vivo* (outside the patient) model of a patient's tumor. The technology around tumor cell extraction from individual patients and culturing techniques, however, has largely remained undeveloped. For instance, we are not aware of any competing diagnostic tests that use live patient tumor cells to measure dynamic cell signaling activity. Studies on the topic have historically highlighted the challenges of deriving a viable patient tumor cell sample from an individual patient tumor specimen.

We have developed a cell microenvironment to extract and expand viable tumor cells from fresh human tumor tissue, which meets the three critical clinical parameters a patient-derived tumor cell sample would need to satisfy in order to meet the regulatory and clinical requirements for a diagnostic test measuring signaling activity:

- **The patient cell sample tested must reflect the starting tumor's composition.** If samples do not reflect the original tumor's composition, test results derived from that sample may not be representative of the patient's tumor.

- **The sample must be available for testing in less than 21 days.** Clinicians generally require test results in cases of complex diseases such as cancer within two to three weeks so they can begin treatment of their patient as soon as the initial symptoms are evaluated or a preliminary diagnosis is made.

- **At least 90% of the tumor specimens obtained from a patient must yield testable samples.** Clinicians will only order tests that require a patient specimen when they are highly likely to receive a test result.

Dynamic patient cell signaling quantification. The second component of our CELsignia platform involves methods to quantify specific dynamic signal transduction events in patient derived tumor cells. The complexity of signal transduction processes is immense, and the permutations of the pathway variables are practically unquantifiable. Current analytical methods to assess these variables use cell fragments. Point-in-time measurements are limited to assessment of the compositional status (e.g., mutation), concentration level (e.g., protein amount), or activation status (e.g., phosphorylation) of a finite number of signaling pathway components. A key insight underlying our technology was our observation that, no matter how sophisticated or detailed, a point-in-time molecular profile would only provide a snapshot. These methods could not provide a complete, dynamic assessment of the signaling activity driving a patient's cancer. These point-in-time molecular analyses would, in many cases, only provide a weak correlation to the presence of the signaling pathway dysfunction driving a patient's cancer. Instead, we concluded that a complete diagnosis of cancer and an assessment of a patient's response to treating their disease requires measurement of the underlying activity of signaling pathways in live patient tumor cells.

To measure live real-time dynamic cell signaling activity, we utilize an impedance biosensor instrument. An impedance biosensor is an analytical platform that converts changes in cellular activity to a measurable electrical signal. When cells are stimulated and change their function, the accompanying changes alter the electrical signal that is measured. The output value is quantified over time and used to determine a Signaling Function Score. To determine the activity of a specific signaling pathway, an activating agent specific to a pathway receptor is used to turn on the pathway and a corresponding inhibitory agent specific to the pathway receptor is used to turn signaling off. When signaling pathways are stimulated in this manner, a change in the electrical signal occurs and Signaling Function Score recorded. By relying on the principle of detecting signaling pathway activity, we believe we can develop tests for a range of disease types and targeted therapies that affect various cellular pathways.

We believe our pioneering efforts have substantially advanced the technology of culturing primary tumor cells and analyzing cell signaling activity to guide therapy selection. We have three issued U.S. patents, five issued international patents, five pending U.S. patent applications, 23 pending non-U.S. patent applications, and one pending international PCT patent application, as well as significant proprietary know-how and trade secrets for the various cell sample preparation and cellular analysis methods we have developed.

New Product Development

We are leveraging our CELsignia technology to discover new cancer sub-types that a genomic test cannot detect. These new sub-types are characterized by the hyperactive signaling pathway our test identifies. These sub-types cannot be detected by genomic tests because they lack a corresponding molecular biomarker to identify it. We will translate our discoveries into companion diagnostic tests.

We have already discovered several new breast cancer sub-types: HER2-negative breast cancers that are ER-positive or ER-negative with either (i) abnormal HER2 signaling, (ii) abnormal HER-family signaling coincident with abnormal c-Met signaling, and (iii) abnormal PI3K signaling.

We are currently conducting research to identify additional cancer sub-types in five solid tumor types. Our research studies to date have identified eight potentially new lung, ovarian, kidney, and bladder cancer sub-types that involve dysregulated oncogenic signaling pathways. Multiple dysregulated pathways were active in each of these tumor types. These studies confirm that the CELsignia platform can be a cancer sub-type discovery engine and that we can create a multi-pathway test to identify the specific driver in a patient's tumor. We expect to eventually expand the tumor types we evaluate to include colon, head and neck, leukemia, esophageal, and gastric cancers.

We will seek to identify individual signaling pathways that may be driving at least 5% to 10% of the total cancers in each tissue area. Once we have characterized the prevalence of the different sub-types of signaling dysfunction in each tumor type and validated the tests for the different pathways, our plan will be to launch a corresponding CELsignia test. Eventually, each CELsignia test will analyze multiple pathways in a patient's tumor to identify the specific pathway dysfunction driving a patient's cancer. Testing multiple pathways will thus provide a system view of the patient's cancer using dynamic functional analysis. We believe this will result in more accurate diagnosis of a patient compared to molecular diagnostics that are using next generation sequencing to assess the status of multiple static biomarkers.

Clinical Trial Approach

A major component of our development and commercial activities is providing clinical data from interventional clinical trials using our CELsignia tests. The goal of our clinical trial strategy is to demonstrate that patients found by a CELsignia test to have abnormal pathway signaling will respond favorably to a matching targeted therapy. Once our first trial demonstrates that our CELsignia test identifies patients responsive to targeted therapies, we expect pharmaceutical companies to partner with us to fund trials to evaluate new potential indications for their drugs with patients identified by one of our CELsignia tests. The trials will be designed to confirm that patients with abnormal pathway signaling obtain a superior clinical response to a therapy targeting that pathway than to the standard-of-care therapy they currently receive.

For trials involving patients not currently eligible for a cancer drug that targets a certain pathway, we would first obtain a tissue specimen from each subject and perform the CELsignia test to identify subjects who have abnormal signaling. These patients would then be randomly assigned to either an arm that receives the current standard-of-care therapy or one that includes the current standard-of-care therapy plus the targeted therapy. All patients would be monitored until their disease progresses or until the end of the treatment regimen.

CELsignia Multi-Pathway Activity Test

Our CELsignia MP Test is a qualitative LDT that measures HER2, c-Met, and PI3K signaling activity in breast and ovarian tumor cells obtained from patients previously diagnosed with cancer to determine whether or not the patients have one of the following cancer sub-types:

1. Abnormal HER2 signaling driven cancer
2. Abnormal c-Met and HER2 signaling driven cancer
3. Abnormal PI3K-involved signaling driven cancer

Abnormal HER2 Signaling Driven Cancer

Approximately 15% of breast cancer patients are diagnosed with HER2+ breast cancer when their tumor cells are found to have overexpressed or amplified levels of HER2. These patients are treated with anti-HER2 targeted therapies in combination with chemotherapies. Results from a number of clinical trial results for HER2 drugs reveal that only about 40% of HER2-positive patients respond to them. In addition, findings from several clinical trials have shown that a sub-set of HER2-negative patients benefit from therapies that target HER2. These results highlight the relatively weak correlation between HER2 receptor or gene amplification status and drug response.

Despite the widely recognized role that a dysregulated HER2-related signaling network plays in promoting breast cancer, only tests measuring a single reactant, HER2 protein, are performed in the clinic to diagnose it; we believe no diagnostic tests are available today that measure HER2 signaling activity within a patient's breast tumor epithelial cells. This focus on measuring HER2 expression-levels reflects the widely-held view that measuring a patient's HER2 status is sufficient to diagnose HER2-driven breast cancers. When only HER2 expression is measured, though, patients classified as HER2-negative but whose tumor cells have abnormal HER2 signaling are diagnosed as not having HER2-driven breast cancer, when, in fact, they do.

Since current genomic methods cannot identify HER2-negative breast cancer patients who have the HER2-driven cancer, a new method was required. Such a method would need to analyze the HER2-signaling pathways (MAPK and PI3K) associated with HER2 cancers in a patient's tumor cells. Our CELsignia MP Test identifies patients whose HER2 status as determined by conventional techniques does not represent the correct diagnosis of their breast cancer at a functional level.

For the sub-group of HER2-negative breast cancer patients diagnosed with abnormal HER2-signaling, it would be intended that they receive treatment with HER2 therapies.

Abnormal c-Met Signaling coincident with Abnormal HER2 signaling

Signaling through c-Met is necessary for normal cell development. Numerous studies have established the significant role of the c-Met pathway in tumor growth and metastasis. Crosstalk between c-Met and HER family receptors is also suspected of playing a role in tumor progression and resistance to HER targeted therapies. Numerous clinical trials have evaluated dual inhibition of c-Met and HER pathways in a variety of tumor types, but they have produced mostly negative results. Since subjects enrolled in these trials were primarily ones with c-Met protein overexpression or gene amplification, other biological factors, such as c-Met and HER signaling activity, are likely more important to measure when identifying patients eligible for c-Met therapies.

Our recent studies found that a subset of HER2-negative breast cancer patients have abnormal c-Met signaling coincident with abnormal HER2 signaling. The c-Met expression level of each patient studied was normal. Strong evidence was found that c-Met and HER2 signaling is co-involved and may explain why a c-Met tyrosine kinase inhibitor is not an effective antagonist when c-Met is hyperactive for this patient sub-set. Additionally, evidence was found that simultaneous inhibition of EGFR/HER1, HER2, and HER3 signaling, in addition to inhibition of c-Met signaling, was necessary to inhibit HER2 and c-Met signaling activity most effectively.

For the sub-group of HER2-negative breast cancer patients and ovarian cancer patients diagnosed with abnormal c-Met and HER2-signaling, it would be intended that they receive treatment with a combination of pan-HER and c-Met inhibitors.

Abnormal PI3K Signaling Tumors

The PI3K signaling pathway is a key regulator of normal cellular processes involved in cell growth, proliferation, metabolism, motility, survival, and apoptosis. Aberrant activation of the PI3K pathway promotes the survival and proliferation of tumor cells in many human cancers. In breast cancer, only patients with certain PI3K mutations are eligible for treatment with a PI3K inhibitor. However, recent clinical trial results suggest that factors other than PIK3CA sequence variance status may be important to measure when identifying patients eligible for PI3K inhibitors. In one Phase III clinical trial, the net increase in the objective response rate of PI3KCA-mutated late stage breast cancer patients who received alpelisib, a PIK3CA inhibitor, and fulvestrant versus those who received fulvestrant alone was less than 20%.

Our studies found hyperactive PI3K involved signaling in a sub-set of HER2-negative breast cancer patients. Strong evidence was found that pan-PI3K inhibitors, rather than inhibitors targeting PI3K-α, may provide the most effective attenuation of dysregulated signaling involving the PI3K-node. Our studies also found that the signaling activity involving PI3K-α is likely more important to measure than the mutational status of PI3K-α when selecting patients for treatment with a PI3K-α inhibitor like alpelisib.

Interventional Clinical Trials in Process using a CELsignia Test to Select Patients for Treatment

FACT-1 Clinical Trial to Evaluate Efficacy of Genentech's HER2 Targeted Therapies

In July 2018, we activated the first site in a clinical trial with NSABP to evaluate the efficacy and safety of Genentech's drugs, Herceptin (trastuzumab) and Perjeta (pertuzumab), and chemotherapy in breast cancer patients selected with our CELsignia test. NSABP serves as the sponsor and principal investigator of the trial and is responsible for, among other things, setting up clinical sites, enrolling patients, and managing clinical data. NSABP contracted separately with Genentech to provide Herceptin and Perjeta for the study at no cost. We are performing the CELsignia HER2 Pathway Activity Test to select patients for the trial and are providing the funding for the trial's patient-related costs. Completing this trial will require, among other things, successful enrollment of patients, meeting trial endpoint goals, and completing the trial in a timely manner. As of February 2021, there were 27 activated sites participating in the FACT-1 trial. The enrollment rate of patients has fallen short of the expectations NSABP originally provided. Based on NSABP's updated estimates of patient enrollment rates to reflect the impact of COVID-19, we expect to obtain interim results in the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later.

NSABP is one of the country's premier clinical research cooperatives. Its members include many of the country's leading medical centers and their investigators are amongst the most respected in the breast cancer field. Genentech is one of the largest biopharmaceutical companies in the world and was the first company to launch a HER2 targeted therapy; their anti-HER2 targeted therapies have more than 50% market share.

We submitted an Investigational Device Exemption, or IDE, application to the FDA to obtain approval to use our CELsignia HER2 Pathway Activity Test in a clinical trial setting. The IDE submission included validation test protocols and study reports, manufacturing process summaries, and relevant publications. The FDA approved our IDE in early 2017.

The goal is to demonstrate that patients who have an abnormal HER2 signaling pathway, as identified by our CELsignia test, respond to treatment with a matching targeted therapy. A synopsis of the trial protocol is provided below.

