Table of Contents

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: 001-36439

PRECIPIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	**91-1789357**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4 Science Park, New Haven, CT	**06511**
(Address of principal executive offices)	**(Zip Code)**

(203) 787-7888
(Registrant's telephone number, including area code)

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, $0.01 par value per share	PRPO	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 __X__

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

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 __X__ 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 X No

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

arge accelerated filer	☐	Accelerated filer	☐
lon-accelerated filer	☒	Smaller reporting company	☒
merging 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 USC. 7262(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 Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based on the last reported closing price per share of Common Stock as reported on the Nasdaq Capital Market on the last business day of the registrant's most recently completed second quarter was approximately $19.5 million.

As of March 25, 2021, the number of shares of common stock outstanding was 18,132,063.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant's definitive Proxy Statement for the Annual Meeting of Stockholders (the "2021 Proxy Statement") is incorporated by reference in Part III of this Form 10-K to the extent stated herein. The 2021 Proxy Statement, or an amendment to this Form 10-K, will be filed with the SEC within 120 days after December 31, 2020. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

Table of Contents

PRECIPIO, INC.
Annual Report on Form 10-K
For the Year Ended December 31, 2020

INDEX

Table of Contents

PART I.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report"), including the sections entitled "Risk Factors" "Management's Discussion & Analysis of Financial Condition and Results of Operations" and "Our Business" contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. These statements are based on management's current views, assumptions or beliefs of future events and financial performance and are subject to uncertainty and changes in circumstances. Readers of this report should understand that these statements are not guarantees of performance or

results. Many factors could affect our actual financial results and cause them to vary materially from the expectations contained in the forward-looking statements. These factors include, among other things: the expected or potential impact of the novel coronavirus ("COVID-19") pandemic which is highly uncertain and will depend on future developments, our expected revenue, income (loss), receivables, operating expenses, supplier pricing, availability and prices of raw materials, insurance reimbursements, product pricing, foreign currency exchange rates, sources of funding operations and acquisitions, our ability to raise funds, sufficiency of available liquidity, future interest costs, future economic circumstances, business strategy, industry conditions and key trends, our ability to execute our operating plans, the success of our cost savings initiatives, competitive environment and related market conditions, expected financial and other benefits from our organizational restructuring activities, actions of governments and regulatory factors affecting our business, projections of future earnings, revenues, synergies, accretion or other financial items, any statements of the plans, strategies and objectives of management for future operations, retaining key employees and other risks as described in our reports filed with the Securities and Exchange Commission (the "SEC"). In some cases these statements are identifiable through the use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "target," "can," "could," "may," "should," "will," "would" or the negative of such terms and other similar expressions.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements. Actual results may differ materially from those suggested by these forward-looking statements for a number of reasons, including those described in Item 1A, "Risk Factors," and other factors identified by cautionary language used elsewhere in this Annual Report.

We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

The following discussion should be read together with our financial statements and related notes contained in this Annual Report. Results for the year ended December 31, 2020 are not necessarily indicative of results that may be attained in the future.

Table of Contents

Item 1. Our Business

Business Description

Precipio, Inc., and its subsidiaries, (collectively, "we", "us", "our", the "Company" or "Precipio") is a cancer diagnostics and reagent technology company providing diagnostic products and services to the oncology market. We have built and continue to develop a platform designed to eradicate the problem of misdiagnosis by harnessing the intellect, expertise and technologies developed within academic institutions, and delivering quality diagnostic information to physicians and their patients worldwide. We operate a cancer diagnostic laboratory located in New Haven, Connecticut and have partnered with various academic institutions to capture the expertise, experience and technologies developed within academia to provide a better standard of cancer diagnostics and aim to solve the growing problem of cancer misdiagnosis. In support of this platform, we also operate a research and development

facility in Omaha, Nebraska which focuses on the development of various technologies, among them our internally developed proprietary products IV-Cell and HemeScreen. To expand our product offering capabilities, the Omaha facility was recently CLIA and CAP certified in order to process a variety of commercial molecular tests previously referenced out and to further expand our capabilities and "know-how" in transitioning R&D lab generated technology into a commercial laboratory environment.

The Company also holds an exclusive license to patented ICE-COLD-PCR, or ICP technology from Dana-Farber Cancer Institute, Inc., or Dana-Farber, at Harvard University. PCR is described further below. We believe that such technology will provide additional services and products directed at improving diagnostic outcomes and providing physicians with options for targeted therapies.

In April 2020, the Company formed a joint venture with Poplar Healthcare PLLC ("Poplar"), which we refer to as the "Joint Venture". The Joint Venture was formed by the Limited Liability Company Agreement of Precipio Oncometrix LLC, a Delaware limited liability company ("POC"), which was entered into as of April 11, 2020 (the "Effective Date"), by and among POC, Poplar, and Precipio SPV Inc. ("Precipio SPV"), a newly formed subsidiary of the Company. The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based physicians, hospitals and medical centers

The Company's business is to offer an integrated platform aimed at mitigating misdiagnoses. We understand the issues of commercial laboratories because we are a commercial lab. We isolate testing process problems, we target testing cost inefficiencies, we develop testing technology to increase diagnostic accuracy and we seek out solutions to address turnaround time. Combining our commercial and development expertise with academia we continually expand relationships with subspecialists in order to provide access for physicians and patients.

Industry

We believe that there is currently a significant problem with unaddressed rates of misdiagnosis across numerous disease states (particularly in blood-related cancers) due to an inefficient and commoditized industry. We believe that the diagnostic industry focuses primarily on competitive pricing and test turnaround times, at the expense of quality and accuracy. Increasingly complex disease states are met with eroding specialization rather than increased subspecialized expertise. According to a study conducted by the National Coalition of Health, this results in an industry with cancer misdiagnosis rates as high as 28%, which is failing to meet the needs of physicians, patients and the healthcare system as a whole. New technologies offer improved accuracy; however, many are either inaccessible or are not economically practical for clinical use. Despite much publicity of the industry transitioning from fee-per-service to value-based payments, this transition has not yet occurred in diagnostics. When a patient is misdiagnosed, physicians end up administering incorrect treatments, often creating adverse effects rather than improving outcomes. We believe that Insurance Providers, Medicare and Medicaid waste valuable dollars on the application of incorrect treatments and can incur substantial downstream costs. According to a report by Pinnacle Health, the estimated cost of misdiagnosis within the healthcare system is $750 billion annually. Most importantly however, patients pay the ultimate price of misdiagnosis with increased morbidity and mortality. We are of the view that the academic path of specialization produces the critical expertise necessary to correctly diagnose disease, and that academic institutions have an untapped potential to address this problem. Our solution is to create a unique platform that harnesses sub-specialist expertise and proprietary technologies to

deliver the highest standard of diagnostic accuracy and patient care. Physicians, hospitals, payers and, most importantly, patients all benefit from more accurate diagnostic outcomes.

Market

Our market is the US domestic oncology market where we participate as a commercial diagnostic laboratory. The Oncology market is estimated to have annual revenues exceeding $20 billion. The Company also services and provides new technologies to the oncology reagent market in the form of the HemeScreen and IV-Cell product offerings. The reagent market is estimated to have annual revenues exceeding $14 billion. The annual growth rate of each market segment is estimated at 5%.

The Company currently provides diagnostic blood cancer testing services in 14 states predominately east of the Mississippi River from its New Haven, Connecticut commercial lab. Building on our commercial laboratory expertise, we have developed several impact reagent technologies that are extremely cost effective and reduce the diagnostic time and material currently needed to perform such tests. The Company anticipates gaining a share of the oncology reagent market as commercial diagnostic laboratories and oncology practices adopt its new cost effective technology. See Recent Development – Business Activities.

Our Solution

Our Platform

Our platform is designed to provide better diagnoses for cancer. To our knowledge, we are the only company focused on addressing the issue of diagnostic accuracy. Third party studies have shown misdiagnoses to be as high as 1 in 5 patients. Our operating platform has been constructed with the mission of not only providing the highest quality pathology testing services but of developing innovative products to mitigate misdiagnoses. Further, our platform enables our commercial lab to be utilized as an incubator for the development of new technologies aimed at addressing misdiagnosis.

Today, the platform is robust and scalable:

- Providing physicians and their patients access to world-class academic experts and technologies;
- Allowing payers to benefit from quality-based outcomes to their patients and increase the likelihood of cost savings;
- Enabling cross-collaboration between physicians and academic institutions to advance research and discovery; and
- Providing new technologies to laboratories worldwide that lower costs and reduce lengthy testing processes.

Our Technology

1. *IV-Cell™*

IV-Cell is a proprietary cell culture media that addresses the problem of selective and serial culturing. IV-Cell is a universal media that enables simultaneous culturing of all 4 hematopoietic cell lineages. This is a significant breakthrough in processing work required by laboratories worldwide. Internally developed by Precipio, the culturing technology ensures that no cell lineage is missed in the diagnostic process. IV-Cell allows the laboratory technician to select any of the 4 lineages during the culturing process.

Hematopoietic Diseases: The diagnostic process of hematopoietic diseases involves chromosomal analysis by conducting cell-culture based tests by a cytogenetics laboratory to imitate in-vivo conditions. The four groups of cell lineages cultured are:

- Myeloid cells – indicating myeloid neoplasms (MDS, AML, CML);

Table of Contents

- B-cells – indicating B-cell neoplasms (B-cell lymphoma, mantle cell lymphoma);
- T-cells – indicating T-cell neoplasms (T-cell lymphoma); and
- Plasma cells – indicating plasma cell neoplasms (multiple myeloma)

IV-Cell, our proprietary media, enables the lab technician to begin culturing all 4 cell lineages simultaneously, effectively mimicking human biology. IV-Cell media ensures that ultimately the correct cell lineage is cultured, avoiding the risk of misalignment caused by current market media, which may result in a compromised diagnosis. Precipio's advanced IV-Cell technology replaces the current time consuming lengthy process whereby the cytogeneticist must decide up front which cell lineage to select to be cultured. In most cases, due to specimen limitation, low cellularity, or cell viability, the cytogeneticist can select only one of the above cell lines to culture. Often, the initial clinical suspicion is not in line with the final diagnosis determined by the pathologist based on the rest of the work up. Our internal data from testing within the Company's commercial lab has shown that this occurs in approximately 40% of bone marrow biopsies. If the wrong cell lineage is selected, the diagnosis may be compromised (or return a false negative diagnosis) because the lab will be culturing and investigating the wrong cells.

Product confirmation: IV-Cell was validated in our laboratory in parallel with existing commercially available reagents and has successfully demonstrated superior results. Subsequently, IV-Cell has been used at our laboratory for the past 3 years on >1,000 clinical specimens, producing superior diagnostic results. IV-Cell also produces chromosomes with an average band resolution of 500, approximately 25% higher than achieved with standard culture media.

We are commercializing this technology by providing major laboratories with access to the media. The IV-Cell technology and media can be purchased via a direct supply contract, whereby Precipio will contract with a manufacturer (under license and non-disclosure) to produce the media.

2. HemeScreen™

HemeScreen technology that was initially developed by the Company targeting Myeloproliferative Neoplasms ("MPN") has evolved into a "suite" of robust genetic diagnostic panels. Today, the Company is marketing MPN blood cancer panel and projects the release of additional diagnostic panels during 2021. Regarding the current MPN HemeScreen panel it is estimated that annually 140,000 patients are diagnosed with the blood cancer diseases. The National Comprehensive Cancer Network (the "NCCN") guidelines require that these patients be tested for genetic mutations in five key genes:

- JAK2 (exon 12);
- JAK2 (exon 13)
  JAK2 14 (including V617F);
- CALR; and
- MPL

Precipio has registered provisional patents on its proprietary screening panel for all of the above genes. The Company's revolutionary technology enables screening to be completed in one rapid scanning process. The HemeScreen test screens for the presence of these mutations in an extremely efficient and very economical manner. In developing HemeScreen, Precipio focused on improving the economics of providing blood cancer diagnostic tests and

reducing laboratory technician time consumed in the testing process. By using Precipio's HemeScreen media laboratories can:

1. Reduce the batch requirements for the test;
2. Significantly reduce the turnaround time for results;
3. Provide improved clinical service to physicians; and
4. Yield significant costs savings.

In addressing the diagnostic results it is very important to understand that the clinical significance of these mutations is substantial to patient treatment. Case in point, a mutation in the JAK2 gene indicates the patient may be eligible for a targeted therapy. A positive result in the CALR or MPL gene indicates a good prognosis, meaning the disease

Table of Contents

is less aggressive, and the physician may therefore choose to treat the patient in a less aggressive manner. The results of these genetic tests are critical to determining a treatment plan, and therefore the importance, and the speed of which the results are delivered, may significantly impact patient care. HemeScreen represents exactly what Precipio's technology and focus is all about, targeting misdiagnoses.

Today, for this type of cancer testing we believe physician ordering patterns for the test are encumbered by the economics (reimbursement less costs to test) and length of time (2 to 4 weeks) for results to be reported. As a result of the costs and length of test reporting time, we believe, patients needing this exact type of testing, to assist in determining therapeutic options, may not be afforded the opportunity. We believe the HemeScreen technology addresses both issues by providing substantial reductions in both time and cost to test for these genetic mutations.

At the current reimbursement levels (approximately $600 for the full panel at Medicare rates) and given the costs of labor and of the existing reagents to process the tests, laboratories running the test in house must either batch samples to gain efficiency, or send the test out to another reference laboratory. Most hospital laboratories don't have the volume and patient frequency to economically justify running the test, and therefore they send the test out. This has created an industry average turnaround time for results of between 2-4 weeks (depending on the lab providing the test).

As a certified CLIA laboratory, Precipio offers HemeScreen testing and 48 hour turnaround. As a product company, Precipio has introduced the HemeScreen Reagent Rental ("HSSR") program to high-end commercial labs, regional hospital groups, large oncology practices and smaller office based oncology practices. The HSSR program is a turn-key solution offering appropriately sized diagnostic equipment, training on the equipment and new technology, and a research use only ("RUO") reagent purchase program size to the account.

At an average reimbursement rate of approximately $600 per test, the current US Market Revenue Potential is approximately $80 million per year, in addition to international demand. We believe HemeScreen is a game changer technology for these tests and we believe HemeScreen has the capability of impacting physician use of the test.

The HemeScreen technology is projected to evolve into a suite of screening products addressing numerous others genes. If successful, we therefore believe our technology may materially increase the HemeScreen market.

3. ICE-COLD-PCR

ICP technology was developed at Harvard and is licensed exclusively to us by Dana-Farber. ICP is a unique, proprietary, patented specimen enrichment technology that increases the sensitivity of molecular based tests from approximately 90-95% to 99.99%. Traditional molecular testing is done on tumor biopsies. These tests are typically conducted at disease onset, when the patient undergoes a biopsy. In the typical course of treatment, a patient is rarely re-biopsied, and therefore, genetic information is based solely on the initial biopsy. Tumors are known to shed cells into the patient's bloodstream where they circulate alongside normal cells; however, existing testing methodologies are not sufficiently sensitive to differentiate between tumor and normal cells. The increased sensitivity provided by ICP allows for testing of genetic mutations that occur within tumors to be conducted on peripheral blood samples, termed liquid biopsies. This technical capability enables physicians to test for genetic mutations through a simple blood test rather than an invasive biopsy extracted from the actual tumor. The results of such tests can be used for diagnosis, prognosis and therapeutic decisions. The technology is encapsulated within a chemical (reagent) used during the specimen preparation process, which enriches (amplifies) the tumor DNA detected within the blood sample while suppressing the normal DNA. In addition to offering this technology as a clinical service, we are developing panels that will be sold as reagent kits to other laboratories to enable this testing in their facilities, thereby improving their test sensitivity and more accurate diagnoses via liquid biopsies. The business model of selling reagents to other laboratories expands the reach and impact of our technology while eliminating the reimbursement risks from running the tests in-house.

Gene sequencing is performed on tissue biopsies taken surgically from the tumor site in order to identify potential therapies that will be more effective in treating the patient. There are several limitations to this process. First, surgical procedures have several limitations, including:

- Cost: surgical procedures are usually performed in a costly hospital environment;

Table of Contents

- Surgical access: various tumor sites are not always accessible (e.g. brain tumors), in which cases no biopsy is available for diagnosis;
- Risk: patient health may not permit undergoing an invasive surgery; therefore, a biopsy cannot be obtained at all; and
- Time: the process of scheduling and coordinating a surgical procedure often takes time, delaying the start of patient treatment.

Second, there are several tumor-related limitations that provide a challenge to obtaining such genetic information from a tumor:

- Tumors are heterogeneous by nature: a tissue sample from one area of the tumor may not properly represent the tumor's entire genetic composition; thus, the diagnostic results from a tumor may be incomplete and non-representative.
- Metastases: in order to accurately test a patient with metastatic disease, ideally an individual biopsy sample should be taken from each site (if those sites are even known). These biopsies are very difficult to obtain; therefore, physicians often rely on biopsies taken only from the primary tumor site.

We license the ICP technology from Dana-Farber through a license agreement referred to herein as the License Agreement. The License Agreement grants us an exclusive license to the ICP technology, subject to a non-exclusive license granted to the U.S. government, in the areas of mutation detection using Sanger (di-deoxy) sequencing and mitochondrial DNA analysis for all research, diagnostic, prognostic and therapeutic uses in humans, animals, viruses, bacteria, fungi, plants or fossilized material. The License Agreement also grants us a non-exclusive license in the areas of mutation detection using DHPLC, surveyor-endonuclease-based mutation detection and next generation sequencing techniques. We paid Dana-Farber an initial license fee and are required to make milestone payments with respect to the first five licensed products or services we develop using the licensed technology, as well as royalties ranging from high single to low double digits on net sales of licensed products and services for sales made by us and sales made to any distributors. The License Agreement remains in effect until we cease to sell licensed products or services under said agreement. Dana-Farber has the right to immediately terminate the License Agreement if (i) we cease to carry on our business with respect to licensed products and services, (ii) we fail to make any payments under the License Agreement (subject to a cure period), (iii) we fail to comply with due diligence obligations under the License Agreement (subject to a cure period), (iv) we default in our obligations to procure and maintain insurance as required by the License Agreement, (v) any of our officers is convicted of a felony relating to the manufacture, use, sale or importation of licensed products under the License Agreement, (vi) we materially breach any provision of the License Agreement (subject to a cure period), or (vii) we or Dana-Farber become insolvent. We may terminate the License Agreement for convenience upon 180 days' prior written notice.

Our Products & Services

Our offerings consist of clinical diagnostic services harnessing the expertise of pathologists from premier academic institutions and the commercialization and application of our various technologies. Our clinical diagnostic services focus on the diagnosis of different hematopoietic or blood-related cancers and the delivery of an accurate diagnosis to oncologists, with demonstrated superior results through the harnessing of subspecialized academic pathologists. Our proprietary cytogenetics media IV-Cell enables laboratories to arrive at more accurate results while reducing inventory and other operating costs. Our proprietary HemeScreen panels enable hospitals and laboratories (whether reference labs or physician-office labs, called POLs) to run an important genetic mutation test at an economically lower cost, resulting in faster results delivered to physicians and their patients. Our liquid biopsy technology, ICP, enables detection of abnormalities in blood samples down to as low as .01%. Our COVID testing distribution agreements enable the Company to provide to Point-of-Care providers an easy to use, highly accurate (<99%) 10 minute FDA approved COVID anti-body test. Our customers are oncologists, hospitals, reference laboratories, POLs, pharma and biotech companies. The Company believes that its technologies enable customers to achieve more accurate results for their patients, with improved economics, as well as providing results that could lead to improvements in clinical outcomes.

We provide our CLIA and CAP certified laboratory services and products in our New Haven CT and Omaha NE facilities. Laboratory operations include sub-departments such as flow cytometry, immuno-histochemistry, cytogenetics,

Table of Contents

and molecular testing. Our laboratory operations are directed by our Chief Medical Officer, a board certified pathologist. As mandated by State and Federal regulations our laboratory is inspected every two years by a Connecticut state-appointed inspector and/or CAP. Furthermore, the laboratory supervisors and medical director must

conduct a self-inspection every two years (rotating with the state inspection) and must submit those results to the state department of health. Our facility in Omaha was also recently certified as a CLIA and CAP facility.

Our Strategy

Our vision is to mitigate the problem of cancer misdiagnosis, caused by two industry-wide problems. The first problem is the lack of access to subspecialist expertise; the second is addressing diagnostic costs and time to test. In order to accomplish our vision we have established two folds to our business. The first is the pathology/diagnostic business which is aimed at addressing the first problem of subspecialist expertise. Our platform enables subspecialist expertise to be aggregated. Utilizing academic expert pathologists across multiple academic institutions enables the Company to provide access for the community based oncologist to subspecialists. The second aspect of our business is the development of products/technologies that improve commercial laboratory testing quality, lower costs and significantly reduce the diagnostic time to test.

In support of our strategy, the Company's commercial laboratory serves two functions. First, it serves our oncology customers by analyzing the patient biopsies received using the technologies we've developed. The goal is to provide them with a diagnosis rendered by an expert and as required an academic subspecialist. The second function of our commercial lab is to serve as an incubator for our R&D center to design, develop and test new technologies. The Company recognizes the importance of development but prides itself on truly understanding how to transition technology from the R&D lab to a commercial lab setting. The importance of being able to prove the efficacy of new technology in a commercial lab environment over long periods of time and a large four-digit sample size is invaluable.

Competition

Our principal competition in clinical pathology services comes largely from two groups. The first group consists of companies that specialize in oncology and offer directly competing services to our diagnostic services. These companies provide a high level of service focused on oncology and offer their services to oncologists and pathology departments within hospitals. Competitors in this group include Neogenomics, GenPath Diagnostics and Inform Diagnostics. The second group consists of large commercial companies that offer a wide variety of laboratory tests ranging from simple chemistry tests to complex genetic testing. Competitors in this group include LabCorp and Quest Diagnostics. Within the liquid biopsy market, our competitors include Foundation Medicine, Guardant Health and Trovagene, Inc.

Competitive Advantage

In addition to our internally generated products, the Company capitalizes on the intellectual expertise and technologies developed by experts within academic institutions. While several industry papers report a case misdiagnosis rate as high as 28%, we believe that leveraging our assets with academic expertise can significantly reduce this rate. In an initial data set of over 100 clinical cases received and processed by us and with a diagnosis rendered by academic pathologists, we believe less than 1% have resulted in misdiagnosis. The diagnostic report provided by us was then requested by a patient or the patient's physician for a second opinion to be conducted by another laboratory. In these instances, less than 1% were in disagreement with our report's original diagnosis. Though less than 5% of all cancer patients are treated in academic centers that benefit from this specialized expertise, the majority of patients are diagnosed by commercial reference laboratories. These commercial laboratories and diagnostic companies have broad access to and serve over 95% of all cancer patients; however, their lack of specialized expertise results in significantly higher misdiagnosis rates. Academic institutions also invest heavily in the development of new technologies, most of which is used internally and does not benefit outside or commercial lab patients. Our platform provides all patients with access to these innovative technologies developed by us and in collaboration with other academic institutions we engage with.

Table of Contents

Government Regulation

The healthcare industry is subject to extensive regulation by a number of governmental entities at the federal, state and local level. Laws and regulations in the healthcare industry are extremely complex and, in many instances, the industry does not have the benefit of significant regulatory or judicial interpretation. Our business is impacted not only by those laws and regulations that are directly applicable to us but also by certain laws and regulations that are applicable to our payers, vendors and referral sources. While our management believes we are in compliance with all of the existing laws and regulations applicable to us, such laws and regulations are subject to rapid change and often are uncertain in their application and enforcement. Further, to the extent we engage in new business initiatives, we must continue to evaluate whether new laws and regulations are applicable to us. There can be no assurance that we will not be subject to scrutiny or challenge under one or more of these laws or that any enforcement actions would not be successful. Any such challenge, whether or not successful, could have a material adverse effect upon our business and consolidated financial statements.

Our current active laboratory certifications can be found on http://www.precipiodx.com/accreditations.html. The laboratory operations are governed by Standard Operating Procedure manuals, or SOPs, which detail each aspect of the laboratory environment including the work flow, quality control, maintenance, and safety. These SOPs are reviewed and approved annually and signed off by the laboratory manager and medical director.

Among the various federal and state laws and regulations that may govern or impact our current and planned operations are the following:

Reimbursement

As blood-related cancers are more likely to be developed later in life, the largest insurance provider is Medicare, which constitutes approximately 40% of our patients' cases. Non-Medicare patients are typically insured by private insurance companies who provide patient coverage and pay for patients' health-related costs. These private insurance companies will often adjust their rates according to the insurance rates annually published by the Center for Medicare and Medicaid Services, or CMS. We, and other providers, typically bill according to the codes relevant to the tests we conduct.

Medicare and Medicaid Reimbursement

Many of the services that we provide are reimbursed by Medicare and state Medicaid programs and are therefore subject to extensive government regulation.

Medicare is a federally funded program that provides health insurance coverage for qualified persons age 65 or older, some disabled persons, and persons with end-stage renal disease and persons with Lou Gehrig's disease. Medicaid programs are jointly funded by the federal and state governments and are administered by states under approved plans.

Medicaid provides medical benefits to eligible people with limited income and resources and people with disabilities, among others. Although the federal government establishes general guidelines for the Medicaid program, each state sets its own guidelines regarding eligibility and covered services. Some individuals, known as "dual eligibles", may be eligible for benefits under both Medicare and a state Medicaid program. Reimbursement under the Medicare and Medicaid programs is contingent on the satisfaction of numerous rules and regulations, including those requiring certification and/or licensure. Congress often enacts legislation that affects the reimbursement rates under government healthcare programs.

Approximately 40% of our revenue for the year ended December 31, 2020 was derived directly from Medicare, Medicaid or other government-sponsored healthcare programs. Also, we indirectly provide services to beneficiaries of Medicare, Medicaid and other government-sponsored healthcare programs through managed care

entities. Should there be material changes to federal or state reimbursement methodologies, regulations or policies, our direct reimbursements from government-sponsored healthcare programs, as well as service fees that relate indirectly to such reimbursements, could be adversely affected.

Table of Contents

Healthcare Reform

In recent years, federal and state governments have considered and enacted policy changes designed to reform the healthcare industry. The most prominent of these healthcare reform efforts, the Affordable Care Act, has resulted in sweeping changes to the U.S. system for the delivery and financing of health care. As currently structured, the Affordable Care Act increases the number of persons covered under government programs and private insurance; furnishes economic incentives for measurable improvements in health care quality outcomes; promotes a more integrated health care delivery system and the creation of new health care delivery.

Research and Development Expenses

For the years ended December 31, 2020 and 2019, we recorded $1.2 million, respectively, of research and development expenses. More information regarding our research and development activities can be found in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" under Item 7 of this Annual Report.

Employees

As of March 25, 2021, Precipio employed fifty-four (54) employees on a full-time basis and three (3) employees on a part-time basis. Of the total, twelve (12) were in Finance, General and Administration, twenty-one (21) were in laboratory operations, ten (10) were in Sales and Marketing, five (5) were in Customer Service and Support and nine (9) were in Research & Development.

Executive Officers of the Registrant

Our executive officers, their ages as of March 25, 2021 and their respective positions are as follows:

Ilan Danieli, Chief Executive Officer, age 49

Mr. Danieli was the founder of Precipio Diagnostics LLC and was the Chief Executive Officer of Precipio Diagnostics LLC since 2011. Mr. Danieli assumed the role of Chief Executive Officer of Precipio, Inc. at the time of a June 2017 merger transaction (the "Merger"). With over 20 years managing small and medium-size companies, some of his previous experiences include COO of Osiris, a publicly-traded company based in New York City with operations in the US, Canada, Europe and Asia; VP of Operations for Laurus Capital Management, a multi-billion dollar hedge fund; and in various other entrepreneurial ventures. Ilan holds an MBA from the Darden School at the University of Virginia, and a BA in Economics from Bar-Ilan University in Israel.

Carl R. Iberger, Chief Financial Officer, age 68

Mr. Iberger was named Chief Financial Officer in October 2016. For the years 1990 through 2015, Mr. Iberger held the positions of Chief Financial Officer and Executive Vice President at Dianon Systems, DigiTrace Care Services and SleepMed, Inc. Mr. Iberger has significant diagnostic healthcare experience in mergers and acquisitions, private equity transactions, public offerings and executive management in high growth environments. Mr. Iberger holds a Master's Degree in Finance from Hofstra University and a Bachelor of Science Degree in Accounting from the University of Connecticut.

Compliance with Environmental Laws

We believe we are in compliance with current environmental protection requirements that apply to us or our business. Costs attributable to environmental compliance are not currently material.

Intellectual Property

Table of Contents

We license the ICP technology from Dana-Farber through the License Agreement. The License Agreement grants us an exclusive license to the ICP technology, subject to a non-exclusive license granted to the U.S. government, in the areas of mutation detection using Sanger (di-deoxy) sequencing and mitochondrial DNA analysis for all research, diagnostic, prognostic and therapeutic uses in humans, animals, viruses, bacteria, fungi, plants or fossilized material. The Company has filed provisional patents for its proprietary HemeScreen and IV-Cell technologies.

Corporate History

Precipio, Inc. was incorporated in Delaware on March 6, 1997. Our principal office is located at 4 Science Park, New Haven, Connecticut 06511.

Our internet address is www.precipiodx.com. Information found on our website is not incorporated by reference into this report. We make available free of charge through our website our Securities and Exchange Commission, or SEC, filings furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors

The following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes, should be considered carefully. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations, and could cause the market price of our common stock to fluctuate or decline.

Risk factor Summary

- There is substantial doubt about our ability to continue as a going concern.
- We will require significant additional financing to sustain our operations and without it we will not be able to continue operations.

- We will need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations.
- We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability
- We are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable.
- We have been, and may continue to be, subject to costly litigation.
- The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payers and the medical community and on our ability to successfully market our product candidates.
- If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.
- We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.
- We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID-19, which could significantly disrupt our operations and impact our financial results.
- We may experience temporary disruptions and delays in processing biological samples at our facilities.
- We depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the execution of our strategy, management of our business and commercialization of our product candidates could be delayed or negatively impacted.
- We will need to increase the size of our organization, and we may experience difficulties in managing growth.

Table of Contents

- We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue.
- Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer.
- Our ability to use net operating loss carryforwards to offset future taxable income for U.S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses.
- We face risks related to the PPP Loan which could negatively impact our financial position.
- Governmental payers and health care plans have taken steps to control costs.
- Changes in payer mix could have a material adverse impact on our net sales and profitability.
- Our laboratories require ongoing CLIA certification.
- Failure to comply with HIPAA could be costly.

- Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations.
- We may become subject to the Anti-Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws.
- We cannot be certain that measures taken to protect our intellectual property will be effective.
- We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling some of our products.
- Third parties may assert ownership or commercial rights to inventions we develop.
- Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.
- The testing, manufacturing and marketing of medical diagnostic devices entails an inherent risk of product liability and personal injury claims.
- All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.
- An impairment in the carrying value of our intangible assets could negatively affect our results of operations
- The price of our common stock may fluctuate significantly, which could negatively affect us and holders of our common stock.
- The price of our stock may be vulnerable to manipulation.
- If we cannot continue to satisfy Nasdaq listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities.
- Increased costs associated with corporate governance compliance may significantly impact our results of operations.
- We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.
- If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.
- The sale or issuance of our common stock to Lincoln Park may cause significant dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

Table of Contents

- The issuance of our common stock to creditors or litigants may cause significant dilution to our stockholders and cause the price of our common stock to fall.

Risks Related to Our Business and Strategy

There is substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has issued an opinion on our consolidated financial statements included in this Annual Report on Form 10-K that states that the consolidated financial statements were prepared assuming we will continue as a going concern. Our consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have used cash in our operating activities for the past few years. As of and for the year ended December 31, 2020, we had a net loss of $10.6 million, negative working capital of $0.5 million and net cash used in operating activities of $7.4 million. Our consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We also cannot be certain that additional financing, if needed, will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations. There remains substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued.

To date, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur substantial net losses for the foreseeable future to further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

Because of the numerous risks and uncertainties associated with further development and commercialization of our diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our diagnostic technology or any future tests, and our business may fail.

We will require significant additional financing to sustain our operations and without it we will not be able to continue operations.

At December 31, 2020, we had a working capital deficit of $0.5 million. We had an operating cash flow deficit of $7.4 million for the year ended December 31, 2020 and a net loss of $10.6 million for the year ended December 31, 2020. We do not currently have sufficient financial resources to fund our operations or those of our subsidiaries. Therefore, we need additional funds to continue these operations.