FACT-1 Clinical Trial Synopsis

Primary Objective	To evaluate the efficacy of neoadjuvant HER2 drug treatment in early-stage HER2-negative breast cancer patients with abnormal HER2 signaling
Sites/Sponsor	Multi-center in collaboration with NSABP and Genentech
Subjects	54 HER2-negative early-stage breast cancer (26 ER+/28ER-)
Endpoint	Pathological complete response (ypT0/Tis ypN0)
Investigational Arm	AC-T + Trastuzumab + Pertuzumab

FACT-2 Clinical Trial to Evaluate Efficacy of Puma's HER2 Targeted Therapy

In July 2019, we activated a clinical trial with Puma and West Cancer Center to conduct a Phase II single-arm interventional trial to evaluate the efficacy and safety of Puma's drug, Nerlynx (neratinib), and chemotherapy in breast cancer patients selected with our CELsignia test. West Cancer Center serves as the sponsor and principal investigator of the trial and is responsible for enrolling patients and managing clinical data. Puma supplies Nerlynx, its pan-HER inhibitor currently approved by the FDA for extended adjuvant treatment of early-stage HER2-positive breast cancer. We provide the CELsignia HER2 Pathway Activity Test to select triple-negative breast cancer patients who have hyperactive HER2-driven signaling pathways for the trial and will initially fund the patient-related trial costs. Based on West Cancer Center estimates to reflect the impact of COVID-19, we expect interim results from this trial in the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later.

We submitted an IDE application to the FDA to use our CELsignia HER2 Pathway Activity Test for this clinical trial and received approval in mid-2018.

The goal of the trial is to demonstrate that triple-negative breast cancer patients who have a hyperactive HER2 signaling tumor, as identified by the CELsignia test, respond to treatment with Nerlynx, a matching HER2 therapy. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for triple-negative breast cancer patients because fewer drug treatment options are available to them relative to other breast cancer sub-types.

A synopsis of the trial protocol is provided below.

FACT-2 Clinical Trial Synopsis

Primary Objective	To evaluate the efficacy of neoadjuvant HER2 drug treatment in early-stage triple-negative breast cancer patients with abnormal HER2 signaling
Sites/Sponsor	Multi-center in collaboration with West Cancer Center and Puma
Subjects	27 early-stage triple-negative breast cancer with abnormal HER2 signaling
Endpoint	Pathological complete response (ypT0/Tis ypN0)
Investigational Arm	Neratinib then Paclitaxel + Carboplatin + Neratinib

FACT-3 Clinical Trial to Evaluate Efficacy of Pfizer's pan-HER and c-Met Targeted Therapies

In January 2021, we announced a clinical trial collaboration with Sarah Cannon Research Institute, a global leader in cancer research, and Pfizer Inc., a global biopharmaceutical company, to conduct a Phase II clinical trial. This open-label Phase II trial will evaluate the efficacy and safety of two Pfizer targeted therapies, Vizimpro (dacomitinib), a pan-HER inhibitor, and Xalkori (crizotinib), a c-Met inhibitor, in previously treated metastatic HER2-negative breast cancer patients selected with our CELsignia Multi-Pathway Activity Test. Under the agreement, Sarah Cannon will serve as the sponsor and principal investigator of the trial and will be responsible for enrolling patients and managing clinical data. Pfizer will supply Vizimpro and Xalkori, targeted therapies currently approved by the FDA to treat metastatic non-small cell lung cancer. We will provide our CELsignia Multi-Pathway Activity Test to select HER2- metastatic breast cancer patients who have hyperactive HER2 and c-Met signaling pathways for the trial and will fund the patient-related trial costs. Based on the Sarah Cannon Research Institute's estimates of patient enrollment rates, we expect to obtain interim results 12 to 15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the second quarter of 2021.

The Sarah Cannon Research Institute is one of the world's leading clinical research organizations and has participated in clinical trials for a majority of approved cancer therapies over the last decade. Pfizer is one of the largest biopharmaceutical companies in the world and offers a number of targeted therapies for cancer patients.

The goal of the trial is to demonstrate that previously treated HER2-negative metastatic breast cancer patients who have hyperactive HER2 and c-Met signaling tumors, as identified by the CELsignia test, respond to treatment with Vizimpro in combination with Xalkori. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HER2-negative breast cancer patients whose disease progressed on prior therapies. The anti-tumor effect of blockading EGFR/HER1, HER2, HER3 and c-Met pathways when the HER2 and c-Met pathways are hyperactive has been demonstrated in animal models.

A synopsis of the trial protocol is provided below.

FACT-3 Clinical Trial Synopsis

Primary Objective	To assess the efficacy of combined Vizimpro plus Xalkori in previously treated HER2-negative metastatic breast cancer subjects with hyperactive HER2 and c-Met signaling tumors
Sites/Sponsor	Multi-center in collaboration with Sarah Cannon Research Institute and Pfizer
Subjects	23 late-stage HER2-negative breast cancer with abnormal HER2/c-Met signaling
Endpoint	Objective response using RECIST 1.1 criteria
Investigational Arm	Vizimpro and Xalkori

FACT-4 Clinical Trial to Evaluate Efficacy of Puma's HER2 Targeted Therapy

In December 2020, we announced a clinical trial collaboration with Massachusetts General Hospital and Puma Biotechnology, a biopharmaceutical company, to conduct a Phase II clinical trial. This open-label Phase II trial will evaluate the efficacy and safety of Puma's drug, Nerlynx (neratinib), and Faslodex (fulvestrant), an AstraZeneca drug, in previously treated metastatic HR-positive (HR+), HER2-negative breast cancer patients selected with our CELsignia HER2 Pathway Activity Test. Under the agreement, Massachusetts General Hospital will serve as the sponsor and the principal investigator of this study, while the UCLA Jonsson Comprehensive Cancer Center and the Vanderbilt-Ingram Cancer Center will serve as co-sponsors. Each of these institutions is amongst the United States' 51 NCI-Designated Comprehensive Cancer Centers tasked with developing new approaches to diagnosing and treating cancer. Puma will supply Nerlynx, its HER2 inhibitor currently approved by the FDA for early and late-stage HER2-positive breast cancer. We will provide our CELsignia HER2 Pathway Activity Test to select HR+, HER2-negative metastatic breast cancer patients who have hyperactive HER2-driven signaling pathways for the trial and will fund the patient-related trial costs. Based on Massachusetts General Hospital's estimates of patient enrollment rates, we expect to obtain interim results 12 to 15 months after the protocol is activated and final results 12 to 15 months later. We expect enrollment to begin in the second quarter of 2021.

The goal of the trial is to demonstrate that previously treated HR+, HER2-negative metastatic breast cancer patients who have hyperactive HER2 signaling tumors, as identified by the CELsignia test, respond to treatment with Nerlynx in combination with Faslodex, a hormonal therapy that targets the estrogen receptor. We believe there is significant clinical interest in finding new diagnostic tests and targeted therapies for metastatic HR+, HER2-negative breast cancer patients whose disease progressed on prior therapies. Of particular interest are new therapeutic combinations that can overcome resistance to anti-estrogen therapies like Faslodex. The blockade of estrogen receptor and HER2 pathways when the HER2 pathway is hyperactive using a combination of Neratinib and Faslodex has been demonstrated in animal models.

A synopsis of the trial protocol is provided below.

FACT-4 Clinical Trial Synopsis

Primary Objective	To assess the efficacy of combining Nerlynx plus Faslodex in previously treated metastatic HR-positive, HER2-negative patients with hyperactive HER2 signaling tumors
Sites/Sponsor	Multi-center in collaboration with Mass General and Puma
Subjects	23 late-stage HR+/HER2-negative breast cancer with abnormal HER2 signaling
Endpoint	Objective response using RECIST 1.1 criteria
Investigational Arm	Nerlynx and Faslodex

Commercialization Strategy

Our commercial activities will target three complementary groups at various phases of the development of our CELsignia tests.

- **Pharmaceutical companies.** For each CELsignia test we develop to diagnose a new cancer sub-type, we will identify the matching targeted therapies, either currently approved or in the investigational phase, and the manufacturer of those therapies. We will initiate discussions and seek to reach development agreements with each of these pharmaceutical companies when we have verified the prevalence of the cancer sub-type and completed successful animal studies.

- **Medical and surgical oncologists.** We will initially target key opinion leaders (KOLs) in each cancer type once we have completed the analytical validation of a CELsignia test. This will allow us to build awareness and credibility for the CELsignia test as we are generating clinical validation data. When a new drug indication is received that requires use of a CELsignia companion diagnostic to identify eligible patients, we will coordinate the pharmaceutical company's go-to-market activities with our own. This coordination will allow us to significantly leverage the pharmaceutical company's sales, marketing, and reimbursement activities, unlike traditional molecular diagnostic companies.

- **Payors.** When a new drug indication is received that requires use of a CELsignia companion diagnostic to identify eligible patients, we expect to coordinate the pharmaceutical company's reimbursement activities with our own.

Our CELsignia tests are LDT's and subject to regulation under CLIA. We completed the analytical validation of our first CELsignia test and received CLIA certification in 2016. Our current focus is to field clinical trials with leading cancer centers in collaboration with pharmaceutical companies to demonstrate that cancer patients diagnosed with an abnormal signaling pathway by a CELsignia test respond efficaciously to treatment with a matching targeted therapy. Once favorable efficacy data is available, we expect to generate revenues from CELsignia tests performed in conjunction with the clinical trials a pharmaceutical company will field during the registrational phase of our partners' drug approval process. We also expect that the agreements we enter into with the pharmaceutical companies partnering with us on these registrational trials will include milestone payments at initiation and completion of trials and perhaps at various other negotiated points during the trials. We expect to generate revenue from the sale of CELsignia tests ordered by physicians upon the approval of our pharmaceutical company's matching drug, as a companion diagnostic. A key requirement for success of these partnerships will be clinical trial results that demonstrate the advantages of using a CELsignia test as a companion diagnostic.

We intend to position our unique and highly differentiated tests as practice changing advancements in patient care. To inform key stakeholders of the value of our solution in order to drive adoption and reimbursement, we expect to employ the following diverse commercialization strategies over time:

- leverage our pharmaceutical partnership and their go-to-market initiatives for the drug with which our companion diagnostic is partnered;
- collaborate with oncology thought leaders, KOLs, and leading institutions on clinical research, publications, and product development;
- build an experienced, oncology-focused sales force in the United States and international distribution channels that are supported by dedicated company personnel;
- integrate into the everyday practice of clinicians through our medical affairs and client services efforts;
- publish important medical and scientific data in peer-reviewed journals and present at major industry conferences, conduct clinical trials; and
- work with patient advocacy groups, leading cancer philanthropic organizations, and medical societies to drive awareness of CELsignia tests and the importance of incorporating functional cellular analysis into cancer treatment.

Through these efforts, we will seek to promote our CELsignia test's unique capabilities throughout the oncology community-from patients, to the physicians treating them, to the third-party payors for these treatments and to biopharmaceutical companies developing new treatments-all with the goal of facilitating better-informed treatment decisions for the greatest number of patients.

A CELsignia test would be launched upon the approval of a pharmaceutical company's matching drug as a companion diagnostic. We would expect physicians, typically a medical or surgical oncologist, to order our tests in conjunction with the roll-out of the pharmaceutical company's matching drug. The physician will prescribe a CELsignia test and coordinate provision of a patient specimen from a biopsy or surgical procedure. The fresh tissue would then be shipped overnight directly to our laboratory where we would use our proprietary methods to extract diseased cell samples from the patient's tissue and perform the CELsignia tests ordered. Test results would typically be available in 10 to 14 days after receipt of the patient specimen. For each patient sample analyzed, a Signaling Function Score would be calculated quantitatively and converted into a final qualitative result: abnormal or normal. For patients found to have an abnormal signaling pathway, clinicians would use the results of the CELsignia test as a guide to select a targeted drug that inhibits the abnormal signaling activity identified.

United States

For our first tests, we will target the estimated 4,300 medical oncologists working in hospitals and cancer centers in the United States. We expect to hire domestic sales professionals with typically over 10 years of experience in clinical oncology sales working at leading biopharmaceutical or specialty reference laboratory companies.

In general, we intend to focus our initial sales efforts on building relationships with KOLs and researchers at leading academic research institutions to demonstrate the scientific credibility of our CELsignia tests. We also plan to build relationships in community oncology practice settings through leading physician networks and community hospitals and community-based cancer centers. We will also attend national and regional clinical meetings focused on cancer treatment for our anti-cancer tests.

We believe the unique and important nature of the results our CELsignia tests provide, and their positioning as a companion diagnostic, will drive many medical oncologists to independently seek out our tests once they become aware of them. We believe this may allow us to achieve our market penetration goals with a sales force and marketing expenses significantly less costly than has been experienced by molecular diagnostic companies.