To facilitate ongoing operations and product development, on March 26, 2020, the Company entered into a purchase agreement with Lincoln Park (the "LP 2020 Purchase Agreement"), pursuant to which Lincoln Park has agreed to purchase up to an aggregate of $10,000,000 of common stock of the Company (subject to certain limitations) from time to time over the term of the LP Purchase Agreement.

The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from Lincoln Park were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $10,000,000 under the Purchase Agreement to Lincoln Park, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively

expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects. As of the date the consolidated financial statements were issued, we have already received $8.8 million from the LP 2020 Purchase Agreement from the sale of 4,980,000 shares of common stock to Lincoln Park from April 1, 2020 through the date the consolidated financial statements were issued.

We will need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations.

As of December 31, 2020, we had cash of $2.7 million and our working capital was approximately negative $0.5 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates and to pay off our obligations. To date, to fund our operations and develop and commercialize our products, we have relied primarily on equity and debt financings. When we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unattractive terms.

We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability.

We have incurred losses since our inception and expect to incur losses in the future. As of and for the year ended December 31, 2020, we had a net loss of $10.6 million, negative working capital of $0.5 million and net cash used in operating activities of $7.4 million. For the year ended December 31, 2020, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur substantial net losses for the foreseeable future to further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

Because of the numerous risks and uncertainties associated with further development and commercialization of our diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our diagnostic technology or any future tests, and our business may fail.

We are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable.

We have had several customers who, from time to time, have individually represented 10% or more of our total revenue, or whose accounts receivable balances individually represented 10% or more of our total accounts receivable.

For the year ended December 31, 2020, no customer individually represented 10% or more of our total revenue. For the year ended December 31, 2019, two customers represented approximately 30% of our total revenue. We expect to maintain the relationship with these customers, however, the loss of, or significant decrease in demand from, any of our top customers could have a material adverse effect on our business, results of operations and financial condition.

At December 31, 2020, no customer represented 10% or more of our total accounts receivable. At December 31, 2019, two customers accounted for approximately 29% of our total accounts receivable. The business risks associated

Table of Contents

with this concentration, including increased credit risks for these and other customers and the possibility of related bad debt write-offs, could negatively affect our margins and profits. Additionally, the loss of any of our top customers, whether through competition or consolidation, or a disruption in sales to such a customer, could result in a decrease of the Company's future sales, earnings and cash flows. Generally, we do not require collateral or other securities to support our accounts receivable and while we are directly affected by the financial condition of our customers, management does not believe significant credit risks exist at December 31, 2020.

We have been, and may continue to be, subject to costly litigation.

We have been, and may continue to be, subject to legal proceedings. Due to the nature of our business and our lack of sufficient capital resources to pay our obligations on a timely basis, we may be subject to a variety of regulatory investigations, claims, lawsuits and other proceedings in the ordinary course of our business. The results of these legal proceedings cannot be predicted with certainty due to the uncertainty inherent in litigation, including the effects of discovery of new evidence or advancement of new legal theories, the difficulty of predicting decisions of judges and juries and the possibility that decisions may be reversed on appeal. Such litigation has been, and in the future, could be, costly, time-consuming and distracting to management, result in a diversion of resources and could materially adversely affect our business, financial condition and operating results.

In addition, we may settle some litigation through the issuance of equity securities which may result in significant dilution to our stockholders.

The commercial success of our product candidates will depend upon the degree of market acceptance of these products among physicians, patients, health care payers and the medical community and on our ability to successfully market our product candidates.

Our products may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our existing and future products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and their potential advantages over existing diagnostics technology;
- the willingness of physicians and patients to utilize our products; and

- the agreement by commercial third-party payers and government payers to reimburse our products, the scope and amount of which will affect patients' willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products.

In addition, physicians may rely on guidelines issued by industry groups, such as the NCCN, medical societies, such as the College of American Pathologists, or CAP, or other key oncology-related organizations before utilizing any diagnostic test. Although we have a study underway to demonstrate the clinical utility of our existing products, none of our products are, and may never be, listed in any such guidelines.

We believe that publications of scientific and medical results in peer-reviewed journals and presentations at leading conferences are critical to the broad adoption of our products. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our products sufficiently novel or worthy of publication. The failure to be listed in physician guidelines or to be published in peer-reviewed journals could limit the adoption of our products. Failure to achieve widespread market acceptance of our products would materially harm our business, financial condition, and results of operations.

If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

The medical diagnostic industry is intensely competitive and characterized by rapid technological progress. We face significant competition from competitors ranging in size from diversified global companies with significant research and development resources to small, specialized firms whose narrower product lines may allow them to be more effective

Table of Contents

in deploying related PCR technology in the genetic diagnostic industry. Our closest competitors fall largely into two groups, consisting of companies that specialize in oncology and offer directly competing services to our diagnostic services, offering their services to oncologists and pathology departments within hospitals, as well as large commercial companies that offer a wide variety of laboratory tests that range from simple chemistry tests to complex genetic testing. The technologies associated with the molecular diagnostics industry are evolving rapidly and there is intense competition within such industry. Certain molecular diagnostics companies have established technologies that may be competitive to our product candidates and any future tests that we develop. Some of these tests may use different approaches or means to obtain diagnostic results, which could be more effective or less expensive than our tests for similar indications. Moreover, these and other future competitors have or may have considerably greater resources than we do in terms of technology, sales, marketing, commercialization and capital resources. These competitors may have substantial advantages over us in terms of research and development expertise, experience in clinical studies, experience in regulatory issues, brand name exposure and expertise in sales and marketing as well as in operating central laboratory services. Many of these organizations have financial, marketing and human resources greater than ours; therefore, there can be no assurance that we can successfully compete with present or potential competitors or that such competition will not have a materially adverse effect on our business, financial position or results of operations.

We are currently engaged in a study, which commenced in July 2017, to demonstrate the impact of academic pathology expertise on diagnostic accuracy. There is no assurance that this study, or other studies or trials we may conduct, will demonstrate favorable results. If the results of this study, or other studies or trials we may conduct,

demonstrate unfavorable or inconclusive results, customers may choose our competitors' products over our products and our commercial opportunities may be reduced or eliminated.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new diagnostic tools or develop existing technologies to compete with our diagnostic technology. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, are more convenient or are less expensive than our product candidates.

We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.

Our success depends on our ability to develop new products and applications for our diagnostic technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems. Existing or future markets for our products, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or effectively manage the transitions to new product offerings, our revenues and results of operations will be adversely impacted.

Competitors may respond more quickly and effectively than we do to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

Table of Contents

We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID-19, which could significantly disrupt our operations and impact our financial results.

Our business could be disrupted and materially adversely affected by the recent outbreak of COVID-19. In December 2019, an outbreak of respiratory illness caused by a strain of novel coronavirus, COVID-19, began in China. As of March 2021, that outbreak has led to numerous confirmed cases worldwide, including in the United States. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce. Global health concerns, such as coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

The spread of COVID-19 has created a worldwide humanitarian and economic crisis. The events we are living through are in many ways unprecedented, with large-scale quarantines, border closings, school closings, and

physical distancing. Governments and communities have been jolted into action to "flatten the curve." As an organization we have accelerated our actions to protect employees, customers and suppliers.

The progression of the outbreak and its effects on our business and operations are uncertain. While we can only estimate the financial impacts to our business, based on current data, we have experienced business interruptions in certain urban markets that continue to range from 30% to 85%. With the understanding that it is extremely difficult to project the full and ongoing impact of state-by-state quarantine and shelter-in-place orders, we anticipate that such rules and restrictions on businesses will continue through 2021 and quite possibly beyond, in various degrees, as the country re-opens state by state, county by county and city by city. Returning to normalcy is conditioned on many factors surrounding the control and or eradication of COVID-19. As such, we are unable to provide additional insight on the impact to our business at this time.

Going forward, we expect that challenges to our business will continue. We have been and will continue to be prudent in managing through this economic crisis. Digital connectivity is now fundamental to the continuity of our business operations. We continually engage our employees and customers in keeping safe. We monitor adherence to governmental guidelines. We have employed remote work where possible. In this unchartered time, we recognize the need for frequent and transparent communication to all parties. As necessary, we will provide additional information related to this economic condition, including the impact to our future operating results due to downturns in global economies and financial markets.

We may experience temporary disruptions and delays in processing biological samples at our facilities.

We may experience delays in processing biological samples caused by software and other errors. Any delay in processing samples could have an adverse effect on our business, financial condition and results of operations.

We depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the execution of our strategy, management of our business and commercialization of our product candidates could be delayed or negatively impacted.

Our success is largely dependent upon the continued contributions of our officers and employees. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. In order to pursue our test development and commercialization strategies, we will need to attract and hire additional personnel with specialized experience in a number of disciplines, including assay development, laboratory and clinical operations, sales and marketing, billing and reimbursement. There is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any future tests could be delayed or negatively impacted. If any of them becomes unable or unwilling to continue in their respective positions, and we are unable to find suitable replacements, our business and financial results could be materially negatively affected.

Table of Contents

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 54 full-time employees as of March 25, 2021. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the

progress of our development of diagnostic technology. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- integrate additional management, administrative, manufacturing and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue.

We have developed limited experience in marketing our products and services. We intend to continue to develop our in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other diagnostic companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to further grow our internal sales, marketing and distribution capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our product candidates or future products, however, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, they may not have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer.

Cybersecurity refers to the combination of technologies, processes and procedures established to protect information technology systems and data from unauthorized access, attack, or damage. We rely on our information systems to provide security for processing, transmission and storage of confidential information about our patients, customers and personnel, such as names, addresses and other individually identifiable information protected by the Health Insurance Portability and Accountability Act, ("HIPAA"), other privacy laws. Cyber-attacks are increasingly more common, including in the health care industry. The regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and with rapidly evolving industry standards may result in our incurring significant expense due to increased investment in technology and the development of new operational processes.

We have not experienced any known attacks on our information technology systems that compromised any confidential information. We maintain our information technology systems with safeguard protection against cyber-attacks including passive intrusion protection, firewalls and virus detection software. However, these safeguards do not ensure that a significant cyber-attack could not occur. Although we have taken steps to protect the security of our information systems and the data maintained in those systems, it is possible that our safety and security measures will not prevent the systems' improper functioning or damage or the improper access or disclosure of personally identifiable information such as in the event of cyber-attacks.

Table of Contents

Security breaches, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches can create system disruptions or shutdowns or the unauthorized disclosure of confidential information. If personal information or protected health information is improperly accessed, tampered with or disclosed as a result of a security breach, we may incur significant costs to notify and mitigate potential harm to the affected individuals, and we may be subject to sanctions and civil or criminal penalties if we are found to be in violation of the privacy or security rules under HIPAA or other similar federal or state laws protecting confidential personal information. In addition, a security breach of our information systems could damage our reputation, subject us to liability claims or regulatory penalties for compromised personal information and could have a material adverse effect on our business, financial condition and results of operations.

Our ability to use net operating loss carryforwards to offset future taxable income for U.S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses.

Under U.S. federal income tax law, a corporation's ability to utilize its net operating losses, or NOLs, to offset future taxable income may be significantly limited if it experiences an "ownership change" as defined in Section 382 of the Internal Revenue Code, as amended. In general, an ownership change will occur if there is a cumulative change in a corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). The annual limitation for a taxable year generally is increased by the amount of any "recognized built-in gains" for such year and the amount of any unused annual limitation in a prior year. On December 22, 2017, a law commonly known as the Tax Cuts and Jobs Act, or the TCJ Act, was enacted in the United States. Certain provisions of the TCJ Act impact the ability to utilize NOLs generated in 2018 and forward; any limitation to our annual use of NOLs could require us to pay a greater amount of U.S. federal (and in some cases, state) income taxes, which could reduce our after-tax income from operations for future taxable years and adversely impact our financial condition. Beginning in 2018, under the Act, federal loss carryforwards have an unlimited carryforward period, however such losses can only offset 80% of taxable income in any one year.

We face risks related to the Paycheck Protection Program loan (PPP Loan), which could negatively impact our financial position.

On April 23, 2020, the Company entered into the Promissory Note evidencing an unsecured $787,200 loan under the PPP. The PPP was established under the recently congressionally-approved CARES Act and is administered by the U.S. Small Business Administration ("SBA"). The PPP Loan to the Company is being made through Webster Bank, N.A.

The term of the PPP Loan is two years. The interest rate on the PPP Loan is 1.00% and payments are deferred for the first six months of the term of the loan. Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payroll costs and mortgage interest, rent or utility costs and the maintenance of employee and compensation levels. The Company believes it used all of the PPP Loan amount for qualifying expenses. On February 11, 2021, the Company filed its application for loan forgiveness with Webster Bank but no assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. If forgiveness is not granted by the SBA, the PPP Loan, in whole or in part, will need to be repaid by the Company, which could have an adverse effect on our future cash flows and financial position.

Reimbursement and Regulatory Risks Relating to Our Business

Governmental payers and health care plans have taken steps to control costs.

Medicare, Medicaid and private insurers have increased their efforts to control the costs of health care services, including clinical testing services. They may reduce fee schedules or limit/exclude coverage for certain types of tests that we perform. Medicaid reimbursement varies by state and is subject to administrative and billing requirements and budget pressures. We expect efforts to reduce reimbursements, impose more stringent cost controls and reduce utilization of

Table of Contents

testing services will continue. These efforts, including changes in laws or regulations, may have a material adverse impact on our business.

Changes in payer mix could have a material adverse impact on our net sales and profitability.

Testing services are billed to physicians, patients, government payers such as Medicare, and insurance companies. Tests may be billed to different payers depending on a particular patient's medical insurance coverage. Government payers have increased their efforts to control the cost, utilization and delivery of health care services as well as reimbursement for laboratory testing services. Further reductions of reimbursement for Medicare and Medicaid services or changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization or a physician or qualified practitioner's signature on test requisitions, may be implemented from time to time. Reimbursement for the laboratory services component of our business is also subject to statutory and regulatory reduction. Reductions in the reimbursement rates and changes in payment policies of other third party payers may occur as well. Such changes in the past have resulted in reduced payments as well as added costs and have decreased test utilization for the clinical laboratory industry by adding more complex new regulatory and administrative requirements. As a result, increases in the percentage of services billed to government payers could have an adverse impact on our net sales.

Our laboratories require ongoing CLIA certification.

The Clinical Laboratory Improvement Amendments of 1988, or CLIA, extended federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. The CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories must also undergo proficiency testing and are subject to inspections.

The sanctions for failure to comply with the CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could have a material adverse effect on us.

We believe that we are in compliance with all applicable laboratory requirements, but no assurances can be given that our laboratories will pass all future certification inspections.

Failure to comply with HIPAA could be costly.

HIPAA and associated regulations protect the privacy and security of certain patient health information and establish standards for electronic health care transactions in the United States. These privacy regulations establish federal standards regarding the uses and disclosures of protected health information. Our laboratories are subject to HIPAA and its associated regulations. If we fail to comply with these laws and regulations we could suffer civil and criminal penalties, fines, exclusion from participation in governmental health care programs and the loss of various licenses, certificates and authorizations necessary to operate our patient testing business. We could also incur liabilities from third party claims.

Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations.

Our research and development and commercial activities involve the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and international laws and regulations governing the use, storage, handling and disposal of hazardous materials and waste products. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. We cannot be certain that accidental contamination or injury will not occur. Any such accident could damage our research and manufacturing facilities and operations, resulting in delays and increased costs.

Table of Contents

We may become subject to the Anti-Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws.

There are several federal laws addressing fraud and abuse that apply to businesses that receive reimbursement from a federal health care program. There are also a number of similar state laws covering fraud and abuse with respect to, for example, private payers, self-pay and insurance. Currently, we receive a substantial percentage of our revenue from private payers and from Medicare. Accordingly, our business is subject to federal fraud and abuse laws, such as the Anti-Kickback Statute, the Stark Law, the False Claims Act, the Civil Monetary Penalties Law and other similar laws. Moreover, we are already subject to similar state laws. We believe we have operated, and intend to continue to operate, our business in compliance with these laws. However, these laws are subject to modification and changes in interpretation, and are enforced by authorities vested with broad discretion. Federal and state enforcement entities have significantly increased their scrutiny of healthcare companies and providers which has led to investigations, prosecutions, convictions and large settlements. We continually monitor developments in this area. If these laws are interpreted in a manner contrary to our interpretation or are reinterpreted or amended, or if new legislation is enacted with respect to healthcare fraud and abuse, illegal remuneration, or similar issues, we may be required to restructure our affected operations to maintain compliance with applicable law. There can be no assurances that any such restructuring will be possible or, if possible, would not have a material adverse effect on our results of operations, financial position, or cash flows.