International

We believe we can serve the international market from our laboratory in Minnesota. We expect to establish an international presence using local distributors that sell to physicians and coordinate shipment of specimens to the United States. To serve international markets, we would expect to add dedicated regional managers located outside the United States to oversee our relationships at the local level.

Pricing and Reimbursement

The principal groups that we expect to pay us in the future for our CELsignia tests include:

- commercial third-party payors;
- government payors, including Medicare and state Medicaid plans;
- biopharmaceutical customers;
- hospitals, cancer centers, and other institutions; and
- patients.

Adequate reimbursement will be an important factor in achieving broad clinical adoption of our CELsignia tests. At the same time, we believe broad clinical adoption will help drive favorable reimbursement decisions. To achieve broad reimbursement coverage with commercial third-party payors and government payors, including Medicare and Medicaid, we plan to demonstrate the economic and clinical value of our CELsignia tests to payors by employing a multi-pronged strategy:

- **Set a high bar for analytical validation.** We expect to present data on the characterization of new cancer sub-types by CELsignia tests at conferences and will seek to publish the results in peer-reviewed journals.

- **Meet the evidence standards necessary to be consistent with leading clinical guidelines.** We believe inclusion in leading clinical practice guidelines plays a critical role in payers' coverage decisions. We plan to conduct clinical validation and clinical utility studies that are consistent with the requirements of the widely recognized National Comprehensive Cancer Network clinical practice guidelines.

- **Execute an internal managed care policy and claims adjudication function as part of our core business operations.** We plan to make obtaining adequate and widespread reimbursement a critical component of our business operations. We expect to hire a team of in-house claims processing and reimbursement specialists who will work with patients and payers to navigate the claims process and obtain maximum reimbursement.

- **Cultivate a network of KOLs.** KOLs are able to influence clinical practice by publishing research and determining whether new tests should be integrated into practice guidelines. We expect to collaborate with KOLs early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our tests to physicians and payers.

- **Compile a growing library of peer-reviewed studies that demonstrate the test is effective.** We will seek to publish peer-reviewed articles and review papers to help support our efforts to obtain widespread adoption and reimbursement of our CELsignia tests. In each disease area we pursue, we intend to conduct studies in order to develop similar supporting literature.

- **Reduce expenditures.** We intend to build economic models to measure the financial benefits of using our CELsignia test in guiding patient treatment and minimizing the use of drugs that will not likely have a positive impact. We plan to use the data we gather through the use of these models as we meet with commercial third-party payors and government payors.

- **Exploit efforts by commercial third-party and government payors to contain healthcare costs.** A major cost reduction opportunity is to reduce expenditures for drug courses that provide no patient benefit. Our technology will enable physicians to prescribe therapies that have significantly higher response rates than has been the case with targeted therapies to date. Since this will lower the drug cost per responsive patient, we believe widespread use of our CELsignia tests is consistent with payors goals of delivering health care more cost effectively.

Our Competition

At present, we are not aware of any other companies that offer diagnostic tests that use a patient's live tumor cells to identify the signaling pathway driving a patient's cancer. There are several companies focused on developing genomic or proteomic analyses of a patient's diseased cells. Initial efforts identified protein targets or genetic mutations, oftentimes referred to as "biomarkers," that are associated with a disease process to enable development of drugs more closely tailored to specific patient populations.

As tools for human genome analysis have become less expensive, a number of companies have also recently launched more complex genomic test panels and gene expression signatures tests. These tests rely on a static measurement of molecular properties and mathematical analysis to identify statistically significant correlations between the selected molecular properties and a clinical condition or outcome of populations of patients with the "same" disease.

These genetic tests often have limited predictive success because they only identify some, but not all, of, the molecular and cellular conditions required for a drug therapy to function in a patient. They may identify the presence of the genes associated with a disease, but they cannot determine how the gene products function in the context of a particular individual.

Providers of genomic or proteomic tests include diagnostic kit manufacturers, hospitals, and independent laboratories. We do not plan to develop tests where a molecular biomarker can identify drug responsive patients, so our current tests will not compete directly against the tests provided by these other companies. The table below provides a summary of the points of differentiation between our signaling function analysis approach and the molecular approaches used by our potential competitors.

Current Molecular Methods vs. Our Pathway Activity Analysis Platform

	Type of Cell Sample Used:	
	Tumor cell fragments (fixed, lysed, DNA)	**Live tumor cells**
Type of Analysis Performed	Single point-in-time mutation(s) status or protein amount, or activation status	Quantify signaling pathway activity over 24-hour period
Relationship to disease driver	Correlative	Direct Cause
Disease driver evaluated	No. Only a single or small set of components of the cell are evaluated	Yes. The activity of the entire signaling pathway is assessed
Drug function evaluated	No. Cannot assess drug function with cell fragments	Yes. Drug's effect on signaling pathway activity in patient's cells quantified
Companies	Foundation Medicine, Caris Life Sciences, NeoGenomics, LabCorp, Quest, Nanostring, Paradigm, Biocept, Exosome Diagnostics, Guardant Health, Roche Diagnostics, Qiagen, Myriad, Genomic Health	Celcuity

We are not aware of any available tests directly comparable to the CELsignia tests. We expect to offer each CELsignia test to patients at list prices ranging from $4,000 to $7,000, depending on the number of pathways evaluated. List prices for several proprietary complex genomic tests fall within this range, and we believe this provides guidance as to the pricing of highly informative tests that guide cancer patient care.

Intellectual Property

We believe one of our core competitive advantages is the strength of our intellectual property portfolio. We developed our CELsignia technology internally. We are seeking both U.S. and non-U.S. patents to protect our inventions. We have three issued U.S. patents, five issued international patents, five pending U.S. patent applications, 23 pending non-U.S. patent applications, and one pending PCT patent application, as well as numerous corresponding non-U.S. patent applications covering our diagnostic approach using cell signaling analysis in living patient cells to guide treatment of patients with targeted therapies. The earliest expiration date of patents is 2033. In addition, we have developed significant proprietary know-how and trade secrets for the various cell sample preparation and cellular analysis methods we have developed.

We understand we must develop and maintain protection on the proprietary aspects of our technologies in order to remain competitive. We rely on a combination of patents, copyrights, trademarks, trade secret and other intellectual property laws and confidentiality, material transfer agreements, invention assignment agreements and other contracts to protect our intellectual property rights.

We plan to develop names for new products and apply for trademarks and as appropriate secure trademark protection for them, including domain name registration, in relevant jurisdictions. We also have developed a number of proprietary methods, materials, processes, and techniques related to the preparation of patient samples and performance of the CELsignia test that we believe are most effectively protected as trade secrets rather than as patented subject matter.

Principal Suppliers

We purchase commercially available reagents and instruments from a variety of suppliers. Our principal reagent suppliers include Bio-Techne Corporation, Selleck Chemicals, Sigma-Aldrich, and VWR International. Our principal instrument suppliers include Agilent Technologies, Integra Biosciences, Invitrogen, and Thermo Fisher Scientific. These items are purchased on a purchase order basis pursuant to the applicable supplier's standard terms and conditions. The items purchased from these suppliers are standard products sold widely to the biotechnology industry. All items purchased are typically available within several days after an order is placed.

Government Regulation

CLIA and CMS

The Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, regulates all clinical laboratory testing (except research) performed on humans in the United States through CLIA. All clinical laboratories that perform clinical lab services on human specimens for the purpose of providing information on the diagnosis, prevention or treatment of disease must receive CLIA certification. This covers approximately 175,000 laboratories as of 2017. Laboratories must obtain CLIA certification and demonstrate compliance with CLIA requirements as confirmed by an inspection by CMS. We received our CLIA certification in 2016. We also had our laboratory certified by the College of American Pathologies, or CAP, in 2016, an organization recognized by CMS as a third-party reviewer of clinical laboratories. Several states, including, among others, New York and California, require licensure of out-of-state labs that receive specimens from the state and compliance with the state's individual laboratory regulations.

If our laboratory is out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain CLIA compliance and certification to be eligible to bill for services provided to Medicare and Medicaid beneficiaries. If we were to be found out of compliance with CLIA program requirements and subjected to sanction, our business could be harmed. Failure to comply with state licensure laws, if applicable, could subject us to additional sanctions imposed by state licensing authorities.

FDA

FDA approval or clearance is not currently required for CELsignia tests offered as a stand-alone LDT 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. Historically, the FDA has exercised enforcement discretion with respect to tests performed solely in a central laboratory, like the CELsignia tests or LDTs. 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).

Although the FDA proposed regulations that would apply to LDTs, the FDA recently decided that, at present, those regulations are not moving forward towards approval and implementation. In mid-2014, the FDA published a draft Guidance Document describing a proposed approach for a regulatory framework for LDTs that would have resulted in most of the high-value LDT tests marketed today eventually being required to obtain 510(k) clearances or PMAs. If implemented, this regulatory framework would require most hospital clinical labs to abandon a number of tests they perform or to pursue regulatory clearances or approvals to perform them. These proposals met significant resistance from Congress, the hospital industry, and independent clinical laboratories. The FDA indicated in late 2016 that it does not intend to finalize the draft Guidance Document at this time. However, the FDA continues to discuss potential regulatory approaches to LDTs.

HIPAA and HITECH

Under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH Act"), the U.S. Department of Health and Human Services, or HHS, issued regulations that establish uniform standards governing the conduct of certain electronic healthcare transactions and protecting the privacy and security of protected health information used or disclosed by healthcare providers and other covered entities. HIPAA includes the following primary sets of regulations: privacy regulations, security regulations, and standards for electronic transactions, which establish standards for certain healthcare transactions. The privacy and security regulations were extensively amended in 2013 to incorporate new requirements from the HITECH Act.

The privacy regulations cover the use and disclosure of protected health information by healthcare providers and other covered entities. They also set forth certain rights that an individual has with respect to his or her protected health information, including, but not limited to, the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. The HITECH Act, among other things, made many of HIPAA's privacy and security standards applicable to business associates of covered entities, and established certain protected health information security breach notification requirements. A covered entity must notify affected individual(s) and HHS when there is a breach of unsecured protected health information. HIPAA also governs patient access to laboratory test reports. Effective October 6, 2014, individuals (or their personal representatives, as applicable), have the right to access test reports directly from clinical laboratories and to direct that copies of those test reports be transmitted to persons or entities designated by the individual.

These laws impose significant fines and other penalties for improper use or disclosure of protected health information. Additionally, to the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied.

In addition to the federal privacy regulations, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to our operations. The HIPAA privacy and security regulations establish a uniform federal "floor" that covered entities and business associates must meet and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information. The compliance requirements of these various state laws, including additional breach reporting requirements, and the penalties for violation vary widely and new privacy and security laws in this area are evolving. We believe that we have taken the steps required for us to comply with health information privacy and security statutes and regulations in all jurisdictions, both state and federal. However, we may not be able to maintain compliance in all jurisdictions where we do business. Failure to maintain compliance, or changes in state or federal laws regarding privacy or security, could result in civil and/or criminal penalties and could have a material adverse effect on our business.

Federal, State and Foreign Fraud and Abuse Laws

In the United States, there are various fraud and abuse laws with which we must comply and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of HHS (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws in connection with our international business activities.

In the United States, the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for patient referrals for, or purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of, any healthcare item or service reimbursable under a governmental payor program. Courts have stated that a financial arrangement may violate the Anti-Kickback Statute if any one purpose of the arrangement is to encourage patient referrals or other federal healthcare program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions, which, if met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions protects against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, federal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus generally non-reimbursable, uses. The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program. If our operations are found to be in violation of any of the federal or state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

In Europe, various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010 faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

Federal and State Physician Self-Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the "Stark Law," there are prohibitions, with certain exceptions, on referrals for certain designated health services, including laboratory services, that are covered by the Medicare and Medicaid programs by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

Other Regulatory Requirements

Our operations use small amounts of hazardous materials in research and development and generate regulated medical waste in the normal course of performing our CELsignia tests. This subjects us to a variety of federal, state and local environmental and safety laws and regulations. Some of the regulations under the current regulatory structure provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products that are or will be regulated by the FDA or CMS. In addition to new legislation, FDA and CMS regulations and policies are often revised or interpreted by the agencies in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or FDA or CMS regulations, guidance, policies or interpretations will be changed, or what the impact of such changes, if any, may be. The 2020 presidential election and the resulting change in administration make it even more difficult to predict if and how federal regulations may change and/or federal agencies might alter their positions.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products we sell. Sales of any of our products will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers, managed care organizations or pharmaceutical companies. The process for determining whether a third-party payor will provide coverage for a test sometimes is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product. Third-party payors may limit coverage to specific testing products on an approved list, which might not include all of the tests available for a particular indication.

In order to obtain coverage and reimbursement for any product, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the test. Whether or not we conduct such studies, our products may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a test does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of tests and drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of testing products, drug products and medical services and questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available tests, they may not cover our products or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls and restrictions on reimbursement. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our testing products or drugs that require use of our testing products and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular test to currently available tests. The downward pressure on healthcare costs in general, particularly prescription drugs and testing products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for testing products may not allow favorable reimbursement and pricing arrangements for any of our products.

Coverage policies, third-party reimbursement rates and test pricing regulation may change at any time. In particular, in the United States, the Affordable Care Act contains provisions that have the potential to substantially change healthcare delivery and financing, including impacting the profitability of testing and drugs. For example, the Affordable Care Act revised the methodology by which rebates owed by manufacturers for covered outpatient drugs are calculated under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of covered drugs dispensed to individuals enrolled in Medicaid managed care organizations and subjected manufacturers to new annual fees for certain branded prescription drugs. As the price of our test may be included in the reimbursement rates for certain drugs, this could significantly impact our pricing. Even if favorable coverage and reimbursement status is attained for one or more products, less favorable coverage policies and reimbursement rates may be implemented in the future.

Corporate History

We were organized as a Minnesota limited liability company in 2011 and commenced operations in 2012. On September 15, 2017, we converted from a Minnesota limited liability company into a Delaware corporation and changed our name from Celcuity LLC to Celcuity Inc.

Employees and Labor Relations

As of December 31, 2020, we had 30 full-time employees, most of which were engaged in research and development activities. None of our employees are currently represented by a labor union or covered by a collective bargaining agreement and we believe that our relations with our employees are good. During 2020, our voluntary turnover rate was less than 4%. Our human capital resources objectives include identifying, recruiting, retaining, and incentivizing our existing and new employees. We maintain an equity incentive plan, the principal purposes of which are to attract, retain and reward personnel through the granting of stock-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

ITEM 1A. Risk Factors

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 an early-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, including our IPO. To generate revenue and become and remain profitable, we must continue to develop and commercialize the CELsignia platform. To do so, we need to successfully complete our four existing clinical trial collaborations, one with Genentech and NSABP, one with Puma and the West Cancer Center, and one with Puma and the Massachusetts General Hospital for our CELsignia HER2 Pathway Activity Test, and a fourth one with the Sarah Cannon Research Institute and Pfizer for our CELsignia Multi-Pathway Activity Test, continue to develop other CELsignia tests for other cancer sub-types and cultivate partnerships with pharmaceutical companies. We must also build operational and financial infrastructure to support commercial operations, train and manage employees, and market and sell 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 initial success is heavily dependent on the success of our first CELsignia tests.

Our business strategy is focused on attracting 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. We do not expect to receive the first interim results for our prospective clinical trials for the CELsignia HER2 Pathway Activity Test until the fourth quarter of 2021 or first quarter of 2022 and with final results expected approximately nine months later. 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, Massachusetts General Hospital, or Sarah Cannon Research Institute 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 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 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.

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.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize our CELsignia platform.

We may require additional capital to finance capital expenditures and operating expenses over the next several years as we launch our CELsignia platform and expand our infrastructure, commercial operations and research and development activities. 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, dilution to our 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.

The COVID-19 pandemic may materially and adversely impact our business, including ongoing clinical trials.

The outbreak of COVID-19 and government measures taken in response have had a significant impact on the global economy, with healthcare systems particularly affected. In response to the COVID-19 outbreak, public health measures have been implemented across much of the United States, Europe and Asia, including in the locations of our offices, clinical trial sites, and partners. Due to these public health measures, we are allowing employees who do not need to be physically present in the lab to perform their work at home. Our increased reliance on employees working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

As a result of the COVID-19 outbreak and related public health measures, we have and may in the future experience 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 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 addressing COVID-19 mitigation and loss of productivity from remote work.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the magnitude of the pandemic, the duration of social distancing in the United States and other countries, business closures or business disruptions, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

Beyond the direct effect of the pandemic, mitigation efforts have had broad economic effects. The extent of the scope and duration of these economic effects cannot currently be predicted, although they are likely to be significant for the near future. The economic impact of COVID-19 will affect us in a variety of ways, including without limitation making our stock price more volatile, making it more difficult to raise additional capital through offerings of equity or debt securities, and reducing the availability of bank loans. As a result, we may face difficulties raising capital and capital raising efforts may be on terms that are less favorable than would have been previously available.

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 Our Reliance on Third Parties

We will rely on collaboration with third parties to conduct our clinical trials, including the current trials involving the CELsignia tests, and those third parties may not perform satisfactorily.

We will rely on third parties to conduct clinical trials for our CELsignia tests. For our FACT-1 clinical trial, we are collaborating with Genentech and NSABP to conduct a 54-patient single-arm interventional trial that is expected to obtain interim results in the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later. We will rely on NSABP to conduct our clinical trial of patients selected using a CELsignia HER2 Pathway Activity Test, including setting up clinical sites, enrolling patients, and managing clinical data and Genentech will supply the drugs. For our FACT-2 clinical trial, we are collaborating with Puma and the West Cancer Center to conduct a 27-patient single-arm interventional trial that is expected to obtain interim results in the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later. We will rely on West Cancer Center to conduct our clinical trial of patients selected using a CELsignia HER2 Pathway Activity Test, including setting up clinical sites, enrolling patients, and managing clinical data and Puma will supply the drugs. For our FACT-3 clinical trial, we are collaborating with Pfizer and the Sarah Cannon Research Institute to conduct a 23-patient single-arm interventional trial that is expected to obtain interim results 12 to 15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the second quarter of 2021. We will rely on the Sarah Cannon Research Institute to conduct our clinical trial of patients selected using a CELsignia Multi-Pathway Activity Test, including setting up clinical sites, enrolling patients, and managing clinical data and Pfizer will supply the drugs. For our FACT-4 clinical trial, we are collaborating with Puma and Massachusetts General Hospital to conduct a 23-patient single-arm interventional trial that is expected to obtain interim results 12 to 15 months after the protocol is activated and final results 12-15 months later. We expect enrollment to begin in the second quarter of 2021. We will rely on Massachusetts General Hospital to conduct our clinical trial of patients selected using a CELsignia HER2 Pathway Activity Test, including setting up clinical sites, enrolling patients, and managing clinical data and Puma will supply the drugs.

We expect to field additional clinical trials to evaluate new potential indications for drugs with patients identified by one of our new CELsignia tests. NSABP, the West Cancer Center, the Sarah Cannon Research Institute, Massachusetts General Hospital, or other contract research organizations or cancer centers that we collaborate with and/or pharmaceutical companies we partner with might not successfully carry out their contractual duties, meet expected deadlines, or conduct our planned clinical trials in accordance with regulatory requirements or our stated protocols. Any of them may also terminate their relationship with us for a variety of reasons. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, we may not be able to complete our clinical trials and may not be able to, or may be delayed in our efforts to, successfully commercialize our potential CELsignia tests.

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 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.

Risks Related to Government Regulation

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 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.

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 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.

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 Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our 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 impaired.

Our ability to compete successfully will depend in part on our ability to obtain and enforce patent protection for our products, preserve our trade secrets and operate without infringing the proprietary rights of third parties. We have applied for patents that protect our technology. Our patent portfolio includes three issued U.S. patents, five issued international patents, five pending U.S. patent applications, 23 pending non-U.S. patent applications, one pending international PCT patent application, and numerous corresponding non-U.S. patent applications. Each patent and patent application covers methods of use. However, we cannot assure you that our intellectual property position will not be challenged or that all patents for 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 highly uncertain. Uncertainties and risks that we face include the 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;
- other parties may claim that our products and designs infringe the proprietary rights of others, and even if we are successful in defending our patents and proprietary rights, such litigation may be costly; and
- other parties 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, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner, or in all jurisdictions. We may choose not to seek patent protection for 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 may 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 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.

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.

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.

Our commercial success 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 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 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 if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for 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 or trade secrets of third parties could have a similar negative impact on our business.

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.

If we are not able to prevent disclosure of our trade secrets and other proprietary information, the value of our 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.

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 clinical trials of our 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 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.

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 are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and may remain an emerging growth company for up to five years. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting of Section 404(b) of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this report. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. 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. If we cease to be an emerging growth company, we will 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, 2020, 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 2. Properties

We currently lease and occupy approximately 16,000 square feet in Minneapolis, Minnesota, which includes our clinical laboratory and offices. The amended lease expires in April 2022 and is renewable with the right to extend the term for one additional year and 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 February 1, 2021, there were approximately 49 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

None.

Issuer Purchases of Equity Securities

None.

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.

Use of Proceeds from Registered Securities

On September 22, 2017, we issued and sold 2,760,000 shares of our common stock in the IPO at a public offering price of $9.50 per share, for aggregate gross proceeds of $26.2 million. All of the shares issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-220128), which was declared effective by the SEC on September 19, 2017. Craig-Hallum Capital Group LLC acted as the sole manager for the offering. The offering terminated on September 22, 2017.

The net offering proceeds to us, after deducting underwriting discounts of approximately $1.8 million and offering expenses paid by us totaling approximately $1.1 million, were approximately $23.3 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates.

At December 31, 2020, the net proceeds from our IPO were held in a diversified portfolio of bank deposits and government money market funds. All investments are highly liquid, with liquidity and capital preservation being the primary investment objectives. There has been no material change in our planned uses of the net proceeds from those described in the Prospectus dated September 19, 2017. From the Effective Date through December 31, 2020, we have used approximately $12.3 million in furtherance of our planned use of proceeds, which includes funding additional research and development for discovery of new cancer sub-types and development and validation of new CELsignia tests; clinical trials to support clinical claims; development of operational processes and capital expenditures; and working capital and other general corporate purposes.

ITEM 6. Selected Financial Data

The following tables present, as of the dates and for the years indicated, our selected historical financial data, as indicated therein. The statement of operations data for the years ended December 31, 2020 and 2019 and the balance sheet data as of December 31, 2020 and 2019 are derived from our audited financial statements that are included elsewhere in this Annual Report. Our historical results are not indicative of the results to be expected in the future.

You should read this information together with our financial statements and the related notes, as well as Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report.

Celcuity Inc.
Statements of Operations

	Years Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 7,683,522	$ 6,269,308
General and administrative	1,872,642	1,535,993
Total operating expenses	9,556,164	7,805,301
Loss from operations	(9,556,164)	(7,805,301)
Other income (expense)		
Interest expense	(120)	(159)
Interest income	82,109	446,096
Other income, net	81,989	445,937
Net loss before income taxes	(9,474,175)	(7,359,364)
Income tax benefits	-	-
Net loss	$ (9,474,175)	$ (7,359,364)
Net loss per share, basic and diluted	$ (0.92)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	10,266,884	10,226,041

	As of December 31,	
	2020	**2019**
Balance Sheet Data:		
Total assets	$ 12,956,747	$ 20,280,800
Total liabilities	1,254,477	983,229
Total stockholders' equity	11,702,270	19,297,571

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.

OVERVIEW

We are developing companion diagnostic tests designed to expand the eligible patient populations for targeted therapies by discovering new cancer sub-types molecular-based approaches cannot detect. 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. We believe our CELsignia platform provides two important improvements over traditional molecular diagnostics. First, molecular diagnostics can only provide a snapshot of the genetic mutations present in a patient's tumor because they analyze cell fragments. Using cell fragments prevents molecular diagnostics from analyzing the dynamic cellular activities, known as cell signaling, that regulate cell proliferation or survival. Cancer can develop when certain cell signaling activity becomes abnormal, or dysregulated. Since genetic mutations are often only weakly correlated to the dysregulated signaling activity driving a patient's cancer, a molecular diagnostic is prone to providing an incomplete diagnosis. CELsignia tests overcome this limitation by measuring dynamic cell signaling activity in a patient's living tumor cells. When a CELsignia test detects abnormal signaling activity, a more accurate diagnosis of the patient's cancer driver is obtained. Second, molecular diagnostics can only estimate the probability of a patient's potential drug response based on a statistical analysis of the drug's clinical trial results. Instead of this indirect estimate of drug response, CELsignia tests directly measure the effectiveness of a targeted therapy in a patient's living tumor cells. This enables physicians to confirm that the therapeutic matching the patient's cancer driver is functional in the patient's tumor cells before prescribing it, which significantly increases the likelihood of a positive clinical outcome.

Our first analytically validated and commercially ready test using our CELsignia platform, the CELsignia HER2 Pathway Activity Test for breast cancer, diagnoses two new sub-types of HER2-negative breast cancer that traditional molecular diagnostics cannot detect. Our internal studies show that approximately 15-20% of HER2-negative breast cancer patients have abnormal HER2 signaling activity similar to levels found in HER2-positive breast cancer cells. As a result, these HER2-negative patients have undiagnosed HER2-driven breast cancer and would be likely to respond to the same anti-HER2 targeted therapies only HER2-positive patients receive today. We have three interventional clinical trials underway to evaluate the efficacy of HER2 targeted therapies in breast cancer patients selected with our CELsignia HER2 Pathway Activity Test.