Anti-Kickback Statute

A federal law commonly referred to as the "Anti-Kickback Statute" prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in return for 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 term "remuneration" has been broadly interpreted to include anything of value such as gifts, discounts, rebates, waiver of payments or providing anything at less than its fair market value. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or the PPACA, amended the intent requirement of the Anti-Kickback Statute such that a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate the statute. Further, the PPACA now provides that claims submitted in violation of the Anti-Kickback Statute constitute false or fraudulent claims for purposes of the federal False Claims Act, or FCA, including the failure to timely return an overpayment. Many states have adopted similar prohibitions against kickbacks and other practices that are intended to influence the purchase, lease or ordering of healthcare items and services reimbursed by a governmental health program or state Medicaid program. Some of these state prohibitions apply to remuneration for referrals of healthcare items or services reimbursed by any third-party payer, including commercial payers and self-pay patients.

Stark Law

Section 1877 of the Social Security Act, or the Stark Law, prohibits a physician from referring a patient to an entity for certain "designated health services" reimbursable by Medicare if the physician (or close family members) has a financial relationship with that entity, including an ownership or investment interest, a loan or debt relationship or a compensation relationship, unless an exception to the Stark Law is fully satisfied. The designated health services covered by the law include, among others, laboratory and imaging services. Some states have self-referral laws similar to the Stark Law for Medicaid claims and commercial claims.

Violation of the Stark Law may result in prohibition of payment for services rendered, a refund of any Medicare payments for services that resulted from an unlawful referral, $15,000 civil monetary penalties for specified infractions, criminal penalties, and potential exclusion from participation in government healthcare programs, and potential false claims liability. The repayment provisions in the Stark Law are not dependent on the parties having an improper intent; rather, the Stark Law is a strict liability statute and any violation is subject to repayment of all amounts arising out of tainted referrals. If physician self-referral laws are interpreted differently or if other legislative restrictions are issued, we could incur significant sanctions and loss of revenues, or we could have to change our arrangements and operations in a way that could have a material adverse effect on our business, prospects, damage to our reputation, results of operations and financial condition.

Table of Contents

False Claims Act

The FCA prohibits providers from, among other things, (1) knowingly presenting or causing to be presented, claims for payments from the Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; (2) knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the federal government; or (3) knowingly making, using or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. The "qui tam" or "whistleblower" provisions of the FCA allow private individuals to bring actions under the FCA on behalf of

the government. These private parties are entitled to share in any amounts recovered by the government, and, as a result, the number of "whistleblower" lawsuits that have been filed against providers has increased significantly in recent years. Defendants found to be liable under the FCA may be required to pay three times the actual damages sustained by the government, plus civil penalties ranging between $5,500 and $11,000 for each separate false claim.

There are many potential bases for liability under the FCA. The government has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, billing for services not provided, and providing care that is not medically necessary or that is substandard in quality. The PPACA also provides that claims submitted in connection with patient referrals that result from violations of the Anti-Kickback Statute constitute false claims for the purpose of the FCA, and some courts have held that a violation of the Stark law can result in FCA liability, as well. In addition, a number of states have adopted their own false claims and whistleblower provisions whereby a private party may file a civil lawsuit in state court. We are required to provide information to our employees and certain contractors about state and federal false claims laws and whistleblower provisions and protections.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person or entity knows or should know is likely to influence the beneficiary's selection of a particular provider or supplier of items or services reimbursable by a federal or state healthcare program. This broad provision applies to many kinds of inducements or benefits provided to patients, including complimentary items, services or transportation that are of more than a nominal value. This law could affect how we have to structure our operations and activities.

Intellectual Property Risks Related to Our Business

We cannot be certain that measures taken to protect our intellectual property will be effective.

We rely upon trade secrets, copyright and trademark laws, non-disclosure agreements and other contractual confidentiality provisions to protect our confidential and proprietary information that we are not seeking patent protection for various reasons. Such measures, however, may not provide adequate protection for our trade secrets or other proprietary information. If such measures do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling some of our products.

We have entered into license agreements with third parties for certain licensed technologies that are, or may become, relevant to the products we market, or plan to market, including our license agreement with Dana-Farber pursuant to which we license our ICP technology. In addition, we may in the future elect to license third party intellectual property to further our business objectives and/or as needed for freedom to operate for our products. We do not and will not own the patents, patent applications or other intellectual property rights that are the subject of these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents, patent applications and other intellectual property rights are or will be subject to the continuation of and compliance with the terms of those licenses.

We might not be able to obtain licenses to technology or other intellectual property rights that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or multiple licenses may be needed for the same product (e.g., stacked royalties). We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In some cases, we do not or may not control the prosecution, maintenance, or filing of the patents or patent applications to which we hold licenses, or the enforcement of these patents against third parties. As a result, we cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, third parties that have been introduced to or have benefited from our inventions may attempt to replicate or reverse engineer our products and circumvent ownership of our inventions. In addition, we may face claims that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

The testing, manufacturing and marketing of medical diagnostic devices entails an inherent risk of product liability and personal injury claims.

To date, we have experienced no product liability or personal injury claims, but any such claims arising in the future could have a material adverse effect on our business, financial condition and results of operations. Potential product liability or personal injury claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, our existing insurance may not be renewed by us at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our cash flow and thus potentially a materially adverse effect on our business, financial condition and results of operations.

All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.

We are performing all of our diagnostic services in our CLIA laboratory located in New Haven, Connecticut and our research and development operations are based in our facility in Omaha, Nebraska. Despite precautions taken by us, any future natural or man-made disaster at these laboratories, such as a fire, earthquake or terrorist activity, could cause

Table of Contents

substantial delays in our operations, damage or destroy our equipment and testing samples or cause us to incur additional expenses.

In addition, we are leasing the facilities where our laboratories operate. We are currently in compliance with all and any lease obligations, but should the leases terminate for any reason, or if at any time either of the laboratories is moved due to conditions outside our control, it could cause substantial delay in our diagnostics operations, damage or destroy our equipment and biological samples or cause us to incur additional expenses. In the event of an extended shutdown of either laboratory, we may be unable to perform our services in a timely manner or at all and therefore would be unable to operate in a commercially competitive manner. This could harm our operating results and financial condition.

Further, if we have to use a substitute laboratory while our facilities were shut down, we could only use another facility with established state licensure and accreditation under CLIA. We may not be able to find another CLIA-certified facility and comply with applicable procedures, or find any such laboratory that would be willing to perform the tests for us on commercially reasonable terms. Additionally, any new laboratory opened by us would be subject to certification under CLIA and licensure by various states, which would take a significant amount of time and result in delays in our ability to continue our operations.

An impairment in the carrying value of our intangible assets could negatively affect our results of operations.

A significant portion of our assets are intangible assets which are reviewed at least annually for impairment. If we do not realize our business plan, our intangible assets may become impaired resulting in an impairment loss in our results of operations.

Risks Related to Our Common Stock

The price of our common stock may fluctuate significantly, which could negatively affect us and holders of our common stock.

There has been, and continues to be, a limited public market for our common stock, and an active trading market for our common stock has not and may never develop or, if developed, be sustained. The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

These factors include:

- actual or anticipated fluctuations in our financial condition and operating results:
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our academic institution partners, or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public and the revision of any financial estimates and projections that we provide to the public;

- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions, transitions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- changes to reimbursement levels by commercial third-party payers and government payers, including Medicare, and any announcements relating to reimbursement levels;
- Government shut-down or partial shut-downs impacting the financial markets, the United States Securities and Exchange Commission and other related agencies;

Table of Contents

- announcement or expectation of additional debt or equity financing efforts;
- sales of our common stock by us, our insiders, or our other stockholders; and
- general economic and market conditions

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of our common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

The price of our stock may be vulnerable to manipulation.

We believe our common stock has been the subject of significant short selling by certain market participants. Short sales are transactions in which a market participant sells a security that it does not own. To complete the transaction, the market participant must borrow the security to make delivery to the buyer. The market participant is then obligated to replace the security borrowed by purchasing the security at the market price at the time of required replacement. If the price at the time of replacement is lower than the price at which the security was originally sold by the market participant, then the market participant will realize a gain on the transaction. Thus, it is in the market participant's interest for the market price of the underlying security to decline as much as possible during the period prior to the time of replacement.

Because our unrestricted public float has been small relative to other issuers, previous short selling efforts have impacted, and may in the future continue to impact, the value of our stock in an extreme and volatile manner to our detriment and the detriment of our shareholders. Efforts by certain market participants to manipulate the price of our common stock for their personal financial gain may cause our stockholders to lose a portion of their investment, may make it more difficult for us to raise equity capital when needed without significantly diluting existing stockholders, and may reduce demand from new investors to purchase shares of our stock.

If we cannot continue to satisfy Nasdaq listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities.

Although our common stock is listed on the Nasdaq Capital Market, we may be unable to continue to satisfy the listing maintenance requirements and rules. If we are unable to satisfy The Nasdaq Stock Market, or Nasdaq, criteria for maintaining our listing, our securities could be subject to delisting.

On April 29, 2020, we received a letter from Nasdaq notifying us that for the past 30 consecutive business days, the closing bid price per share of our common stock was below the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market, as required by Nasdaq Listing Rule 5550(a)(2), or the Bid Price Rule. As a result, we were notified by Nasdaq that we were not in compliance with the Bid Price Rule. Nasdaq provided us until December 28, 2020 to regain compliance with the Bid Price Rule.

On June 29, 2020, the Company received a letter from Nasdaq stating that because the Company's shares had a closing bid price at or above $1.00 per share for a minimum of ten (10) consecutive business days, the Company's stock had regained compliance with the Minimum Bid Price Requirement for continued listing on Nasdaq, and that the matter is now closed.

We are currently in compliance with Nasdaq listing requirements, however, if Nasdaq were to delist our securities, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;

Table of Contents

- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading;
- activity in the secondary trading market for our common stock;
- limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

In addition, we would no longer be subject to Nasdaq rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards.

Increased costs associated with corporate governance compliance may significantly impact our results of operations.

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and NASDAQ. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance and executive compensation

related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports that we file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. If we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline.

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective.

Table of Contents

These developments could make it more difficult for us to retain qualified members of our Board of Directors, or qualified executive officers. We are presently evaluating and monitoring regulatory developments and cannot estimate the timing or magnitude of additional costs we may incur as a result. To the extent these costs are significant, our general and administrative expenses are likely to increase.

We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.

No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common

stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or if they issue other unfavorable commentary or cease publishing reports about us or our business.

The sale or issuance of our common stock to Lincoln Park may cause significant dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

On March 26, 2020, we entered into the LP 2020 Purchase Agreement pursuant to which Lincoln Park has agreed to purchase up to an aggregate of $10,000,000 of our common stock (subject to certain limitations) from time to time over the term of the LP 2020 Purchase Agreement. The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. The purchase price for the shares that we may sell to Lincoln Park under the LP 2020 Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall. We generally have the right to control the timing and amount of any future sales of our shares to Lincoln Park. Additional sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. We may ultimately decide to sell to Lincoln Park all, some or none of the additional shares of our common stock that may be available for us to sell pursuant to the LP 2020 Purchase Agreement. If and when we do sell shares to Lincoln Park, after Lincoln Park has acquired the shares, Lincoln Park may resell all, some or none of those shares at any time or from time to time in its discretion. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

As of the date of the consolidated financial statements were issued, we have already received approximately $8.8 million from the LP 2020 Purchase Agreement from the sale of 4,980,000 shares of common stock to Lincoln Park from April 1, 2020 through the date the consolidated financial statements were issued, leaving the Company an additional $1.2 million to draw subsequent to the filing of this Annual Report.

The issuance of our common stock to creditors or litigants may cause significant dilution to our stockholders and cause the price of our common stock to fall

Table of Contents

We may seek to settle outstanding obligations to vendors, debtholders or litigants in any litigation through the issuance of our common stock or other security to such persons. Such issuances may cause significant dilution to our stockholders and cause the price of our common stock to fall.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 7,630 square feet of laboratory and office space in New Haven, Connecticut, which we occupy under a lease expiring in December 2021 with annual rental payments of $0.2 million. We also lease approximately 5,300 square feet of laboratory space in Omaha, Nebraska, which we occupy under a lease expiring in May 2022 with annual rental payments of less than $0.1 million. We believe that these facilities are adequate to meet our current and planned needs. We believe that if additional space is needed in the future, we could find alternate space at competitive market rates as needed.

Item 3. Legal Proceedings

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not limited to, matters such as licensure, accreditation, government healthcare program participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

The outcome of legal proceedings and claims brought against us are subject to significant uncertainty. Therefore, although management considers the likelihood of such an outcome to be remote, if one or more of these legal matters were resolved against us in the same reporting period for amounts in excess of management's expectations, our financial statements for such reporting period could be materially adversely affected. In general, the resolution of a legal matter could prevent us from offering our services or products to others, could be material to our financial condition or cash flows, or both, or could otherwise adversely affect our operating results.

The Company is involved in legal proceedings related to matters, which are incidental to its business and is delinquent on the payment of outstanding accounts payable for certain vendors and suppliers who have taken or have threatened to take legal action to collect such outstanding amounts. See below for a discussion on these matters.

CPA Global provides us with certain patent management services. On February 6, 2017, CPA Global claimed that we owe approximately $0.2 million for certain patent maintenance services rendered. CPA Global has not filed claims against us in connection with this allegation. A liability of less than $0.1 million has been recorded and is reflected in accounts payable within the accompanying consolidated balance sheets at December 31, 2020 and 2019.

On February 17, 2017, Jesse Campbell ("Campbell") filed a lawsuit individually and on behalf of others similarly situated against us in the District Court for the District of Nebraska alleging we had a materially incomplete and misleading proxy relating to a potential merger and that the merger agreement's deal protection provisions deter superior offers. On June 21, 2019, the parties filed a stipulation of settlement, in which defendants are released from all claims and expressly deny that that they have committed any act or omission giving rise to any liability. The stipulation includes a settlement payment of $1.95 million. On July 10, 2019, the Court entered an order preliminarily approving the settlement. During the

Table of Contents

third quarter of 2019, both the Company and the insurance company paid their respective amounts of $0.27 million and $1.68 million, respectively, to an escrow account where the funds were held until they were approved for distribution. On June 3, 2020, the Court approved the settlement and entered an order of dismissal. As of the date the consolidated financial statements were issued, the escrow funds have been released and this matter is closed.

Item 4. Mine Safety Disclosures

Not Applicable.

Table of Contents

PART II

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

Market Information. Since June 30, 2017, our common stock has traded on the NASDAQ Capital Market under the symbol "PRPO."

The following table sets forth the high and low closing prices for our common stock during each of the quarters of 2020 and 2019 as reported on the market exchange noted above. The per share prices reflect a 1-for-15 reverse stock split effected on April 26, 2019:

	High	Low
uarter Ended March 31, 2021		
rst Quarter (through March 25, 2021)	$ 3.89	$ 2.10
ear Ended December 31, 2020		
rst Quarter	$ 2.30	$ 0.68
econd Quarter	$ 1.51	$ 0.58
hird Quarter	$ 7.00	$ 1.16
ourth Quarter	$ 2.64	$ 1.94
ear Ended December 31, 2019		
rst Quarter	$ 3.90	$ 1.83
econd Quarter	$ 9.15	$ 1.89
hird Quarter	$ 4.08	$ 2.18

ɔurth Quarter $ 2.60 $ 1.81

Performance Graph. We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

Holders. At March 25, 2021, there were 18,132,063 shares of our common stock outstanding and approximately 54 holders of record.

Dividends. No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income.

Issuer Purchases of Equity Securities. We made no purchases of our common stock during the year ended December 31, 2020. Therefore, tabular disclosure is not presented.

Recent Sales of Unregistered Securities. Not applicable.