Our second CELsignia test for breast cancer evaluates independent c-Met signaling activity and its involvement with HER family signaling in HER2-negative breast cancer tumor cells. Our internal studies show that approximately 20%-25% of HER2-negative breast cancer patients have abnormal c-Met signaling activity that is co-activated with abnormal HER family signaling. These studies suggest that this sub-group of HER2-negative breast cancer patients may best respond to treatment with a combination of HER family and c-Met inhibitors.

Our third CELsignia test for breast cancer evaluates PI3K signaling in HER2-negative breast cancer tumor cells. Our internal studies demonstrate how measurement of PI3K-involved signaling may provide a more sensitive and specific method of identifying patients most likely to benefit from PI3K inhibitors than current genetic tests that measure PI3K mutations.

We intend to combine these three tests to create the CELsignia Multi-Pathway Activity Test, or CELsignia MP Test. With this next generation CELsignia test, we plan to provide an analysis of EGFR/HER1, HER2, HER3, c-MET, and PI3K-node involved signaling activity for each patient tumor specimen received.

We completed development of our first CELsignia test for ovarian cancer in 2020. This test identifies a new sub-group of ovarian cancer patients with tumors that have abnormal c-Met and HER2 signaling activity. These findings suggest that a significant sub-group of ovarian cancer patients may respond to treatment with a combination of ErbB and c-Met inhibitors. Nearly 15,000 women a year die from ovarian cancer, a disease that has less than a 50% five-year survival rate and a limited range of targeted therapy options. There is thus a significant unmet need for additional therapeutic options for ovarian cancer patients. As a companion diagnostic, our CELsignia test for ovarian cancer will be intended to help pharmaceutical companies obtain new drug indications and expand treatment options for this challenging tumor type. We initiated discussions with pharmaceutical companies about collaborating on clinical trials in late 2020.

We also made significant progress in 2020 developing a new CELsignia test intended to diagnose cancers driven by dysregulated RAS signaling. Dysregulation of RAS signaling, which includes the RAF/MEK/ERK and PI3K/AKT/mTOR pathways, is estimated to drive 30%-40% of all cancers. Pharmaceutical companies have developed numerous drugs that target RAS-involved pathways. However, the number of interactions amongst RAS-regulated pathways has made it extremely difficult to use molecular tests to identify patients with dysregulated RAS signaling tumors. The challenge of diagnosing a cancer driven by a dysregulated RAS signaling network is magnified because two or more different pathways are typically involved. Recent research has also found that RAS mutations play a much less important role in dysregulated RAS signaling than previously thought. Our CELsignia platform is uniquely suited to untangle the complexity of dysregulated RAS signaling tumors and identify the targeted therapy combination capable of treating it.

Once development of the new RAS test is completed, we intend to add it to our current CELsignia Multi-Pathway Activity test for breast and ovarian cancer. This next generation CELsignia test would provide an analysis of EGFR/HER1, HER2, HER3, c-MET, PI3K, and RAS-involved signaling activity for each patient tumor specimen received. Our current CELsignia test has the potential to diagnose oncogenic signaling activity undetectable by molecular tests in up to one in three HER2-negative breast cancer patients. If our efforts to develop a RAS dynamic signaling test are successful, the percentage of cancer patients who could benefit from a CELsignia test would further increase.

In addition to our CELsignia tests for HER2-negative breast cancer and ovarian cancer, we expect to develop CELsignia tests to diagnose eight new potential cancer sub-types we have discovered in lung, ovarian, kidney, and bladder cancers. Approved or investigational drugs are currently available to treat these new potential cancer sub-types. We expect to launch these additional tests on a staggered basis over the next few years while continuing our research to identify additional new cancer sub-types. Our overall commercialization strategy is to develop diagnostics that expand the patient population eligible for targeted therapies. We have four collaborations underway that rely on the CELsignia test for breast cancer to select breast cancer patients for treatment with HER2 or a combination of pan-HER and c-Met targeted therapies. For the first one of these collaborations, we are fielding a prospective clinical trial with Genentech and NSABP (FACT-1) to evaluate the efficacy of Genentech's HER2 targeted therapies in patients with abnormal HER2 signaling. For the second of these collaborations, we are fielding a prospective clinical trial with Puma and West Cancer Center (FACT-2) to evaluate the efficacy and safety of Puma's drug, Nerlynx, and chemotherapy, in breast cancer patients selected with our CELsignia test. For our third collaboration, we are fielding a prospective open-label Phase II clinical trial with Puma Massachusetts General Hospital, the UCLA Jonsson Comprehensive Cancer Center and the Vanderbilt-Ingram Cancer Center to evaluate the efficacy of Puma's drug, Nerlynx, and Faslodex, an AstraZeneca drug, in previously treated metastatic HR-positive, HER2-negative breast cancer patients selected with our CELsignia HER2 Pathway Activity Test. For our fourth collaboration, we are fielding a prospective open-label Phase II clinical trial with Pfizer Inc. and Sarah Cannon Research Institute to evaluate the efficacy of two Pfizer targeted therapies, Vizimpro, a pan-HER inhibitor, and Xalkori, a c-Met inhibitor, in previously treated metastatic HER2-negative breast cancer patients selected with our CELsignia Multi-Pathway Activity Test.

An additional collaboration to evaluate tissue samples from a Phase II study evaluating Puma's pan-HER inhibitor, Nerlynx, Genentech's HER2 antibody, Herceptin, and Bristol-Myers Squibb's EGFR inhibitor, Erbitux, in metastatic colorectal cancer patients is expected to be completed in late 2022. Unlike the four clinical trial collaborations, our CELsignia test will be used solely to evaluate tissue samples after they have been enrolled in this trial. We will not receive payment for the testing we perform. We expect our CELsignia test will provide critical insight after the trial is completed about the patient characteristics most correlative to drug response.

In conjunction with the development of our CELsignia tests, we will seek collaborations with pharmaceutical companies to field clinical trials to advance the clinical development of their targeted therapies with the eventual goal of obtaining U.S. Food and Drug Administration ("FDA") approval of a new drug indication. Collaborations are expected to involve initially Phase I or Phase II interventional clinical trials to evaluate the efficacy of our collaboration partners' targeted therapies patients selected with one of our CELsignia tests. We are currently evaluating, or expect to evaluate, a variety of targeted therapies in combination with other targeted therapies, hormonal therapies, or chemotherapies, including: i) pan-HER and c-Met inhibitors; ii) pan-HER inhibitors and endocrine therapy; iii) pan-HER inhibitors and chemotherapies; and iv) PI3K inhibitors and endocrine therapy. The FDA has approved three c-Met inhibitors, six HER-family inhibitors, and four PI3K inhibitors for cancer treatment. Additional c-Met, HER-family, and PI3K inhibitors are being evaluated in on-going clinical trials.

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, 2020 and 2019, we reported a net loss of approximately $9.5 million and $7.4 million, respectively. As of December 31, 2020, we had a combined accumulated deficit of approximately $12.6 million under Celcuity LLC and $26.3 million under Celcuity Inc. As of December 31, 2020, we had cash and cash equivalents of approximately $11.6 million.

Impact of COVID-19 on our Business

A novel strain of coronavirus (COVID-19) was first identified in Wuhan, China in December 2019, and subsequently declared a pandemic by the World Health Organization. The impact of the COVID-19 pandemic on our business is discussed in further detail below:

Health and Safety

To help protect the health and safety of our employees, suppliers and collaborators, we took proactive, aggressive action from the earliest signs of the outbreak. We enacted rigorous safety measures in our laboratory and administrative offices, including implementing social distancing protocols, allowing working from home for those employees that do not need to be physically present in a lab to perform their work, suspending travel, implementing temperature checks at the entrances to our facilities, extensively and frequently disinfecting our workspaces and providing masks to those employees who must be physically present. We expect to continue with these measures until the COVID-19 pandemic is contained and we may take further actions as government authorities require or recommend or as we determine to be in the best interests of our employees, suppliers, and collaborators.

Clinical Trials and Collaborations

As a result of the COVID-19 pandemic, governmental authorities have implemented and are continuing to implement numerous and constantly evolving measures to try to contain the virus, such as travel bans and restrictions, limits on gatherings, quarantines, shelter-in-place orders, and business shutdowns. As we continue to advance our clinical trial collaborations, we are in close contact with our current clinical sponsors, and principal investigators, as well as prospective pharmaceutical company and clinical collaborators, to assess the impact of COVID-19 on our trial enrollment timelines and collaboration discussions. In light of the COVID-19 pandemic, the focus of healthcare providers and hospitals on fighting the virus, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, we are experiencing delays in the enrollment of patients in our ongoing clinical trials. We now expect interim results from the FACT-1 and FACT-2 trials to be delayed until the fourth quarter of 2021 or first quarter of 2022 and final results approximately nine months later. As the impact of COVID-19 on our industry becomes clearer, we may need to reassess the timing of our anticipated clinical milestones. Prospective clinical trial collaborations with pharmaceutical companies and sponsors may also be delayed but the impact on the timing of finalizing agreements is not yet known.

Research and Development

While our facility currently remains operational, the evolving measures to try to contain the virus have impacted and may further impact our workforce and operations, as well as those of our vendors and suppliers. Our laboratory remains operational as of this date, but, in response to the COVID-19 pandemic, we have implemented protective policies that reduce the number of research and development staff operating in our laboratory at any one time. While governmental measures may be modified or extended, we expect that our research and development and clinical laboratory will remain operational. However, in light of the focus of healthcare providers and hospitals on fighting the virus, several of the clinical sites that provide us tumor tissue for research have halted this service, reducing the number of new tumor tissue specimens we would typically expect to receive. These various constraints may slow or diminish our research and development activities. In addition, cancer research-related industry meetings, such as the American Association for Cancer Research (AACR), were delayed for several months. Our submissions to present research results at these meetings were accepted, but the release of the results was postponed in conjunction with the delayed meeting schedules.

Liquidity

Although there is uncertainty related to the anticipated impact of the recent COVID-19 outbreak on our future results, we believe our existing balance of cash and cash equivalents will be sufficient to meet our cash needs arising in the ordinary course of business for at least the next twelve months. We continue to monitor the rapidly evolving situation and guidance from federal, state and local public health authorities and may take additional actions based on their recommendations. In these circumstances, there may be developments outside our control requiring us to adjust our operating plan. In addition, see Item 1A of Part I of this Annual Report for additional information on risks associated with pandemics in general and COVID-19 specifically and how those risks may impact our business and operations.

RESULTS OF OPERATIONS

Components of Operating Results

Revenue

To date, we have not generated any revenue. Initially, our ability to generate revenue will depend primarily upon our ability to obtain partnership agreements with pharmaceutical companies to provide companion diagnostics for such pharmaceutical partners' existing or investigational targeted therapies. We expect these partnerships to generate significant revenue from the sale of tests to identify patients eligible for clinical trials, from milestone payments, and, potentially, from royalties on the incremental drug revenues our tests enable. Once 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 our CELsignia platform, development and validation of our CELsignia tests, and research related to the discovery of new cancer sub-types. 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;
- 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 expand clinical trials to evaluate 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 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 of our CELsignia platform and corresponding CELsignia tests. We expect to begin to incur increased selling and marketing expenses in anticipation of the commercialization of our first CELsignia tests. These increased expenses are expected to include payroll-related costs as we add employees in the commercial departments, costs related to the initiation and operation of our sales and distribution network and marketing related costs.

Interest Expense

Interest expense is the result of finance lease obligations.

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

	Years Ended December 31,		Increase (Decrease)	
	2020	2019	$	Percent Change
Statements of Operations Data:				
Operating expenses:				
Research and development	$ 7,683,522	$ 6,269,308	$ 1,414,214	23%
General and administrative	1,872,642	1,535,993	336,649	22
Total operating expenses	9,556,164	7,805,301	1,750,863	22
Loss from operations	(9,556,164)	(7,805,301)	(1,750,863)	22
Other income (expense)				
Interest expense	(120)	(159)	39	n/a
Interest income	82,109	446,096	(363,987)	(82)
Other income, net	81,989	445,937	(363,948)	(82)
Net loss before income taxes	(9,474,175)	(7,359,364)	(2,114,811)	29
Income tax benefits	-	-	-	-
Net loss	$ (9,474,175)	$ (7,359,364)	$ (2,114,811)	29%

Research and Development

For the year ended December 31, 2020, our total research and development expenses increased approximately $1.41 million, or 23%, to approximately $7.68 million from $6.27 million for the prior year. The increase primarily resulted from a $1.15 million increase in compensation related expenses, including approximately $0.49 million in non-cash stock-based compensation to support development of our CELsignia platform. In addition, other research and development expenses increased $0.26 million due to clinical validation and laboratory studies, and operational and business development activities.

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 discover new cancer sub-types and to 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.

General and Administrative

For the year ended December 31, 2020, our total general and administrative expenses increased approximately $0.34 million, or 22%, to approximately $1.87 million from $1.53 million for the prior year. The increase primarily resulted from a $0.28 million increase in compensation related expenses, including approximately $0.24 million of non-cash stock-based compensation. In addition, other general and administrative expenses increased $0.06 million primarily due to professional fees associated with being a public company.