Item 6. Selected Financial Data

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Table of Contents

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

Forward-Looking Information

This Annual Report on Form 10-K, including this Management's Discussion and Analysis, contains forward-looking statements. These statements are based on management's current views, assumptions or beliefs of future events and financial performance and are subject to uncertainty and changes in circumstances. Readers of this report should understand that these statements are not guarantees of performance or results. Many factors could affect our actual financial results and cause them to vary materially from the expectations contained in the forward-looking statements. These factors include, among other things: the expected or potential impact of COVID-19 which is highly uncertain and will depend on future developments, our expected revenue, income (loss), receivables, operating expenses, supplier pricing, availability and prices of raw materials, insurance reimbursements, product pricing, sources of funding operations and acquisitions, our ability to raise funds, sufficiency of available liquidity, future interest costs, future economic circumstances, business strategy, industry conditions, our ability to execute our operating plans, the success of our cost savings initiatives, competitive environment and related market conditions, expected financial and other benefits from our organizational restructuring activities, actions of governments and regulatory factors affecting our business, retaining key employees and other risks as described in our reports filed with the Securities

and Exchange Commission. In some cases these statements are identifiable through the use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "target," "can," "could," "may," "should," "will," "would" or the negative versions of these terms and other similar expressions.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements. Actual results may differ materially from those suggested by the forward-looking statements that we make for a number of reasons, including those described in Part I, Item 1A, "Risk Factors," of this Annual Report on Form 10-K.

We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

We are a cancer diagnostics and reagent technology company providing diagnostic products, reagents and services to the oncology market. We have built and continue to develop a platform designed to eradicate the problem of misdiagnosis by harnessing the intellect, expertise and technologies developed in collaboration with academic institutions, and delivering quality diagnostic information to physicians and their patients worldwide. We operate a cancer diagnostic laboratory located in New Haven, Connecticut and have partnered with various academic institutions to capture the expertise, experience and technologies developed within academia to provide a better standard of cancer diagnostics and aim to solve the growing problem of cancer misdiagnosis. In support of this platform, we also operate a research and development facility in Omaha, Nebraska which focuses on the development of various technologies, among them our internally developed proprietary products IV-Cell and HemeScreen. To expand our product offering capabilities, the Omaha facility was recently CLIA and CAP certified in order to process a variety of commercial molecular tests previously referenced out and to further expand our capabilities and know-how in transitioning R&D lab generated technology into a commercial laboratory environment.

The Company also holds an exclusive license to patented ICE-COLD-PCR, or ICP technology from Dana-Farber Cancer Institute, Inc., or Dana-Farber, at Harvard University. We believe that such technology will provide additional services and products directed at improving diagnostic outcomes and providing physicians with options for targeted therapies.

In April 2020, we formed a Joint Venture with Poplar. Poplar provides specialized laboratory testing services to a nationwide client base of gastroenterologists, dermatologists, oncologists, urologists, gynecologists and their patients. The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based

Table of Contents

physicians, hospitals and medical centers. Under the terms of the Joint Venture, Precipio SPV has a 49% ownership interest in the Joint Venture, with Poplar having a 51 % ownership. We have determined that we hold a variable

interest in the Joint Venture and that we are the primary beneficiary of the Joint Venture. Due to this determination, we consolidate the Joint Venture. See Note 2 - Summary of Significant Accounting Policies for further discussion.

The following discussion should be read together with our financial statements and related notes contained in this Annual Report. Results for the year ended December 31, 2020 are not necessarily indicative of results that may be attained in the future.

Recent Developments

Business Activities - HemeScreen

During late Q3-2020, we launched the HemeScreen Reagent Rental (HSRR) program. Capitalizing on the well documented significant reductions in both time and material in running the genetic test, the Company created a turn-key test offering for office based oncologists, large oncology practices and local hospitals. The HSRR program offers our patent-pending HemeScreen technology coupled with an attractive equipment lease, training and test validation. Through this program, the oncology practice leases to own the diagnostic equipment from the Company that ordinarily they could not afford and also enters into a reagent rental contract with the Company. The HSRR program enables the practice to generate in-house testing revenue instead of sending out the same tests to large commercial reference laboratories as well as allowing the oncology practice to benefit from obtaining faster results; thus ultimately providing better patient care. During the fourth quarter of 2020 the Company signed three accounts. These practices are now in the training and validation periods and we expect recurring revenues from these customers in the first quarter 2021. Through our announced partnership with ION, the Company has accelerated its marketing efforts as ION is a US-based oncology distributor providing services to more than 5,000 oncology accounts nationwide. To date in 2021, co-marketing efforts have accelerated and four regional oncology accounts have signed onto the HSRR program.

Business Activities – COVID Testing

During Q4 2020 the Company announced it entered into an agreement with a South Korean company to market and distribute an FDA-authorized COVID-19 serology antibody test that has recently received EUA (Emergency Use Authorization). Distribution of the product will take place in the U.S. as well as in other markets worldwide. The EUA allows the Company to distribute to all Point of Care facilities and any healthcare provider that has a National Provider Identifier ("NPI") number.

Code of Conduct

On March 1, 2021, certain stylistic, technical and administrative amendments to the Company's Code of Business Conduct and Ethics applicable to directors, officers and employees of the Company and its subsidiaries, were approved by the Board, upon recommendation from the Governance and Nominating Committee.

The foregoing description of the amendment to the Company's Code of Business Conduct and Ethics is qualified in its entirety by reference to the Company's Code of Business Conduct and Ethics, as amended on March 1, 2021, which is available for review or download in the Corporate Governance section of the Company's website, www.precipiodx.com.

We expect that any further amendments to the Code of Business Conduct and Ethics, or any waivers of its requirements, will also be disclosed on the Company's website.

Going Concern

The consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America ("GAAP") applicable for a going concern, which assume that the Company will realize its assets and discharge its liabilities in the ordinary course of business. The Company has incurred substantial operating losses and has used cash in its operating activities for the past several years. As of December 31, 2020, the Company had a net loss of $10.6 million, negative working capital of $0.5 million and net cash used in operating activities of $7.4 million. The

Table of Contents

Company's ability to continue as a going concern over the next twelve months from the date the consolidated financial statements were issued is dependent upon a combination of achieving its business plan, including generating additional revenue, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

To meet its current and future obligations the Company has taken the following steps to capitalize the business and successfully achieve its business plan:

- On March 26, 2020, the Company entered into a second agreement (the "LP 2020 Purchase Agreement") with Lincoln Park Capital Fund LLC ("Lincoln Park"), pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $10.0 million of common stock of the Company (subject to certain limitations) from time to time over the term of the LP 2020 Purchase Agreement. The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. As of the date of the consolidated financial statements were issued, we have already received approximately $8.8 million from the LP 2020 Purchase Agreement from the sale of 4,980,000 shares of common stock to Lincoln Park from April 1, 2020 through the date the consolidated financial statements were issued, leaving the Company an additional $1.2 million to draw subsequent to the filing of this Annual Report. See Note 11 Stockholders' Equity for further discussion on Lincoln Park agreements;

- During 2020, the Company received $0.8 million in funds from the PPP Loan and on February 11, 2021, the Company filed its application for loan forgiveness. There is no assurance that the Company will obtain forgiveness of the PPP Loan in whole or in part, however, the Company believes it used all of the PPP Loan amount for qualifying expenses and may be granted forgiveness during 2021; and

- The Company filed with the SEC a registration statement on Form S-3 on March 27, 2020, as amended on April 9, 2020, to register an indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities and such indeterminate number of warrants to purchase common stock, preferred stock or debt securities as shall have an aggregate initial offering price not to exceed $50 million. This registration statement was declared effective by the SEC on April 13, 2020 and allows the Company, from time to time, to offer up to $50 million of any combination of the securities described in the Form S-3 in one or more offerings. In order for the Company to utilize the effective S-3, it will have to file subsequent prospectus supplement(s) with regard to the securities it will offer, as applicable from time to time. As of the date of issuance of this Form 10-K, no subsequent prospectus supplements to this effect have been filed by the Company.

Notwithstanding the aforementioned circumstances, there remains substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued. There can be no assurance that the Company will be able to successfully achieve its initiatives summarized above in order to continue as a going concern. The accompanying financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result should the Company be unable to continue as a going concern as a result of the outcome of this uncertainty.

Outlook - COVID-19 related

The COVID-19 outbreak, which spread worldwide in the first quarter of 2020, has caused significant business disruption. The extent of the impact of the ongoing COVID-19 pandemic on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, and impact on the Company's customers, employees and vendors, all of which are uncertain and cannot be predicted. These uncertainties could have a material adverse effect on our business, financial condition or results of operations. We have been actively monitoring the COVID-19 situation and its impact on the global economy and the Company. As the global pandemic evolves, we will continue to monitor the extent to which COVID-19 impacts our revenues, expenses and liquidity.

Table of Contents

Results of Operations for the Years Ended December 31, 2020 and 2019

Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Years Ended December 31,		Change	
	2020	2019	$	%
Service revenue, net, less allowance for doubtful accounts	$ 5,872	$ 3,083	$ 2,789	90 %
Other	220	44	176	400 %
Net Sales	$ 6,092	$ 3,127	$ 2,965	95 %

Net sales for the year ended December 31, 2020 were $6.1 million, an increase of $3.0 million, as compared to the same period in 2019. During the year ended December 31, 2020, patient diagnostic service revenue had an increase of $2.9 million as compared to the same period in 2019 due to an increase in cases processed. We billed 3,677 cases during the year ended December 31, 2020 as compared to 1,672 cases during the same period in 2019, or a 120% increase in cases. Case volume increased in 2020 as the Company increased its customer base by 26%; coupled with a steady increase in ordering volume from existing customers. Unless the states have another complete lockdown, as the country experienced in the early months of the COVID-19 pandemic, we believe the 2020 organic growth will be sustained. Patient diagnostic service revenue accounted for 89% and 80% of our total net sales for the years ended December 31, 2020 and 2019, respectively. For the year ended December 31, 2020 as compared to the same period in 2019, other revenues increased by $0.2 million and contract diagnostic service revenue decreased by $0.1 million.

Cost of Sales. Cost of sales includes material and supply costs for the patient tests performed and other direct costs (primarily personnel costs, pathologist interpretation costs and rent) associated with the operations of our laboratory. Cost of sales increased by $2.0 million for the year ended December 31, 2020 as compared to the same period in 2019. The increase included an increase in patient diagnostic costs offset by a decrease in contract diagnostic costs which are in line with the changes in related revenues discussed above.

Gross Profit. Gross profit and gross margins were as follows:

	Dollars in Thousands			
	Years Ended December 31,		Margin %	
	2020	2019	2020	2019
Gross Profit	$ 1,150	$ 219	19 %	7 %

Gross margin was 19% of total net sales, for the year ended December 31, 2020, compared to 7% of total net sales for the same period in 2019 and the gross profit was approximately $1.2 million and $0.2 million during the years ended December 31, 2020 and 2019, respectively. The gross margin increased during the year ended December 31, 2020, as compared to the prior year period, as a result of increases in case volume and revenue. We operate a fully staffed CLIA and CAP certified clinical pathology and molecular laboratory. As such, it is necessary to maintain appropriate staffing levels to provide industry standard laboratory processing and reporting to ordering physicians. The increase in case volume enabled our laboratory to yield economies of scale and to leverage fixed expenses. We anticipate case volume to increase in 2021 and for our costs per case to improve as additional economies of scale are possible.

Operating Expenses. Operating expenses primarily consist of personnel costs, professional fees, travel costs, facility costs and depreciation and amortization, including any intangible asset impairment. Our operating expenses decreased by $0.9 million to $10.3 million for the year ended December 31, 2020 as compared to $11.2 million for the year ended December 31, 2019. This decrease is the result of a decrease in intangible asset impairment of $1.6 million and a decrease in general and administrative costs of $0.1 million. The decreases were partially offset by an increase of $0.8 million in sales and marketing costs, which is primarily increased personnel costs related to our increase in patient diagnostic service revenues.

Table of Contents

Other Income (Expense). We recorded net other expense, of $1.5 million and $2.4 million for the years ended December 31, 2020 and 2019, respectively. The current year period net expense of $1.5 million includes $0.3 million of interest expense from the amortization of debt discounts, net of accretion of debt premiums, related to convertible notes, $0.2 million of other interest expense and $1.2 million in expense for loss on extinguishment of convertible notes which was recorded in conjunction with the March 2020 Amendment. The expenses were partially offset by $0.2 million of other income and gains on settlements of liabilities. Approximately $0.1 million of the other income is funds we received from the U.S. Department of Health and Human Services (“HHS”). As part of the CARES Act, HHS distributed funds to healthcare providers that received Medicare fee-for-service reimbursements in 2019. The payments from HHS are not loans and will not be required to be repaid.

During the year ended December 31, 2019, net other expense of approximately $2.3 million included expense from warrant and derivative revaluations of $1.1 million, a loss on issuance of convertible notes of $1.9 million, a loss on litigation of $0.3 million and net interest expense of approximately $0.5 million. These expense items were partially offset by gains on settlements of liabilities of $1.4 million.

Liquidity and Capital Resources

Our working capital positions at December 31, 2020 and 2019 were as follows:

	Dollars in Thousands		
	December 31, 2020	December 31, 2019	Change
Current assets (including cash of $2,656 and $848 respectively)	$ 4,204	$ 1,878	$ 2,326
Current liabilities	4,656	4,334	322
Working capital	$ (452)	$ (2,456)	$ 2,004

During the year ended December 31, 2020 we received gross proceeds of $8.9 million from sale of 5,770,654 shares of our common stock and $0.8 million from the PPP Loan. We also converted $2.2 million of convertible notes, including interest, into 3,908,145 shares of our common stock.

Analysis of Cash Flows - Years Ended December 31, 2020 and 2019

Net Change in Cash. Cash increased by $1.8 million and $0.5 million during the years ended December 31, 2020 and 2019, respectively.

Cash Flows Used in Operating Activities. The cash flows used in operating activities of $7.4 million during the year ended December 31, 2020 included a net loss of $10.6 million, an increase in accounts receivable of $1.6 million, an increase in inventories and other assets of $0.2 million and a decrease in accounts payable and operating lease liabilities of $0.5 million. These were partially offset by an increase in accrued expenses and other liabilities of $0.7 million and non-cash adjustments of $4.8 million. The non-cash adjustments included $1.3 million for the change in provision for losses on doubtful accounts. We routinely provide a reserve for doubtful accounts as a result of having limited in-network payer contracts. Non-cash adjustments also included $1.2 million for loss on extinguishment of convertible notes, which resulted from a March 2020 amendment to certain Bridge Notes whereby, among other things, the floor price at which conversions may occur was amended from $2.25 to $0.40. See Note 6 – Convertible Notes for further discussion. The other non-cash adjustments to net loss of approximately $2.3 million include, among other things, depreciation and amortization, warrant revaluations and stock based compensation. The cash flows used in operating activities in the year ended December 31, 2019 included the net loss of $13.2 million, an increase in accounts receivable of $0.8 million, a decrease in accounts payable of $1.9 million and a decrease in operating lease liabilities of $0.2 million. These were partially offset by a decrease in other assets of $0.4 million and non-cash adjustments of $6.6 million.

Cash Flows Used In Investing Activities. Cash flows used in investing activities were $0.1 million for the years ended December 31, 2020 and 2019, respectively, resulting from purchases of property and equipment partially offset by proceeds from sales of fixed assets.

Table of Contents

Cash Flows Provided by Financing Activities. Cash flows provided by financing activities totaled $9.3 million for the year ended December 31, 2020, which included proceeds of $8.9 million from the issuance of common stock and proceeds of $0.8 million from the PPP Loan. These proceeds were partially offset by payments on our long-term debt and finance lease obligations of $0.4 million. Cash flows provided by financing activities totaled $9.7 million for the year ended December 31, 2019, which included proceeds of $6.6 million from the issuance of common

stock, $1.6 million from the exercise of warrants and $2.1 million from the issuance of convertible notes. These proceeds were partially offset by payments on our long-term debt and convertible notes of $0.5 million and payments for our finance lease obligations and deferred financing costs of $0.1 million.