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 CELsignia tests, an expanding infrastructure, and increased professional fees associated with being a public company.

Interest Expense

For the years ended December 31, 2020 and 2019, interest expense is related to finance lease liabilities.

Interest Income

For the year ended December 31, 2020, interest income decreased approximately $0.36 million, or 82%, to $0.08 million from $0.44 million for the prior year. The decrease was primarily the result of lower market interest rates.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have incurred losses and cumulative negative cash flows from operations. Through December 31, 2020, we raised capital of approximately $13.7 million and $7.5 million through private placements of common equity and unsecured convertible notes, respectively. On September 22, 2017, we closed on the IPO of our common stock, which generated approximately $23.3 million of additional cash after taking into account underwriting discounts and commissions and offering expenses. On June 5, 2020, we entered into an At Market Issuance Sales Agreement with B. Riley, FBR, Inc (the “ATM Agreement”). The ATM Agreement allows us to sell shares of common stock up to an aggregate offering price of $10.0 million. Through December 31, 2020, we generated approximately $0.08 million of additional cash through sales pursuant to the ATM Agreement, after taking into account commissions and offering expenses. Cash from these capital raising activities has been our primary source of funds for our operations since inception. As of December 31, 2020, our cash and cash equivalents were approximately $11.6 million, and we had a combined accumulated deficit of approximately $12.6 million under Celcuity LLC and $26.3 million under Celcuity Inc.

We expect that our research and development and general and administrative expenses will increase as we continue to develop our CELsignia platform and additional CELsignia tests, conduct research related to the discovery of new cancer sub-types, conduct clinical trials, and pursue other business development activities. We will also start to incur sales and marketing expenses as we commercialize our CELsignia tests. We expect to use cash on hand to fund our research and development expenses, capital expenditures, working capital, sales and marketing expenses, and general corporate expenses, as well as for the increased costs associated with being a public company.

Based on our current business plan, we believe that our current cash on hand will provide sufficient cash to finance operations and pay obligations when due for at least the next twelve months.

We may seek to raise additional capital to expand our business, pursue strategic investments, and 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 at all.

Cash Flows

The following table sets forth the primary sources and uses of cash for the years ended December 31:

	2020	2019
Net cash provided by (used in):		
Operating activities	$ (7,145,689)	$ (5,998,711)
Investing activities	(89,371)	8,529,799
Financing activities	137,969	259,305
Net increase (decrease) in cash and cash equivalents	$ (7,097,091)	$ 2,790,393

Operating Activities

Net cash used in operating activities was approximately $7.14 million for the year ended December 31, 2020 and consisted primarily of a net loss of approximately $9.47 million, adjusted for working capital changes of approximately $0.18 million and non-cash items of approximately $2.15 million. The working capital change was primarily due to approximately $0.19 million increase in accrued expenses. Non-cash expense items of approximately $2.15 million consisted of depreciation of approximately $0.39 million and stock-based compensation expense of approximately $1.76 million.

Net cash used in operating activities was approximately $6.0 million for the year ended December 31, 2019 and consisted primarily of a net loss of approximately $7.36 million and working capital changes of approximately $0.06 million, adjusted for non-cash items of approximately $1.42 million. The working capital change was primarily due to approximately $0.19 million increase in payroll tax receivable, offset by a $0.11 million increase in accrued expenses. Non-cash expense items of approximately $1.42 million consisted of depreciation of approximately $0.34 million, stock-based compensation expense of approximately $1.04 million and interest income of approximately $0.04 million.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 was approximately $0.09 million and consisted of purchases of property and equipment.

Net cash provided by investing activities for the year ended December 31, 2019 was approximately $8.53 million and consisted of approximately $8.91 million of net proceeds from investments in certificates of deposit and government securities (U.S. Treasury Notes and U.S. government agency securities), adjusted by approximately $0.38 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 was approximately $0.14 million and primarily reflects net proceeds from the sale of shares of our common stock through the ATM Agreement and employee stock purchases.

Net cash provided by financing activities for the year ended December 31, 2019 was approximately $0.26 million and consisted of proceeds from the exercise of common stock warrants and stock options, and employee stock purchases.

OFF-BALANCE SHEET ARRANGEMENTS

We do not currently have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

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 is 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.

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, 2020 and 2019 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, 2020, 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, 2020 and 2019 and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, 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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

/s/ Boulay PLLP

We have served as the Company's auditor since 2017.

Minneapolis, Minnesota
February 16, 2021

Celcuity Inc.
Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 11,637,911	$ 18,735,002
Deposits	22,009	22,009
Deferred transaction costs	-	28,743
Payroll tax receivable	190,000	190,000
Prepaid assets	317,040	274,600
Total current assets	12,166,960	19,250,354
Property and equipment, net	558,876	833,463
Operating lease right-of-use assets	230,911	196,983
Total Assets	$ 12,956,747	$ 20,280,800
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 217,377	$ 142,773
Finance lease liabilities	5,810	5,769
Operating lease liabilities	187,518	178,466
Accrued expenses	774,612	584,319
Total current liabilities	1,185,317	911,327
Finance lease liabilities	8,299	14,109
Operating lease liabilities	60,861	57,793
Total Liabilities	1,254,477	983,229
Stockholders' Equity:		
Preferred stock, $0.001 par value: 2,500,000 shares authorized; 0 shares issued and outstanding as of December 31, 2020 and December 31, 2019	-	-
Common stock, $0.001 par value: 25,000,000 shares authorized; 10,299,822 and 10,253,988 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	10,300	10,254
Additional paid-in capital	38,013,551	36,134,723
Accumulated deficit	(26,321,581)	(16,847,406)
Total Stockholders' Equity	11,702,270	19,297,571
Total Liabilities and Stockholders' Equity	$ 12,956,747	$ 20,280,800

See accompanying notes to the financial statements

Celcuity Inc.
Statements of Operations

	Years Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 7,683,522	$ 6,269,308
General and administrative	1,872,642	1,535,993
Total operating expenses	9,556,164	7,805,301
Loss from operations	(9,556,164)	(7,805,301)
Other income (expense)		
Interest expense	(120)	(159)
Interest income	82,109	446,096
Other income, net	81,989	445,937
Net loss before income taxes	(9,474,175)	(7,359,364)
Income tax benefits	-	-
Net loss	$ (9,474,175)	$ (7,359,364)
Net loss per share, basic and diluted	$ (0.92)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	10,266,884	10,226,041

Celcuity Inc.
Statements of Changes in Stockholders' Equity

	Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2018	10,186,382	$ 10,186	$ 34,827,467	$ (9,488,042)	$ 25,349,611
Exercise of common stock warrants	395	-	3,752	-	3,752
Stock-based compensation	-	-	1,040,989	-	1,040,989
Exercise of common stock options, net of shares withheld for exercise price	58,127	59	174,899	-	174,958
Employee stock purchases	9,084	9	87,616	-	87,625
Net loss	-	-	-	(7,359,364)	(7,359,364)
Balance at December 31, 2019	10,253,988	10,254	36,134,723	(16,847,406)	19,297,571
Stock-based compensation	15,686	16	1,763,863	-	1,763,879
Employee stock purchases	12,423	12	60,291	-	60,303
Issuance of common stock in an at-the-market ("ATM") offering	17,725	18	182,676	-	182,694
Issuance costs associated with ATM offering	-	-	(128,002)	-	(128,002)
Net loss	-	-	-	(9,474,175)	(9,474,175)
Balance at December 31, 2020	10,299,822	$ 10,300	$ 38,013,551	$ (26,321,581)	$ 11,702,270

See accompanying notes to the financial statements

Celcuity Inc.
Statements of Cash Flows

	Years Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (9,474,175)	$ (7,359,364)
Adjustments to reconcile net loss to net cash used for operations:		
Depreciation	385,591	338,996
Stock-based compensation	1,763,879	1,040,989
Non-cash interest income, net of cash received	-	42,907
Changes in operating assets and liabilities:		
Payroll tax receivable	-	(190,000)
Prepaid assets and deposits	(42,440)	(20,143)
Accounts payable	52,971	45,617
Accrued expenses	190,293	111,403
Non-cash operating lease, net	(21,808)	(9,116)
Net cash used for operating activities	(7,145,689)	(5,998,711)
Cash flows from investing activities:		
Proceeds from sale of investments	-	8,910,000
Purchases of property and equipment	(89,371)	(380,201)
Net cash provided by (used for) investing activities	(89,371)	8,529,799
Cash flows from financing activities:		
Proceeds from exercise of common stock warrants	-	3,752
Proceeds from exercise of employee stock options	-	174,958
Proceeds from employee stock purchases	60,303	87,625
Gross proceeds from an ATM offering	182,694	-
Payments for secondary registration statement costs	(99,259)	(1,300)
Payments for finance leases	(5,769)	(5,730)
Net cash provided by financing activities	137,969	259,305
Net change in cash and cash equivalents	(7,097,091)	2,790,393
Cash and cash equivalents:		
Beginning of period	18,735,002	15,944,609
End of period	$ 11,637,911	$ 18,735,002
Supplemental disclosures of non-cash investing and financing activities:		
Property and equipment included in accounts payable	$ 24,333	$ 2,700

See accompanying notes to the financial statements

CELCUITY INC.
NOTES TO FINANCIAL STATEMENTS

1. Organization

Nature of Business

Celcuity Inc., a Delaware corporation (the "Company"), is a clinical stage biotechnology company translating discoveries of new cancer sub-types into pioneering companion diagnostics and expanded therapeutic options for cancer patients. The Company's 3rd generation diagnostic platform, CELsignia, analyzes living tumor cells to untangle the complexity of the cellular activity driving a patient's cancer. This allows the Company to discover new cancer sub-types molecular diagnostics cannot detect. The Company is driven to improve outcomes for patients and to transform how pharmaceutical companies define the patient populations for their targeted therapies. The Company's proprietary CELsignia diagnostic platform is currently the only commercially ready technology the Company is aware of that uses a patient's living tumor cells to evaluate the functional status of the cell signaling pathways associated with cancer. 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.

2. Summary of Significant Accounting Policies

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, 2020 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 primarily at one financial institution. At times throughout the year, the Company's cash balances may exceed amounts insured by the Federal Deposit Insurance Corporation. At December 31, 2020 and December 31, 2019, the Company had $11,378,685 and $18,369,229, respectively, in money market funds that are considered cash equivalents and not insured by the Federal Deposit Insurance Corporation.

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:

Asset Description	Estimated Lives
Furniture and Equipment	4-5
Leasehold Improvements	2-3

Long-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 primarily consist of legal fees, SEC filing fees and other fees relating to the Company's Registration Statement on Form S-3 filed on September 21, 2018. The deferred transaction costs were capitalized as incurred and were offset against proceeds from the sale of shares of common stock pursuant to the ATM Agreement.

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 diagnostic tests, ability to obtain regulatory approval of 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, 2020 and December 31, 2019, 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.

Stock-Based Compensation

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 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

Research and development costs are expensed as incurred. Research and development costs amounted to $7,683,522 for the year ended December 31, 2020 and $6,269,308 for the year ended December 31, 2019.

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 include 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 accrues for these costs based on factors such as estimates of the work completed and in accordance with service agreements with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its prepaid assets or accrued expenses. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in an adjustment to expense in future periods. 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.

Application of New or Revised Accounting Standards

Pursuant to the JOBS Act, a company constituting an "emerging growth company" is, among other things, entitled to rely upon certain reduced reporting requirements. The Company is an emerging growth company but has irrevocably elected not to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. As a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies.

Recently Adopted Accounting Pronouncements

Effective January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842),* which requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous guidance. The original guidance required application on a modified retrospective basis with the earliest period presented. In August 2018, the FASB issued ASU 2018-11, Targeted Improvements to ASC 842, which included an option to not restate comparative periods in transition and elect to use the effective date of ASC 842 as the date of initial application of transition, which the Company elected. As a result of the adoption of ASC 842 on January 1, 2019, the Company recorded both operating lease right-of-use ("ROU") assets of $356,539 and lease liabilities of $404,931 and eliminated deferred rent of $63,875 and prepaid rent of $15,483. The adoption of ASC 842 had no impact on the Company's Statement of Operations and Statement of Cash Flows for the year ended December 31, 2019. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed the Company to carry forward the historical lease classification. Additional information and disclosures required by this new standard are contained in Note 9.

3. Liquidity

Based on the Company's cash and cash equivalents on hand at December 31, 2020 of $11,637,911, the Company believes that its cash 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 options and warrants 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 years ended December 31, 2020 and 2019, potentially dilutive securities excluded from the computations of diluted weighted-average shares outstanding were options to purchase 849,949 and 585,215 shares of common stock, respectively, warrants to purchase 353,585 shares of common stock, and 15,686 and 0 shares of restricted common stock, respectively.