Off-Balance Sheet Arrangements

At each of December 31, 2020 and December 31, 2019, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Contractual Obligations and Commitments

At December 31, 2020, our contractual obligations and other commitments were as follows:

	Payments Due By Period				
(in thousands)	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long term debt[1]	$1,068	$ 664	$ 247	$ 70	$ 87
Finance lease obligations[2]	188	60	87	41	—
Operating lease obligations[2]	342	241	83	18	—
Purchase obligations[3]	1,735	1,068	447	220	—
	$3,333	$2,033	$ 864	$ 349	$ 87

(1) See Note 5 - "Long-Term Debt" to our accompanying consolidated financial statements included with this Annual Report on Form 10-K.
(2) See Note 8 - "Leases" to our accompanying consolidated financial statements included with this Annual Report on Form 10-K.
(3) These amounts represent purchase commitments, including all open purchase orders.

Critical Accounting Policies and Estimates

The following discussion and analysis of financial condition and results of operations are based upon the Company's consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. The Company's significant accounting policies are more fully described in Note 2 of the notes to Consolidated Financial Statements included with this Annual Report on Form 10-K. Certain accounting estimates are particularly important to the understanding of the Company's financial position and results of operations and require the application of significant judgment by the Company's management and can be materially affected by changes from period to period in economic factors or conditions that are outside the control of management. The Company's management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on historical operations, future business plans and projected financial results, the terms of existing contracts, the observance of trends in the industry, information provided by

customers and information available from other outside sources, as appropriate. The following discusses the Company's critical accounting policies and estimates:

Revenue Recognition

The Company derives its revenues from diagnostic testing - histology, flow cytometry, cytology and molecular testing; clinical research from bio-pharma customers, state and federal grant programs; and from biomarker testing from bio-pharma customers.

Service revenues are comprised of patient diagnostic services for cancer as well as contract diagnostic services for pharmacogenomics trials. Service revenue is recognized upon completion of the testing process and when the diagnostic result is delivered to the ordering physician and/or customer. Net patient service revenue is reported at the estimated net realizable amounts from patients, third-party payers and others for services rendered, including retroactive adjustment under reimbursement agreements with third-party payers. Revenue under third-party payer agreements is subject to audit and retroactive adjustment. Provisions for third-party payer settlements are provided in the period in which the related services are rendered and adjusted in the future periods, as final settlements are determined.

Revenue from clinical research grant is recognized over time as the service is being performed using a proportional performance method. The Company uses an "efforts based" method of assessing performance. If the arrangement requires the performance of a specified number of similar acts (i.e. test), then revenue is recognized in equal amounts as each act is completed.

Other revenues are comprised of the Company's ICP technology kit sales to bio-pharma customers, clinical research, HemeScreen and COVID-19 antibody tests.

For the year ended December 31, 2020, service revenue represented 96% of our consolidated revenues and other revenues represented 4%. For the year ended December 31, 2019, service revenue represented 99% of our consolidated revenues and other revenues represented 1%.

Allowance for Contractual Discounts

We are reimbursed by payers for services we provide. Payments for services covered by payers average less than billed charges. We monitor revenue and receivables from payers and record an estimated contractual allowance for certain revenue and receivable balances as of the revenue recognition date to properly account for anticipated differences between amounts estimated in our billing system and amounts ultimately reimbursed by payers. Accordingly, the total revenue and receivables reported in our financial statements are recorded at the amounts expected to be received from these payers. For service revenue, the contractual allowance is estimated based on several criteria, including unbilled claims, historical trends based on actual claims paid, current contract and reimbursement terms and changes in customer base and payer/product mix. The billing functions for the remaining portion of our revenue are contracted and fixed fees for specific services and are recorded without an allowance for contractual discounts.

Allowance for Doubtful Accounts

The allowance for doubtful accounts is based on estimates of losses related to receivable balances. The risk of collection varies based upon the service, the payer (commercial health insurance and government) and the patient's ability to pay the amounts not reimbursed by the payer. We estimate the allowance for doubtful accounts based upon several factors including the age of the outstanding receivables, the historical experience of collections, adjusting for current economic conditions and, in some cases, evaluating specific customer accounts for the ability to pay. Collection agencies are employed and legal action is taken when we determine that taking collection actions is reasonable relative to the probability of receiving payment on amounts owed. Management judgment is used to assess the collectability of accounts and the ability of our customers to pay. Judgment is also used to assess trends in collections and the effects of systems and business process changes on our expected collection rates. We review the

estimation process quarterly and make changes to the estimates as necessary. When it is determined that a customer account is uncollectible, that balance is written off against the existing allowance.

Table of Contents

Accounts Receivable

Accounts Receivable results from diagnostic services provided to self-pay and insured patients, project based testing services, clinical research and miscellaneous product sales. The services provided by the Company are generally due within 30 days from the invoice date. Accounts receivable are reduced by an allowance for doubtful accounts. In evaluating the collectability of accounts receivable, the Company analyzes and identifies trends for each of its sources of revenue to estimate the appropriate allowance for doubtful accounts. For receivables associated with self-pay patients, including patients with insurance and a deductible and copayment, the Company records an allowance for doubtful accounts in the period of services on the basis of past experience of patients unable or unwilling to pay for service fee for which they are financially responsible. For receivables associated with services provided to patients with third-party coverage, the Company analyzes contractually due amounts and provides an allowance, if necessary. The difference between the standard rates and the amounts actually collected after all reasonable collection efforts have been exhausted is charged against the allowance for doubtful accounts.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the grantee's requisite vesting period on a straight-line basis. For the purpose of valuing stock options granted to our employees, directors and officers, we use the Black-Scholes option pricing model. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, and is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining the trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions and will adjust our Black-Scholes option pricing assumptions as appropriate

Impairment of Long-Lived Assets

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to our carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results.

Recently Adopted Accounting Pronouncements

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13 "*Fair Value Measurement (Topic 820)*", which modifies certain disclosure requirements in Topic

820, such as the removal of the need to disclose the amount of and reason for transfers between Level 1 and Level 2 of the fair value hierarchy, and several changes related to Level 3 fair value measurements. The Company adopted this guidance on January 1, 2020. The adoption of this guidance was not material to our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15 "*Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350-40)*", which aligns the requirements for capitalizing implementation costs incurred in a cloud computing hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal use software. The Company adopted this guidance on January 1, 2020. The adoption of this guidance was not material to our consolidated financial statements.

Recently Accounting Pronouncements Not Yet Adopted

In August 2020, the FASB issued ASU 2020-06 "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*." This ASU amends the guidance on convertible instruments and the

Table of Contents

derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12 "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*", which is intended to improve consistent application and simplify the accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance. This standard is effective for annual reporting periods beginning after December 15, 2020, including interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact of adoption of this ASU and does not expect the adoption of this new standard to have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 "*Measurement of Credit Losses on Financial Instruments*", which replaces current methods for evaluating impairment of financial instruments not measured at fair value, including trade accounts receivable and certain debt securities, with a current expected credit loss model. This ASU, as amended, is effective for the Company for reporting periods beginning after December 15, 2022. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

Impact of Inflation

We do not believe that price inflation or deflation had a material adverse effect on our financial condition or results of operations during the periods presented.

Item 7A. Quantitative and Qualitative Disclosure about Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Table of Contents

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of
Precipio**,** Inc**.**

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Precipio, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 audit**s** in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit**s** to obtain reasonable assurance about whether the consolidated 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 audit**s** 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 audit**s** included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated financial statements. Our audit**s** also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit**s** provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit

Table of Contents

matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Assessment of the estimation for collections over diagnostic testing for which revenue is recognized.

Description of Matter
As described in Note 2 to the consolidated financial statements, the Company records its service revenues from diagnostic testing net of contractual and collection allowances that are estimated based on historical trends and anticipated reimbursement from third party payers. As of December 31, 2020, the Company recognized gross revenue of approximately $15.9 million along with contractual allowances of approximately $8.5 million and collection allowances of approximately $1.3 million. The net revenue figure of approximately $6.1 million is recorded as net sales on the consolidated statements of operations.

The principal considerations for our determination that performing procedures over revenue recognition relating to the service revenue is a critical audit matter is based on the significant judgments by management in estimating the amount to be recognized as revenue as well as the effort and complexity in assessing audit evidence in performing procedures to evaluate the amount recognized. The calculation involves estimating adjustments to gross revenue based upon sales mix and third party contractual terms, such as Medicare rates or variations of Medicare rates.

How We Addressed the Matter
We obtained an understanding of the design of controls in place over the Company’s process to calculate the various allowances. Our audit procedures included the evaluation of significant inputs through the evaluation of the Company's retrospective analysis of allowances as compared to actual payments received, evaluation of estimates based on historical collections by payer and performance of analytical procedures and sensitivity analyses over the Company’s significant inputs to assess the Company’s ability to accurately estimate the allowances. We also tested the underlying

data used in management's calculations for accuracy and completeness, which included detail testing of the service revenue.

Evaluation of changes in convertible debt in determining proper accounting treatment.

Description of Matter
As described in Note 6 to the consolidated financial statements, the Company entered into an amended debt agreement in March 2020 related to convertible bridge notes, which, among other terms, amended the conversion price from $2.25 to $0.40. Based on such modifications, the Company concluded that the amendment should be treated as an extinguishment, which resulted in a loss on extinguishment of debt of $1.2 million. The loss is recorded within other (expense) income on the consolidated statements of operations.

The principal considerations for our determination that the extinguishment of debt is a critical audit matter is based on the inherent complexity and the significant judgments made by management in determining extinguishment through calculating the fair values of the convertible bridge notes at both the pre and post modification date, including the beneficial conversion feature of the securities.

How We Addressed the Matter
Our audit procedures included testing the source information and assumptions made by management underlying the determination of extinguishment, as well as utilizing our valuation specialists to assess the Company's calculated value for reasonableness of the fair value of the convertible bridge notes at the pre and post modification date.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2016.

Hartford, CT
March 29, 2021

Table of Contents

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2020 and 2019
(Dollars in thousands, except share data)

	2020	2019
ASSETS		
CURRENT ASSETS:		
Cash	$ 2,656	$ 848
Accounts receivable, net	874	574
Inventories	350	184
Other current assets	324	272

Total current assets	4,204	1,878
PROPERTY AND EQUIPMENT, NET	452	431
OTHER ASSETS:		
Operating lease right-of-use assets	335	519
Intangibles, net	15,667	16,658
Other assets	55	25
Total assets	$ 20,713	$ 19,511
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt, less debt issuance costs	$ 648	$ 321
Current maturities of convertible notes, less debt discounts and debt issuance costs	—	142
Current maturities of finance lease liabilities	48	52
Current maturities of operating lease liabilities	225	209
Accounts payable	1,693	1,936
Accrued expenses	2,036	1,639
Deferred revenue	6	35
Total current liabilities	4,656	4,334
LONG TERM LIABILITIES:		
Long-term debt, less current maturities and debt issuance costs	362	198
Finance lease liabilities, less current maturities	116	119
Operating lease liabilities, less current maturities	92	317
Common stock warrant liabilities	1,325	1,338
Total liabilities	6,551	6,306
COMMITMENTS AND CONTINGENCIES (Note 9)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.01 par value, 15,000,000 shares authorized at December 31, 2020 and December 31, 2019, 47 shares issued and outstanding at December 31, 2020 and December 31, 2019, liquidation preference of $243 at December 31, 2020	—	—
Common stock, $0.01 par value, 150,000,000 shares authorized at December 31, 2020 and December 31, 2019, 17,576,916 and 7,898,117 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	176	79
Additional paid-in capital	85,523	74,065
Accumulated deficit	(71,564)	(60,939)
Total Precipio, Inc. stockholders' equity	14,135	13,205
Noncontrolling interest in joint venture	27	—
Total stockholders' equity	14,162	13,205
Total liabilities and stockholders' equity	$ 20,713	$ 19,511

See notes to consolidated financial statements.

Table of Contents

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2020 and 2019
(Dollars in thousands, except per share data)

	2020	2019
SALES:		
Service revenue, net	$ 7,211	$ 4,051
Other	220	44
Revenue, net of contractual allowances and adjustments	7,431	4,095
less allowance for doubtful accounts	(1,339)	(968)
Net sales	6,092	3,127
COST OF SALES:		
Cost of service revenue	4,842	2,908
Other	100	—
Total cost of sales	4,942	2,908
Gross profit	1,150	219
OPERATING EXPENSES:		
Operating expenses	10,296	9,623
Impairment of intangible assets	—	1,590
TOTAL OPERATING EXPENSES	10,296	11,213
OPERATING LOSS	(9,146)	(10,994)
OTHER (EXPENSE) INCOME:		
Interest expense, net	(470)	(473)
Warrant revaluation	13	416
Loss on modification of warrants	—	(1,128)
Derivative revaluation	—	(415)
Gain on settlement of liability, net	77	1,437
Loss on extinguishment of debt	(1,225)	(20)
Loss on litigation	—	(266)
Loss on issuance of convertible notes	—	(1,870)
Other income	153	—
Total other (expense) income	(1,452)	(2,319)
LOSS BEFORE INCOME TAXES	(10,598)	(13,313)
INCOME TAX BENEFIT	—	70
NET LOSS	(10,598)	(13,243)
Less: Net income attributable to noncontrolling interest in joint venture	(27)	—
Deemed dividends related to beneficial conversion feature of preferred stock and fair value of warrant down round features	(3,344)	—
NET LOSS ATTRIBUTABLE TO PRECIPIO, INC. COMMON STOCKHOLDERS	$ (13,969)	$ (13,243)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.85)	$ (2.33)
BASIC AND DILUTED WEIGHTED-AVERAGE SHARES OF COMMON STOCK OUTSTANDING	16,477,074	5,695,159

See notes to consolidated financial statements.

Table of Contents

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2020 and 2019
(Dollars in thousands)

	Preferred Stock		Common Stock		Additional			Noncontrolling	
	Outstanding Shares	Par Value	Outstanding Shares	Par Value	Paid-in Capital	Accumulated Deficit	Total Precipio, Inc.	Interest in Joint Venture	Total
Balance, January 1, 2019	47	$ —	2,298,738	$ 23	$ 53,796	$ (47,696)	$ 6,123	$ —	$ 6,123
Net loss	—	—	—	—	—	(13,243)	(13,243)	—	(13,243)
Conversion of convertible notes into common stock	—	—	2,511,173	25	7,528	—	7,553	—	7,553
Issuance of common stock in connection with purchase agreements	—	—	2,778,077	28	6,600	—	6,628	—	6,628
Proceeds upon issuance of common stock from exercise of warrants	—	—	310,200	3	1,572	—	1,575	—	1,575
Write-off warrant liability in conjunction with warrant exercises	—	—	—	—	2,364	—	2,364	—	2,364
Beneficial conversion feature on issuance of convertible notes	—	—	—	—	1,792	—	1,792	—	1,792
Write-off debt discounts (net of debt premiums) in conjunction with convertible note conversions	—	—	—	—	(731)	—	(731)	—	(731)
Write-off debt derivative liability in conjunction with convertible note conversions	—	—	—	—	477	—	477	—	477
Non-cash stock-based compensation	—	—	—	—	668	—	668	—	668
Payment of fractional common shares in conjunction with reverse stock split	—	—	(71)	—	(1)	—	(1)	—	(1)
Balance, December 31, 2019	47	$ —	7,898,117	$ 79	$ 74,065	$ (60,939)	$ 13,205	$ —	$ 13,205
Net loss	—	—	—	—	—	(10,625)	(10,625)	27	(10,598)
Conversion of convertible notes into common stock	—	—	3,908,145	39	2,137	—	2,176	—	2,176
Issuance of common stock in connection with purchase agreements	—	—	5,770,654	58	8,871	—	8,929	—	8,929

Write-off debt premiums (net of debt discounts) in conjunction with convertible note conversions	—	—	—	—	270	—	270	—	270
Write-off beneficial conversion feature in conjunction with convertible note extinguishment	—	—	—	—	(523)	—	(523)	—	(523)
Non-cash stock-based compensation	—	—	—	—	703	—	703	—	703
Balance, December 31, 2020	47	$ —	17,576,916	$ 176	$ 85,523	$ (71,564)	$ 14,135	$ 27	$ 14,162

See notes to consolidated financial statements.

Table of Contents

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2020 and 2019
(Dollars in thousands)

	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (10,598)	$ (13,243)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	1,093	1,118
Amortization of operating lease right-of-use asset	213	231
Amortization of finance lease right-of-use asset	50	63
Amortization (accretion) of deferred financing costs, debt discounts and debt premiums	320	111
Loss on extinguishment of debt	—	20
Gain on settlement of liability, net	(77)	(1,437)
Loss on litigation	—	266
Loss on issuance of convertible notes	—	1,870
Loss on extinguishment of convertible notes	1,225	—
Stock-based compensation	703	668
Impairment of intangible assets and goodwill	—	1,590
Provision for losses on doubtful accounts	1,339	966
Warrant revaluation	(13)	(416)
Loss on modification of warrants	—	1,128
Derivative revaluation	—	415

Gain from sale of fixed asset	(55)	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,639)	(850)
Inventories	(166)	13
Other assets	(59)	427
Accounts payable	(243)	(1,884)
Operating lease liabilities	(209)	(223)
Accrued expenses and other liabilities	682	26
Net cash used in operating activities	(7,434)	(9,141)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(151)	(55)
Proceeds from sale of fixed asset	55	—
Net cash used in investing activities	(96)	(55)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on finance lease obligations	(56)	(46)
Payment of deferred financing costs	—	(120)
Payment of fractional common shares in conjunction with reverse stock split	—	(1)
Issuance of common stock, net of issuance costs	8,929	6,628
Proceeds from exercise of warrants	—	1,575
Proceeds from PPP Loan	787	—
Proceeds from convertible notes	—	2,150
Principal payments on convertible notes	—	(50)
Principal payments on long-term debt	(322)	(473)
Net cash flows provided by financing activities	9,338	9,663
NET CHANGE IN CASH	1,808	467
CASH AT BEGINNING OF PERIOD	848	381
CASH AT END OF PERIOD	$ 2,656	$ 848

See notes to consolidated financial statements.

Table of Contents

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS - continued
For the Years Ended December 31, 2020 and 2019
(Dollars in thousands)

	2020	2019
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the period for interest	$ 20	$ 36

SUPPLEMENTAL DISCLOSURE OF CONSULTING SERVICES OR ANY OTHER NON-CASH COMMON STOCK RELATED ACTIVITY		
Purchases of equipment financed through accounts payable	—	1
Equipment financed through finance lease obligations	22	23
Discount of 9% on issuance of convertible bridge notes	—	188
Conversion of convertible debt, plus interest, into common stock	2,176	7,553
Beneficial conversion feature on issuance of convertible notes	—	1,792
Initial valuation of warrant liability recorded in conjunction with issuance of convertible notes	—	1,858
Liabilities exchanged for convertible notes	—	2,150
Prepaid insurance financed with loan	23	434
Write-off of beneficial conversion feature in conjunction with convertible note extinguishment	523	—
Right-of-use assets obtained in exchange for operating lease obligations	—	750
Right-of-use assets obtained in exchange for finance lease obligations	29	—
Write-off warrant liability in conjunction with warrant exercises	—	2,364
Write-off of (debt premiums) debt discounts, net, in conjunction with convertible note conversions	(270)	731
Write-off of derivative liability in conjunction with convertible note conversions	—	477

See notes to consolidated financial statements.

Table of Contents

PRECIPIO, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the Years Ended December 31, 2020 and 2019

1. BUSINESS DESCRIPTION

Business Description.

Precipio, Inc., and its subsidiaries, (collectively, “we”, “us”, “our”, the “Company” or “Precipio”) is a cancer diagnostics and reagent technology company providing diagnostic products, reagents and services to the oncology market. We have built and continue to develop a platform designed to eradicate the problem of misdiagnosis by harnessing the intellect, expertise and technologies developed in collaboration with academic institutions, and delivering quality diagnostic information to physicians and their patients worldwide. We operate a cancer diagnostic laboratory located in New Haven, Connecticut and have partnered with various academic institutions to capture the expertise, experience and technologies developed within academia to provide a better standard of cancer diagnostics and aim to solve the growing problem of cancer misdiagnosis. In support of this platform, we also operate a research

and development facility in Omaha, Nebraska which focuses on the development of various technologies, among them our internally developed proprietary products IV-Cell and HemeScreen. To expand our product offering capabilities, the Omaha facility was recently CLIA and CAP certified in order to process a variety of commercial molecular tests previously referenced out and to further expand our capabilities and know-how in transitioning R&D lab generated technology into a commercial laboratory environment.

The Company also holds an exclusive license to patented ICE-COLD-PCR, or ICP technology from Dana-Farber Cancer Institute, Inc., or Dana-Farber, at Harvard University. PCR is described further below. We believe that such technology will provide additional services and products directed at improving diagnostic outcomes and providing physicians with options for targeted therapies.

Joint Venture.

In April 2020, the Company formed a joint venture with Poplar Healthcare PLLC ("Poplar"), which we refer to as the "Joint Venture". The Joint Venture was formed by the Limited Liability Company Agreement of Precipio Oncometrix LLC, a Delaware limited liability company ("POC"), which was entered into as of April 11, 2020 (the "Effective Date"), by and among POC, Poplar, and Precipio SPV Inc. ("Precipio SPV"), a newly formed subsidiary of the Company, together with such other persons who from time to time become party to the Limited Liability Company Agreement by executing a counterpart signature page in accordance with the terms hereof. POC was formed as a limited liability company on April 2, 2020 in accordance with the statutes and laws of the State of Delaware relating to limited liability companies, including, without limitation, the Delaware Act, by the filing of a Certificate of Formation with the office of the Secretary of State of the State of Delaware. Precipio SPV was incorporated in the State of Delaware on March 10, 2020 for the sole purpose of being a party to the Joint Venture.

Under the terms of the Joint Venture, Precipio SPV has a 49% ownership interest in the Joint Venture, with Poplar having a 51 % ownership. Pursuant to the Limited Liability Company Agreement, Poplar, at any time, has the right to require Precipio SPV to purchase all, but not less than all, of Poplar's shares in the Joint Venture (the "Poplar Put Right"). The purchase price for Poplar's shares shall be $1.00 per share, or fifty-one dollars, and Precipio SPV would, therefore, become the sole 100% owner of the Joint Venture at the time the Poplar Put Right became effective. The Company has determined that it holds a variable interest in the Joint Venture and is the primary beneficiary of the variable interest entity ("VIE"). See Note 2 - Summary of Significant Accounting Policies for further discussion regarding consolidation of variable interest entities.

The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based physicians, hospitals and medical centers. Operational services of the Joint Venture are performed entirely by its members and employees of its members. Precipio SPV's responsibilities include product and account management services, selling & marketing, laboratory diagnostic services and general & administrative services. Precipio SPV is

Table of Contents

entitled to a management fee for the services it provides. This management fee is established through service agreements which were executed in conjunction with the formation of the Joint Venture. Poplar receives a similar fee for the billing services that it provides.

Going Concern.

The consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America ("GAAP") applicable for a going concern, which assume that the Company will realize its assets and discharge its liabilities in the ordinary course of business. The Company has incurred substantial operating losses and has used cash in its operating activities for the past several years. As of December 31, 2020, the Company had a net loss of $10.6 million, negative working capital of $0.5 million and net cash used in operating activities of $7.4 million. The Company's ability to continue as a going concern, for the next twelve months from the date the consolidated financial statements were issued, is dependent upon a combination of achieving its business plan, including generating additional revenue and avoiding potential business disruption due to the novel coronavirus ("COVID-19") pandemic, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

To meet its current and future obligations the Company has taken the following steps to capitalize the business and successfully achieve its business plan:

- On March 26, 2020, the Company entered into a second agreement (the "LP 2020 Purchase Agreement") with Lincoln Park Capital Fund LLC ("Lincoln Park"), pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $10.0 million of common stock of the Company (subject to certain limitations) from time to time over the term of the LP 2020 Purchase Agreement. The extent we rely on Lincoln Park as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. As of the date the consolidated financial statements were issued, we have already received approximately $8.8 million from the LP 2020 Purchase Agreement from the sale of 4,980,000 shares of common stock to Lincoln Park from April 1, 2020 through the date the consolidated financial statements were issued, leaving the Company an additional $1.2 million to draw subsequent to the filing of this Annual Report. See Note 11 Stockholders' Equity for further discussion on Lincoln Park agreements;

- During 2020, the Company received $0.8 million in funds from the PPP Loan and on February 11, 2021, the Company filed its application for loan forgiveness. There is no assurance that the Company will obtain forgiveness of the PPP Loan in whole or in part, however, the Company believes it used all of the PPP Loan amount for qualifying expenses and may be granted forgiveness during 2021; and

- The Company filed with the SEC a registration statement on Form S-3 on March 27, 2020, as amended on April 9, 2020, to register an indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities and such indeterminate number of warrants to purchase common stock, preferred stock or debt securities as shall have an aggregate initial offering price not to exceed $50 million. This registration statement was declared effective by the SEC on April 13, 2020 and allows the Company, from time to time, to offer up to $50 million of any combination of the securities described in the Form S-3 in one or more offerings. In order for the Company to utilize the effective S-3, it will have to file subsequent prospectus supplement(s) with regard to the securities it will offer, as applicable from time to time. As of the date of issuance of this Form 10-K, no subsequent prospectus supplements to this effect have been filed by the Company.

Notwithstanding the aforementioned circumstances, there remains substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued. There can be no assurance that the Company will be able to successfully achieve its initiatives summarized above in order to continue as a going concern. The accompanying financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments that might result should the Company be unable to continue as a going concern as a result of the outcome of this uncertainty.

Table of Contents

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation.

The consolidated financial statements include the accounts of Precipio, Inc. and our wholly owned subsidiaries, and the Joint Venture which is a VIE in which we are the primary beneficiary. Refer to the section titled "Consolidation of Variable Interest Entities" for further information related to our accounting for the Joint Venture. All inter-company balances and transactions have been eliminated in consolidation.

Use of Estimates.

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of net sales and expenses during the reporting period. The most significant estimates and assumptions with regard to these consolidated financial statements relate to the allowance for doubtful accounts, assumptions used within the fair value of debt and equity transactions, contractual allowances and related impairments. These assumptions require considerable judgment by management. Actual results could differ from the estimates and assumptions used in preparing these consolidated financial statements.

Risks and Uncertainties.

Certain risks and uncertainties are inherent in our day-to-day operations and in the process of preparing our financial statements. The risks and uncertainties may be heightened by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. The more significant of those risks are presented below and throughout the notes to the consolidated financial statements.

The Company operates in the healthcare industry which is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not necessarily limited to, matters such as licensure, accreditation, government healthcare program participation requirements, reimbursement for patient services, and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers. Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation as well as regulatory actions unknown or unasserted at this time.

Fair Value.

Unless otherwise specified, book value approximates fair value. The common stock warrant liabilities are recorded at fair value. See Note 12 - Fair Value for additional information.

Other Current Assets.

Other current assets of $0.3 million as of December 31, 2020 include prepaid insurance of approximately $0.3 million and prepaid assets and other receivables of less than $0.1 million. Other current assets of $0.3 million as

of December 31, 2019 include prepaid assets of less than $0.1 million, prepaid insurance of $0.2 million and other receivables of less than $0.1 million.

Concentrations of Risk.

From time to time, we may maintain a cash position with financial institutions in amounts that exceed Federal Deposit Insurance Corporation insured limits of up to $250,000 per depositor per financial institution. We have not experienced any losses on such accounts as of December 31, 2020.

Table of Contents

Service companies in the health care industry typically grant credit without collateral to patients. The majority of these patients are insured under third-party insurance agreements. The services provided by the Company are routinely billed utilizing the Current Procedural Terminology (CPT) code set designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. CPT codes are currently identified by the Centers for Medicare and Medicaid Services and third-party payers. The Company utilizes CPT codes for Pathology and Laboratory Services contained within codes 80000-89398.

Inventories.

Inventories consist of laboratory supplies and are valued at cost (determined on an average cost basis, which approximates the first-in, first-out method) or net realizable value, whichever is lower. We evaluate inventory for items that are slow moving or obsolete and record an appropriate reserve for obsolescence if needed. We determined that no allowance for slow moving or obsolete inventory was necessary at December 31, 2020 and 2019.

Property and Equipment, net.

Property and equipment are carried at cost, net of accumulated depreciation and amortization. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization are computed by the straight-line method over the estimated useful lives of the related assets as follows:

Furniture and fixtures	5 to 7 years
Laboratory equipment	3 to 10 years
Computer equipment and software	3 to 7 years

For assets sold or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the accounts, and any related gain or loss is reflected in operations for the period. Expenditures for major betterments that extend the useful lives of property and equipment are capitalized.

Intangible Assets.

We review our amortizable long-lived assets for impairment annually or whenever events indicate that the carrying amount of the asset (group) may not be recoverable. An impairment loss may be needed if the sum of the

future undiscounted cash flows is less than the carrying amount of the asset (group). The amount of the loss would be determined by comparing the fair value of the asset to the carrying amount of the asset (group). There were no impairment charges on our amortizable long-lived assets during the years ended December 31, 2020 and 2019.

In-process research and development ("IPR&D") represents the fair value assigned to research and development assets that were not fully developed when acquired. Until the IPR&D projects are completed, the assets are accounted for as indefinite-lived intangible assets and subject to impairment testing. The IPR&D principally related to research projects that were not related to IV-Cell, HemeScreen or ICP. During 2019, the Company made a determination to suspend further research and analysis of these projects, and, as a result, it was more likely than not that the IPR&D was fully impaired, resulting in an impairment charge of $1.6 million in 2019. There was zero IPR&D within the accompanying consolidated balance sheets at December 31, 2020 and 2019, respectively.

Debt Issuance Costs, Debt Discounts and Debt Premiums.

Debt issuance costs, debt discounts and debt premiums are being amortized or accreted over the lives of the related financings on a basis that approximates the effective interest method. Costs and discounts are presented as a reduction of the related debt and premiums are presented as an increase to the related debt in the accompanying balance sheets. The amortization amount recorded was expense, net of income, of $0.3 million and $0.1 million for the years ended December 31, 2020 and 2019, respectively. Debt discounts and debt premiums are amortized or accreted to interest expense and interest income on the consolidated statement of operations, respectively. See Note 5 – Long Term Debt and Note 6 – Convertible Notes for further discussion.

Table of Contents

Stock-Based Compensation.

All stock-based awards to date have exercise prices equal to the market price of our common stock on the date of grant and have ten-year contractual terms. Stock-based compensation cost is based on the fair value of the portion of stock-based awards that is ultimately expected to vest. The Company utilizes the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. Unvested awards as of December 31, 2020 had vesting periods of up to four years from the date of grant. At December 31, 2020 and 2019, 53,334 unvested awards outstanding are subject to performance vesting conditions, respectively. No awards outstanding at December 31, 2020 and 2019, respectively, are subject to market-based vesting.

Net Sales Recognition.

Revenue recognition occurs when a customer obtains control of the promised goods and service. Revenue assigned to the goods and services reflects the consideration which the Company expects to receive in exchange for those goods and services.

The Company derives its revenues from diagnostic testing - histology, flow cytometry, cytology and molecular testing; clinical research from bio-pharma customers, state and federal grant programs; biomarker testing from bio-pharma customers and from other product sales. All sources of revenue are recorded net of accruals for estimated chargebacks, rebates, cash discounts, other allowances, and returns. Due to differences in the substance of these

revenue types, the transactions require, and the Company utilizes, different revenue recognition policies for each. See more detailed information on revenue in Note 14 – Sales Service Revenue, Net And Accounts Receivable.

The Company recognizes revenue utilizing the five-step framework of ASC 606. Control of the laboratory testing services is transferred to the customer at a point in time. As such, the Company recognizes revenue for diagnostic testing at a point in time based on the delivery method (web-portal access or fax) for a patient's laboratory report. Diagnostic testing service revenue is reported at the estimated net realizable amounts from patients, third-party payers and others for services rendered, including retroactive adjustment under reimbursement agreements with third-party payers. Provisions for third-party payer settlements are provided in the period in which the related services are rendered and adjusted in the future periods, as final settlements are determined. For clinical research and biomarker services, the Company utilizes an "effort based" method of assessing performance and measures progress towards satisfaction of the performance obligation based upon the delivery of results per the contract. When we receive payment in advance, we initially defer the revenue and recognize it when we deliver the service.

Deferred net sales included in the balance sheet as deferred revenue was less than $0.1 million as of December 31, 2020 and 2019.

Taxes collected from customers and remitted to government agencies for specific net sales producing transactions are recorded net with no effect on the income statement.