5. Payroll Tax Receivable

The payroll tax receivable initially recorded in 2019, is the result of the Company's utilization of research and development tax credits as authorized by the Path Act. The balance at December 31, 2020 and December 31, 2019 was $190,000.

6. Prepaid Assets

Prepaid assets consisted of the following at December 31:

	2020	2019
Current:		
Directors & officers' insurance	$ 288,750	$ 229,167
Other	28,290	45,433
Total	$ 317,040	$ 274,600

7. Property and Equipment

Property and equipment consisted of the following at December 31:

	2020	2019
Leasehold improvements	$ 302,848	$ 302,848
Furniture and equipment	1,461,512	1,350,508
	1,764,360	1,653,356
Less: Accumulated depreciation	(1,205,484)	(819,893)
Total	$ 558,876	$ 833,463

Depreciation expense was $385,591 and $338,996 for the years ended December 31, 2020 and 2019, respectively.

8. Accrued Expenses

Accrued expenses consisted of the following at December 31:

	2020	2019
Accrued compensation	$ 628,121	$ 461,452
Employee Stock Purchase Plan	9,471	10,121
Other	137,020	112,746
Total	$ 774,612	$ 584,319

9. Commitments

Operating and Finance Leases

The Company leases its corporate space in Minneapolis, Minnesota. In September 2017, the Company entered into a non-cancelable operating lease agreement for building space. The new lease commenced, and the Company moved to the facility in May 2018, 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 2020 the Company signed an amendment to extend this lease through April 30, 2022. 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 ROU asset and lease liability.

The lease agreement, as amended, includes the option to extend the term for one additional year. The option to extend is at the Company’s discretion and because the Company has not determined if the option to extend will be exercised, the extended lease term is not included in the ROU assets and lease liabilities. The Company regularly evaluates the renewal options and when it is reasonably certain of exercise, the Company will include the renewal period in its lease term.

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.

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, 2020:

Operating Lease	
Right-of-use assets	$ 230,911
Operating lease liability	$ 248,379
Less: short term portion	(187,518)
Long term portion	$ 60,861
Finance Lease	
Furniture and equipment	$ 28,932
Less: Accumulated depreciation	(14,948)
Net book value of property and equipment under finance lease	$ 13,984
Finance lease liability	$ 14,109
Less: short term portion	(5,810)
Long term portion	$ 8,299

Maturity analysis under lease agreements consisted of the following as of December 31, 2020:

	Operating Leases	Finance Leases
2021	$ 194,821	$ 7,255
2022	64,940	7,255
2023	-	3,022
Total minimum lease payments	259,761	17,532
Less: Present value discount	(11,382)	(122)
Less amount representing services	-	(3,301)
Present value of net minimum lease payments	$ 248,379	$ 14,109

Weighted Average	Remaining Lease Term	Discount Rate
Operating lease	1.3 years	4.0%
Finance lease	2.4 years	1.0%

Lease costs for the year ended December 31:

	2020	2019
Operating lease cost	$ 171,530	$ 164,252
Finance lease cost:		
Amortization	5,786	5,786
Interest	119	159
Variable lease cost	85,265	82,885
	$ 262,700	$ 253,082

Supplemental cash flow information related to leases for the year ended December 31:

	2020	2019
Cash paid for amounts included in operating and finance leases:		
Operating cash outflow from operating leases	$ 278,603	$ 248,450
Operating cash outflow from finance leases	119	159
Financing cash outflow from finance leases	5,769	5,730
	$ 284,491	$ 254,339

Clinical Research Studies

In May 2017, the Company entered into an agreement with a clinical research organization to conduct a clinical research study. The Company made payments of $100,000 and $50,000 in 2020 and 2019, respectively, and $550,000 prior to 2019. Additional payments will be due as certain milestones are met and clinical sites are added. The maximum amount of these additional payments is estimated to be approximately $2,620,000 over the course of the agreement.

In October 2018, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. The Company made payments of approximately $70,000 in 2019. Additional payments of approximately $112,000 will be due as certain milestones are met.

In December 2020, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. The Company made zero payments in 2020. Future payments of approximately $740,000 will be due as certain milestones are met.

In January 2021, the Company entered into an agreement with a biopharmaceutical company and a cancer research center to conduct a clinical research study. Future payments of approximately $1,210,600 will be due as certain milestones are met.

10. Stockholders' Equity

On June 5, 2020, the Company entered into an At Market Issuance Sales Agreement (the "ATM Agreement") with B. Riley FBR, Inc. (the "Agent"). Pursuant to the ATM Agreement, the Company may offer and sell from time to time, at its option, shares of common stock having an aggregate offering price of up to $10,000,000, par value $0.001 per share (the "Placement Shares"), through the Agent.

The Placement Shares have been registered under the Securities Act of 1933, as amended, pursuant to the Registration Statement on Form S-3 (File No. 333-227466), which was originally filed with the SEC on September 21, 2018 and declared effective by the SEC on October 4, 2018, the base prospectus contained within the Registration Statement, and a prospectus supplement that was filed on June 5, 2020. Sales of the Company's common stock, if any, under this prospectus supplement may be made by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended.

During the year ended December 31, 2020, the Company sold 17,725 shares of common stock pursuant to the ATM Agreement, at an average selling price of $10.31 per share.

On September 15, 2017, in connection with its IPO, Celcuity LLC filed a certificate of conversion, whereby Celcuity LLC effected a corporate conversion from a Minnesota limited liability company to a Delaware corporation and changed its name to Celcuity Inc. Pursuant to the conversion, units of membership interest in the limited liability company were converted into shares of common stock of the corporation at a conversion ratio of 40 units for one share of common stock. The Company had 257,604,208 units issued and outstanding as of September 15, 2017. After giving effect to the corporate conversion, the number of common shares outstanding as of such date was 6,440,139. As a result of the corporate conversion, accumulated deficit was reduced to zero on the date of the corporate conversion, and the corresponding amount was credited to additional paid-in capital. The corporate conversion was approved by members holding a majority of the outstanding units of Celcuity LLC, and in connection with such conversion, the Company filed a certificate of incorporation and adopted bylaws. The Company determined that the corporate conversion is equivalent to a change in the Company's capital structure.

On September 22, 2017, the Company completed its IPO whereby it sold 2,760,000 shares of common stock at a public offering price of $9.50 per share. The aggregate net proceeds received by the Company from the IPO were approximately $23.3 million, net of underwriting commissions of approximately $1.8 million and offering expenses of approximately $1.1 million. Upon the closing of the IPO, 10,082,050 shares of common stock were outstanding, which included 881,911 shares of common stock issued as a result of the conversion of the Company's convertible notes. Shares of the Company's common stock began trading on September 20, 2017 on The Nasdaq Capital Market under the symbol "CELC".

On May 11, 2018, the Company filed an amendment to its certificate of incorporation with the Secretary of State of the State of Delaware to decrease the number of authorized shares of its common stock and preferred stock. Pursuant to the Company's amended certificate of incorporation, the Company is authorized to issue up to 25,000,000 shares of common stock, $0.001 par value per share and 2,500,000 shares of preferred stock, $0.001 par value per share.

At December 31, 2020 and 2019, the Company had 10,299,822 and 10,253,988 shares of common stock outstanding, respectively.

Warrants

In connection with the 2016 private placement offering of units, the Company issued ten-year warrants to the placement agent of the private placement. The warrants allow the placement agent to purchase up to 55,249 shares of common stock at $7.56 per share. The warrants were immediately exercisable and expire on January 14, 2026 and May 2, 2026. These warrants are equity classified and the $330,607 fair value of the warrants is reflected as additional paid-in capital.

In connection with the private placement offering of convertible notes, the Company issued ten-year warrants to the placement agent to purchase 48,615 shares of common stock at a price of $8.42 per share. The warrants were immediately exercisable and expire on April 28, 2027 and May 17, 2027. These warrants are equity classified and the $286,999 fair value of the warrants is reflected as additional paid-in-capital.

In addition, the Company granted the purchasers of the convertible notes the right to receive a seven-year warrant to purchase 131,675 shares of common stock at an exercise price equal to the conversion price of the convertible notes. With the completion of the IPO on September 22, 2017, these warrants were issued. These warrants were immediately exercisable and expire on September 22, 2024. These warrants are equity classified and the $776,717 fair value of the warrants is reflected as additional paid-in-capital.

In connection with the IPO, the Company issued a five-year warrant to the underwriter. The warrant allows the underwriter to purchase up to 138,000 shares of common stock at $10.45 per share. This warrant was immediately exercisable and expires on September 19, 2022. This warrant is equity classified and the $784,111 fair value of the warrant is reflected as additional paid-in-capital.

At December 31, 2020 and 2019, the Company had warrants to purchase 353,585 shares of common stock outstanding, at a weighted average exercise price of $9.42. A total of 0 and 395 warrants were exercised in the years ended December 31, 2020 and 2019, respectively.

11. Stock-Based Compensation

2012 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.

2017 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 102,540 shares on January 1, 2020 and will increase automatically on January 1 of each of 2021 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. 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:

	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	585,215	$ 14.37	478,503	$ 9.73
Granted	277,986	7.17	248,756	19.69
Exercised	-	-	(66,489)	5.13
Forfeited/Expired	(13,252)	11.54	(75,555)	10.55
Balance at December 31	849,949	$ 9.33	585,215	$ 14.37
Options exercisable at December 31:	397,425	$ 10.35	264,280	$ 9.52
Weighted Average Grant Date Fair Value for Options Granted During the year:		$ 4.63		$ 13.46

The following table summarizes additional information about stock options outstanding and exercisable at December 31, 2020:

Options 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
849,949	7.92	$ 9.33	$ 2,010,091	397,425	$ 10.35	$ 762,234

The Company recognized stock-based compensation expense for stock options of $1,668,859 and $990,839 for the years ended December 31, 2020 and 2019, respectively. 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 for the year ended December 31, 2020 was approximately $83,000. The effect on stock-based compensation over the remaining service period will be approximately $136,000.

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:

	2020	2019
Risk-free interest rate	.35% - 1.66%	1.42% -2.47%
Expected volatility	73.3% - 77.1%	76.2%-80.0%
Expected life (years)	5.5 to 6.1	5.2 to 6.3
Expected dividend yield	0%	0%

The inputs for the Black-Scholes valuation model require management's significant assumptions. Prior to the Company's IPO, 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 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 the Company's 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 the Company terminates any of its consulting agreements, the unvested options issued in connection with such agreements would also be cancelled.

Restricted stock awards were granted to two members of the Company's board during the year ended December 31, 2020. The Company had 15,686 and 0 shares of restricted stock outstanding as of December 31, 2020 and 2019, respectively, and 0 and 2,571 shares of restricted stock vested during the years ended December 31, 2020 and 2019. The Company recognized stock-based compensation expense for restricted stock of $52,727 and $17,047 for the years ended December 31, 2020 and 2019, respectively.

The total remaining shares available for grant under the 2017 Plan is 198,922.

Total unrecognized compensation cost related to stock options and restricted stock is estimated to be recognized as follows:

2021	$ 1,387,174
2022	1,057,679
2023	704,222
2024	200,244
Total estimated compensation cost to be recognized	$ 3,349,319

2017 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 51,270 shares on January 1, 2020 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, 2020 is 112,211.

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 $42,293 and $33,103 for the years ended December 31, 2020 and 2019, respectively.

The Company recognized total stock-based compensation expense, as follows for the years ended December 31:

	2020	2019
Stock-based compensation expense in operating expenses:		
Research and development	$ 1,055,094	$ 567,305
General and administrative	708,785	473,684
Total	$ 1,763,879	$ 1,040,989

12. 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 2020 and 2019, 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:

	2020	2019
Tax benefit at statutory federal rate	$ (1,990,000)	$ (1,545,000)
State income tax benefit, net of federal tax effect	(16,000)	(24,000)
Change in valuation allowance on deferred tax assets	2,159,000	1,781,000
Research and Development Credits	(450,000)	(138,000)
Other permanent items	297,000	(74,000)
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. Among the significant changes to the U.S. Internal Revenue Code, the Tax Act lowered the U.S. federal corporate income tax rate ("Federal Tax Rate") from 35% to 21% effective January 1, 2018. The Act also made changes related to the use and limitation of net operating loss carryforwards generated in tax years beginning after December 31, 2017. For years beginning after December 31, 2017 net operating losses have an indefinite carryforward and the utilization of losses is limited to 80% of taxable income each year.

In response to the COVID-19 pandemic, the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") was signed into law on March 27, 2020. The CARES Act lifts certain deduction limitations originally imposed by the Tax Act. Corporate taxpayers may carryback net operating losses originating during 2018 through 2020 for up to five years, which was not previously allowed under the Tax Act. The CARES Act also eliminates the 80% of taxable income limitation allowing corporate entities to fully utilize net operating loss carryforwards to offset taxable income in 2018, 2019 and 2020. The enactment of the CARES Act did not result in any material impact to the Company's income tax provision.

On December 27, 2020 the Consolidated Appropriations Act, 2021 ("CAA") was signed into law. The CAA includes the COVID-related Tax Relief Act of 2020 ("COVID TRA"). The Company is continuing to assess the effect of the CAA and does not believe it will result in a material impact to the Company's income tax benefit.

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, 2020. The tax effects of temporary differences and carryforwards that give rise to significant portions of the deferred tax assets are as follows:

	2020	2019
Deferred tax assets (liabilities):		
Accrued expenses	$ 79,000	$ 8,000
Share-based compensation	528,000	435,000
Property and equipment	255,000	175,000
Right-of-use assets	(49,000)	(41,000)
Lease liability	53,000	50,000
Start-up expenditures	2,610,000	2,038,000
Net operating losses and tax credits	3,242,000	1,894,000
Valuation allowance	(6,718,000)	(4,559,000)
Net deferred tax assets (liabilities)	$ -	$ -

At December 31, 2020, the Company had federal and state net operating loss carryforwards resulting in deferred tax assets of approximately $10.2 million and $0.5 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, 2020 and 2019.

At December 31, 2020, the Company had federal and state research and development tax credit carryforwards resulting in deferred tax assets of approximately $0.6 million and $0.6 million, respectively. The federal and state credit carryforwards will begin to expire in the years ending December 31, 2037 and December 31, 2032, respectively. These deferred tax assets were subject to a full valuation allowance as of December 31, 2020 and 2019.

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, 2020, and 2019, 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 2016, the Company is no longer subject to U.S. federal or state income tax examinations. The Company's policy is to recognize interest and penalties related to uncertain tax positions as a component of general and administrative expenses.

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

None

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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, 2020, 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, 2020 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 an "emerging growth company," as defined in the JOBS Act.

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, 2020 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

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

Directors

Brian F. Sullivan, age 59, 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 25 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. Since 2003, Mr. Sullivan has served on the board of directors of Entegris, Inc., a publicly-held company. Mr. Sullivan has received seven 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 59, 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 15 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 19 U.S. patents and has an additional 24 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 71, 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 62, 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 74, 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.

Richard J. Nigon, age 73, 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 Tactile Systems Technology since September 2012 and 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 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 54, joined as our Chief Financial Officer in July 2017. She has more than 20 years of financial leadership experience, including the most recent 10 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 code is 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 Code of Business Conduct and Ethics that are required to be disclosed by SEC rules.

Additional information required by this Item 10 will be contained in our definitive proxy statement for our 2021 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 STATEMENTS

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Report of Independent Registered Public Accounting Firm	45
Balance Sheets - December 31, 2020 and 2019	46
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Statements of Stockholders' Equity - Years ended December 31, 2020 and 2019	48
Statements of Cash Flows - Years ended December 31, 2020 and 2019	49
Notes to Consolidated Financial Statements	50

FINANCIAL STATEMENT SCHEDULES

None.

EXHIBITS

See Exhibit Index immediately following the signature page hereto, which is incorporated herein by reference.

ITEM 16. Form 10-K Summary

None.

SIGNATURES

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

Dated: February 16, 2021

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 Brian F. Sullivan	Chairman and Chief Executive Officer (Principal Executive Officer)	February 16, 2021
/s/ Vicky Hahne Vicky Hahne	Chief Financial Officer (Principal Financial and Accounting Officer)	February 16, 2021
/s/ Lance G. Laing Lance G. Laing	Chief Science Officer, Vice President and Secretary, and Director	February 16, 2021
/s/ Richard E. Buller Richard E. Buller	Director	February 16, 2021
/s/ Dave F. Dalvey Dave F. Dalvey	Director	February 16, 2021
/s/ Leo T. Furcht Leo T. Furcht	Director	February 16, 2021
/s/ Richard J. Nigon Richard J. Nigon	Director	February 16, 2021

EXHIBIT INDEX
CELCUITY INC.
FORM 10-K

Exhibit 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 (incorporated by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018).
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).
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 No. 1 to Celcuity Inc. 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2018).
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).
10.5+	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10	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).

10.11	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).
10.12	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).
10.13	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).
10.14	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*	Clinical Trial Agreement, Amendment No. 1, between NSABP Foundation, Inc and Celcuity Inc., dated October 15, 2020.
10.16+	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+	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+	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	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	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).
10.21	At Market Issuance Sales Agreement, dated June 5, 2020, between Celcuity Inc. and B. Riley FBR, Inc. (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on June 5, 2020).
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.
101	Financial statements from the Annual Report on Form 10-K of the Company for the year ended December 31, 2020, 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.
104	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.

EXHIBIT 10.15

Amendment No. 1
CLINICAL TRIAL AGREEMENT FOR FB-12 PHASE II STUDY

By and Between
NSABP Foundation, Inc.
and
Celcuity, Inc.

This Amendment No. 1 (the "Amendment") to the Clinical Trial Agreement for the FB-12 Phase II Study (the "Agreement') entered into and effective as of May 8, 2017 (the "Effective Date"), by and between NSABP Foundation, Inc., ("NSABP"), and Celcuity, Inc., ("Celcuity"), is effective as of _____, 2020 ("Amendment Effective Date").

WHEREAS, NSABP and Celcuity desire to make certain changes to the Agreement, primarily related to the Study being deemed by the FDA for exemption of IND regulations and the inclusion of additional funding.

NOW THEREFORE, in consideration of the covenants and conditions contained herein, the Parties agree as follows:

1. All instances of the term "Celcuity, LLC" found in the Agreement shall be deleted and replaced with the term "Celcuity, Inc."

2. Section 1.32 shall be replaced in its entirety with the following: ""Sponsor" shall mean NSABP."

3. Section 3.2 shall be revised by removing the definition of "Applicable Laws" and replacing it with the following: ""Applicable Laws" shall mean, as applicable, (a) all applicable requirements of the U.S. investigational new drug ("IND") regulations (Title 21, Part 312.1 et seq., as applicable to an IND exemption); (b) GCP, as may be amended from time to time; (c) the Code of Federal Regulations governing informed consent and IRBs (Title 21, Parts 50 and 56) and privacy of patient health information (Title 45, Parts 160 and 164 promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA")); and (d) other applicable federal, state, provincial, and local laws, legally binding regulations, and guidelines having the force and effect of law."

4. Section 3.3 shall be replaced in its entirety with the following: "The FDA has deemed FB-12 to meet all of the requirements for exemption of IND regulations and, therefore, an IND is not required."

5. Section 3.6(d) shall be deleted in its entirety.

6. Section 9.4 shall be revised by the deletion of "NSABP agrees to provide Celcuity with copies of the annual reports to the IND filed for the Study."

7. The Budget and Payment Schedule sections of Appendix B, Budget, Payment Schedule, and Task List, shall be replaced in their entirety with the following Budget and Revised Payment Schedule, as attached to this Amendment No. 1.

8. Capitalized terms shall have the meaning assigned to them in the Agreement. Except as expressly and unambiguously stated herein, no other changes are made to the Agreement. All other terms and conditions of the Agreement shall remain in full force and effect. The Agreement and this Amendment constitute the entire understanding of the Parties with respect to the subject matter hereof and supersede any prior understanding, oral or written, between the Parties with respect thereto.

BINDING EXECUTION

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate by proper persons thereunto duly authorized.

NSABP FOUNDATION, INC.

By: /S/ RON SUGAR
AUTHORIZED SIGNATURE

RONALD SUGAR
AUTHORIZED REPRESENTATIVE

CHIEF FINANCIAL OFFICER
TITLE

10/15/2020
DATE

CELCUITY, INC.

By: /S/ BRIAN SULLIVAN
AUTHORIZED SIGNATURE

BRIAN SULLIVAN
AUTHORIZED REPRESENTATIVE

CHIEF EXECUTIVE OFFICER
TITLE

10/15/2020
DATE

NSABP Foundation, Inc.
Budget: FB-12
October 15, 2020

	Unit Type	Unit Volume	Cost Per Unit	Total Budget
Site Costs				
Site Start Up and Annual Administrative Fees	CM sites *	24	$ 15,000	$ 360,000
Pharmacy Fees	CM sites *	24	2,000	48,000
Site IRB Fees	IRBs	27	12,500	337,500
Participating Site Payment	Patients	55	6,946	382,030
Participating Site Payment - Pregnancy SAE	Patients	1	150	150
Non-Routine Patient Care Costs	Procedures	275	1,100	302,500
Screen Failures	Screen Failures	220	250	55,000
Participating Site - Tissue Samples	Samples	330	300	99,000
Overhead on Site Payments				396,045
Subtotal Site Costs	**Patients**	**55**	**$ 41,423**	**$ 1,980,225**
Specimen Procurement/Storage				
NSABP Biospecimen Bank				$ 5,500
Subtotal Specimen Procurement/Storage				**$ 5,500**
Program and Administrative Services				
NSABP Operations Center				$ 815,489
Biostatistical, Data Management, EDC Support				438,961
Drug Distribution				46,564
NSABP Central IRB Fees				9,519
Travel Reimbursement (Pass-Through)				20,000
Subtotal Program and Administrative Services				**$ 1,330,532**
Total Budget	**Patients**	**55**	**$ 60,296**	**$ 3,316,257**

* Central Monitored Sites

FB-12
Payment Schedule
October 15, 2020

PAYMENT PERIOD	PAYMENT TIMING	PATIENT MILESTONES	CALENDAR YEAR	PAYMENT AMOUNT	CUMULATIVE TOTAL
Start-Up Activities	Initial Payment - Within 30 days of execution of the Agreement	0 to 5	2020	$ 300,000	$ 300,000
Accrual and Treatment Period					
Per-Patient Randomized	$34,925.14	6 - 10	2021	174,626	474,626
		11 - 20	2021	349,251	823,877
	amount per patient to be invoiced as actual	21 - 30	2021	349,251	1,173,129
	accrual reaches enrollment milestone (projected	31 - 40	2021	349,251	1,522,380
	payment plan is based upon budgeted accrual)	41 - 50	2021	349,251	1,871,631
		51 - 55	2021	174,626	2,046,257
Quarterly Payments @	$50,000				
	Yr 01 - 2017 (1 quarterly payment)		2017	50,000	2,096,257
	Yr 02 - 2018 (4 quarterly payments)		2018	200,000	2,296,257
	Yr 03 - 2019 (1 quarterly payment)		2019	50,000	2,346,257
Quarterly Payments @	$100,000				
	Yr 04 - 2020 (2 quarterly payments) Paid on:		2020	200,000	2,546,257
	October 15, 2020			100,000	
	December 20, 2020			100,000	
Quarterly Payments @	$100,000				
	Yr 05 - 2021 (2 quarterly payments) Paid on:		2021	200,000	2,746,257
	March 20, 2021			100,000	
	June 20, 2021			100,000	
Quarterly Payments @	$50,000				
	Yr 05 - 2021 (2 quarterly payments) Paid on:		2021	100,000	2,846,257
	September 20, 2021			50,000	
	December 20, 2021			50,000	
Quarterly Payments @	$50,000				
	Yr 06 - 2022 (4 quarterly payments) Paid on:		2022	200,000	3,046,257
	March 20, 2022			50,000	
	June 20, 2022			50,000	
	September 20, 2022			50,000	
	December 20, 2022			50,000	
Primary Endpoint	Upon completion of the primary endpoint analysis and submission of the primary endpoint manuscript to Celcuity		2023	250,000	3,296,257
Pass Through Costs	Travel Reimbursement - invoice as incurred		2017-2023	$ 20,000	$ 3,316,257
	TOTAL CELCUITY SUPPORT				$ 3,316,257

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report, dated February 16, 2021, with respect to the financial statements included in the Annual Report of Celcuity Inc. on Form 10-K for the year ended December 31, 2020. We hereby consent to the incorporation by reference in the Registration Statements of Celcuity Inc. on Form S-8 (File No. 333-221117 and 333-238787) and on Form S-3 (File No. 333-227466).

/s/Boulay PLLP

Minneapolis, Minnesota
February 16, 2021

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 material fact or omit to state a material fact necessary to make the statement 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: February 16, 2021

By /s/ Brian F. Sullivan
Brian F. Sullivan
Chairman and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vicky Hahne, 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 material fact or omit to state a material fact necessary to make the statement 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: February 16, 2021

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer

EXHIBIT 32.1

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

I, Brian F. Sullivan, certify that:

1. I have reviewed this annual report on Form 10-K of Celcuity Inc.; and

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

Date: February 16, 2021

By /s/ Brian F. Sullivan
Brian F. Sullivan
Chairman and Chief Executive Officer

EXHIBIT 32.2

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

I, Vicky Hahne, certify that:

1. I have reviewed this annual report on Form 10-K of Celcuity Inc.; and

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

Date: February 16, 2021

By /s/ Vicky Hahne
Vicky Hahne
Chief Financial Officer