Accounts Receivable

Accounts Receivable result from diagnostic services provided to self-pay and insured patients, project based testing services and clinical research. The payment for services provided by the Company are generally due within 30 days from the invoice date. Accounts receivable are reduced by an allowance for doubtful accounts. In evaluating the collectability of accounts receivable, the Company analyzes and identifies trends for each of its sources of revenue to estimate the appropriate allowance for doubtful accounts. For receivables associated with self-pay patients, including patients with insurance and a deductible and copayment, the Company records an allowance for doubtful accounts in the period of services on the basis of past experience of patients unable or unwilling to pay for service fee for which they are financially responsible. For receivables associated with services provided to patients with third-party coverage, the Company analyzes contractually due amounts and provides an allowance, if necessary. The difference between the standard rates and the amounts actually collected after all reasonable collection efforts have been exhausted is charged against the allowance for doubtful accounts.

Table of Contents

Presentation of Insurance Claims and Related Insurance Recoveries.

The Company accounts for its insurance claims and related insurance recoveries at their gross values as standards for health care entities do not allow the Company to net insurance recoveries against the related claim liabilities. There were no insurance claims or insurance recoveries recorded during the years ended December 31, 2020 and 2019.

Advertising Costs.

Advertising costs are expensed as incurred and are included in operating expenses on the consolidated statement of operations. Advertising costs charged to operations totaled approximately $0.1 million in 2020 and 2019, respectively.

Research and Development Costs.

All costs associated with internal research and development are expensed as incurred. These costs include salaries and employee related expenses, operating supplies and facility-related expenses. Research and development costs charged to operations totaled $1.2 million for the years ended December 31, 2020 and 2019, respectively.

Income Taxes.

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities at each balance sheet date using tax rates expected to be in effect in the year the differences are expected to reverse. The effect on the deferred tax assets and liabilities of a change in tax rates is recognized in the period when the change in tax rates is enacted.

A valuation allowance is established when it is determined that it is more likely than not that some portion or all of the deferred tax assets will not be realized. A full valuation allowance has been applied against the Company's net deferred tax assets as of December 31, 2020 and 2019, due to projected losses and because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets.

Management's conclusions regarding uncertain tax positions may be subject to review and adjustment at a later date based upon ongoing analysis of, or changes in tax laws, regulations and interpretations thereof as well as other factors. The Company's policy is to record interest and penalties directly related to income taxes as income tax expense in the accompanying consolidated statements of operations, of which there was none for the years ended December 31, 2020 and 2019.

Common Stock Warrants.

The Company classifies the issuance of common stock warrants as equity any contracts that (i) require physical settlement or net-stock settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own stocks (physical settlement or net-stock settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside of the Company's control), or (ii) gives the counterparty a choice of net-cash settlement or settlement in stock (physical settlement or net-stock settlement).

Certain of our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity and accordingly, are recorded as a liability ("Common Stock Warrant Liability"). We are required to present these instruments at fair value at each reporting date and any changes in fair values are recorded as an adjustment to earnings.

Beneficial Conversion Features.

The intrinsic value of a beneficial conversion feature ("BCF") inherent to a convertible note payable, which is not bifurcated and accounted for separately from the convertible note payable and may not be settled in cash upon conversion, is treated as a discount to the convertible note payable. This discount is amortized over the period from the date of issuance to the first conversion date using the effective interest method. If the note payable is retired prior to the

end of its contractual term, the unamortized discount is expensed in the period of retirement to interest expense. In general, the BCF is measured by comparing the effective conversion price, after considering the relative fair value of detachable instruments included in the financing transaction, if any, to the fair value of the common shares at the commitment date to be received upon conversion.

Deemed dividends are also recorded for the intrinsic value of conversion options embedded in preferred shares based upon the differences between the fair value of the underlying common stock at the commitment date of the transaction and the effective conversion price embedded in the preferred shares. When the preferred shares are non-redeemable the BCF is fully amortized into additional paid-in capital and preferred discount. If the preferred shares are redeemable, the discount is amortized from the commitment date to the first conversion date.

Consolidation of Variable Interest Entities.

We evaluate any entity in which we are involved to determine if the entity is a VIE and if so, whether we hold a variable interest and are the primary beneficiary. We consolidate VIEs that are subject to assessment when we are deemed to be the primary beneficiary of the VIE. The process for determining whether we are the primary beneficiary of the VIE is to conclude whether we are a party to the VIE holding a variable interest that meets both of the following criteria: (1) has the power to make decisions that most significantly affect the economic performance of the VIE, and (2) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE.

We have determined that we hold a variable interest in the Joint Venture, have the power to make significant operational decisions on behalf of the VIE and also have the obligation to absorb the majority of the losses from the VIE. As such we have also determined that we are the primary beneficiary of the VIE. The following table presents information about the carrying value of the assets and liabilities of the Joint Venture which we consolidate and which are included on our consolidated balance sheets. Intercompany balances are eliminated in consolidation and not reflected in the following table.

(dollars in thousands)	December 31, 2020
Assets:	
Accounts receivable, net	$ 538
Total assets	$ 538
Liabilities:	
Accrued expenses	$ 27
Total liabilities	$ 27
Noncontrolling interest in Joint Venture	$ 27

The Company entered into the Joint Venture during 2020 and, as such, there are no assets or liabilities of the Joint Venture as of December 31, 2019.

Loss Per Share.

Basic loss per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted loss per share includes shares issuable upon exercise of outstanding stock options, warrants or conversion rights that have exercise or conversion prices below the market value of our common stock. Options, warrants and conversion rights pertaining to 1,846,989 and 2,281,701 shares of our common stock have been excluded

from the computation of diluted loss per share at December 31, 2020 and 2019, respectively, because the effect is anti-dilutive due to the net loss.

Table of Contents

The following table summarizes the outstanding securities not included in the computation of diluted net loss per share:

	December 31,	
	2020	2019
tock options	822,992	490,330
Warrants	906,497	909,189
referred stock	117,500	20,888
onvertible notes	—	861,294
otal	1,846,989	2,281,701

Recently Adopted Accounting Pronouncements.

In August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-13 "*Fair Value Measurement (Topic 820)*", which modifies certain disclosure requirements in Topic 820, such as the removal of the need to disclose the amount of and reason for transfers between Level 1 and Level 2 of the fair value hierarchy, and several changes related to Level 3 fair value measurements. The Company adopted this guidance on January 1, 2020. The adoption of this guidance was not material to our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15 "*Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350-40)*", which aligns the requirements for capitalizing implementation costs incurred in a cloud computing hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal use software. The Company adopted this guidance on January 1, 2020. The adoption of this guidance was not material to our consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted.

In August 2020, the FASB issued ASU 2020-06 "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*." This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12 "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*", which is intended to improve consistent application and simplify the accounting for income taxes.

This ASU removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance. This standard is effective for annual reporting periods beginning after December 15, 2020, including interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the impact of adoption of this ASU and does not expect the adoption of this new standard to have a material impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 "*Measurement of Credit Losses on Financial Instruments*", which replaces current methods for evaluating impairment of financial instruments not measured at fair value, including trade accounts receivable and certain debt securities, with a current expected credit loss model. This ASU, as amended, is effective for the Company for reporting periods beginning after December 15, 2022. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

Table of Contents

3. PROPERTY AND EQUIPMENT, NET

A summary of property and equipment at December 31, 2020 and 2019 is as follows:

	2020	2019
ırniture and fixtures	$ 12	$ 12
aboratory equipment	330	299
omputer equipment and software	533	463
quipment under finance leases	467	425
onstruction in process	53	23
	1,395	1,222
ess—accumulated depreciation and amortization	(943)	(791)
Total	$ 452	$ 431

Depreciation expense was approximately $0.2 million and $0.1 million for the years ended December 31, 2020 and 2019, respectively. Depreciation expense during each year includes depreciation related to equipment acquired under finance leases.

4. INTANGIBLES

Intangible assets consist of the following:

	Dollars in Thousands December 31, 2020		
Cost	Accumulated Amortization	Impairment Charge	Net Book Value

Technology	$ 18,990	$ 3,323	$ —	$ 15,667
Customer relationships	250	250	—	—
Backlog	200	200	—	—
Covenants not to compete	30	30	—	—
Trademark	40	40	—	—
	$ 19,510	$ 3,843	$ —	$ 15,667

	Dollars in Thousands December 31, 2019			
	Cost	Accumulated Amortization	Impairment Charge	Net Book Value
Technology	$ 18,990	$ 2,374	$ —	$ 16,616
Customer relationships	250	208	—	42
Backlog	200	200	—	—
Covenants not to compete	30	30	—	—
Trademark	40	40	—	—
IPR&D	1,590	—	1,590	—
	$ 21,100	$ 2,852	$ 1,590	$ 16,658

	Estimated Useful Life
Technology	20 years
Customer relationships	3 years
Backlog	1 year
Covenants not to compete	1 year
Trademark	2 years

Our IPR&D projects were accounted for as indefinite-lived intangible assets and subject to impairment testing. During 2019, the Company reviewed its IPR&D for impairment and determined that it was more likely than not that the

Table of Contents

IPR&D was fully impaired, resulting in an impairment charge of $1.6 million in 2019. For the year ended December 31, 2020, there was no impairment of IPR&D.

Amortization expense for intangible assets was $1.0 million during the years ended December 31, 2020 and 2019. Amortization expense for intangible assets is expected to be $0.9 million for each of the years ending December 31, 2021, 2022, 2023, 2024 and 2025, respectively.

5. LONG-TERM DEBT

Long-term debt consists of the following:

	Dollars in Thousands	
	December 31, 2020	December 31, 2019
Department of Economic and Community Development (DECD)	$ 233	$ 249
DECD debt issuance costs	(22)	(24)
Financed insurance loan	12	260
September 2018 Settlement	—	34
Paycheck Protection Program	787	—
Total long-term debt	1,010	519
Current portion of long-term debt	(648)	(321)
Long-term debt, net of current maturities	$ 362	$ 198

Department of Economic and Community Development

On January 8, 2018, the Company received gross proceeds of $400,000 when it entered into an agreement with DECD by which the Company received a grant of $100,000 and a loan of $300,000 secured by substantially all of the Company's assets (the "DECD 2018 Loan".) The DECD 2018 Loan is a ten-year loan due on December 31, 2027 and includes interest paid monthly at 3.25%.

Due to the economic impact of COVID-19, DECD offered financial relief to all businesses with certain loans, including the Company's DECD 2018 Loan. The relief includes the option to defer all payments from April 1, 2020 to August 1, 2020 and the deferred payments will be added to the end of the loan. The Company chose to defer its payments and the maturity date of the DECD 2018 Loan was extended to May 31, 2028. The payment deferral modification did not have a material impact on the Company's cash flows for the year ended December 31, 2020

Debt issuance costs associated with the DECD 2018 Loan were approximately $31,000. Amortization of the debt issuance cost was approximately $2,000 and $3,000 for the years ended December 31, 2020 and 2019, respectively. Net debt issuance costs were approximately $22,000 and $24,000 at December 31, 2020 and 2019, respectively, and are presented as a reduction of the related debt in the accompanying consolidated balance sheets. Amortization for each of the next five years is expected to be approximately $3,000.

Financed Insurance Loan.

The Company finances certain of its insurance premiums (the "Financed Insurance Loans"). In July 2018, the Company financed $0.4 million with a 4.89% interest rate and fully paid off such loan as of July 2019. In July 2019, the Company financed $0.4 million with a 5.0% interest rate and made monthly payments through May of 2020. In July 2020, the Company financed less than $0.1 million with a 5.0% interest rate and will make monthly payments through May 2021. As of December 31, 2020 and 2019, the Financed Insurance Loan outstanding balance of less than $0.1 million and $0.3 million, respectively, was included in current maturities of long-term debt in the Company's consolidated balance sheets. A corresponding prepaid asset was included in other current assets.

Table of Contents

Settlement Agreement.

On September 21, 2018, the Company entered into a settlement and forbearance agreement with a creditor (the "September 2018 Settlement") pursuant to which, the Company agreed to make monthly principal and interest payments to the creditor over a two year period, from November 1, 2018 to November 1, 2020, in full and final settlement of $0.1 million of indebtedness that was owed to the creditor on the date of the September 2018 Settlement. The settlement amount accrued interest at the rate of 10% per annum and was paid in full during the fourth quarter on 2020. As of December 31, 2019, the September 2018 Settlement outstanding balance of approximately $0.1 million was included in current maturities of long-term debt in the Company's consolidated balance sheet.

Paycheck Protection Program.

On April 23, 2020, the Company entered into a promissory note (the "Promissory Note") evidencing an unsecured $787,200 loan under the Paycheck Protection Program (the "PPP Loan"). The Paycheck Protection Program (or "PPP") was established under the recently congressionally-approved Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The PPP Loan to the Company was made through Webster Bank, N.A.

The term of the PPP Loan is two years. The interest rate on the PPP Loan is 1.00% and payments are deferred for the first six months of the term of the loan. Under the terms of the CARES Act, PPP Loan recipients can apply for and be granted forgiveness for all or a portion of loans granted under the PPP. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payroll costs and mortgage interest, rent or utility costs and the maintenance of employee and compensation levels. The Company will use the eight-week forgiveness period and will apply for forgiveness of the PPP Loan in accordance with the terms of the PPP.

On February 11, 2021, the Company filed its application for loan forgiveness with Webster Bank but no assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part. The Company believes it used all of the PPP Loan amount for qualifying expenses. As of the date of issuance of this Report on Form 10-K, using the eight-week forgiveness period, the Company has incurred approximately $0.8 million in payroll, payroll related costs and other anticipated qualifying expenses.

The Promissory Note contains customary events of default relating to, among other things, payment defaults, breach of representations and warranties, or provisions of the Promissory Note. The occurrence of an event of default may result in the repayment of all amounts outstanding, collection of all amounts owing from the Company, and/or filing suit and obtaining judgment against the Company.

As of December 31, 2020, $0.6 million the PPP Loan's outstanding balance was included in current maturities of long-term debt and $0.2 million was included in long-term debt in the Company's consolidated balance sheets.

The aggregate future maturities required on gross long-term debt at December 31, 2020 are as follows:

	2021	2022	2023	2024	2025	2026 and thereafter	Total
DECD loan	$ 28	$ 29	$ 30	$ 31	$ 32	$ 83	$ 233
Financed Insurance Loan	12	—	—	—	—	—	12
Paycheck Protection Program	611	176	—	—	—	—	787
	$ 651	$ 205	$ 30	$ 31	$ 32	$ 83	$ 1,032

Table of Contents

6. CONVERTIBLE NOTES.

Convertible notes consists of the following:

	Dollars in Thousands	
	December 31, 2020	December 31, 2019
Convertible bridge notes	$ —	$ 1,938
Convertible bridge notes discount and debt issuance costs	—	(1,796)
Total convertible notes	—	142
Current portion of convertible notes	—	(142)
Convertible notes, net of current maturities	$ —	$ —

Convertible Bridge Notes.

On April 20, 2018, the Company entered into a securities purchase agreement (the "2018 Note Agreement") with certain investors (the "April 2018 Investors"), as amended on November 29, 2018 (the "Amendment Agreement") and amended on April 16, 2019 ("Amendment No.2 Agreement"). During 2018, pursuant to the 2018 Note Agreement, the Company issued approximately $4.5 million in Senior Secured Convertible Promissory Notes (the "Bridge Notes") along with warrants.

On April 16, 2019, the Company entered into the Amendment No.2 Agreement which provided the Company with approximately $0.9 million of gross proceeds for the issuance of notes with an aggregate principal of $1.0 million (the "April 2019 Bridge Notes") together with applicable warrants, with substantially the same terms and conditions as the previously issued Bridge Notes and related warrants. The 9% discount associated with the April 2019 Bridge Notes was approximately $0.1 million and was recorded as a debt discount. In connection with the April 2019 Bridge Note issuances, the Company issued to the investors 147,472 warrants to purchase shares of common stock of the Company with a five year term and exercise price of $5.40 (the "April 2019 Warrants"). The April 2019 Warrants had an initial value of approximately $1.0 million at the date of issuance and were recorded as a liability with an offset to debt discount. See Note 12 – Fair Value for further discussion. The April 2019 Bridge Notes were issued to investors that previously participated in the 2018 Note Agreement.

The conversion price of the April 2019 Bridge Notes shall be equal to the greater of $3.75 or $0.75 above the closing bid price of our common stock on the date prior to the original issue date. In the event the notes are not paid in full prior to 180 days after the original issue date, the conversion price shall be equal to 80% of the lowest volume weighted average price ("VWAP") in the 10 trading days prior to the date of the notice of conversion, but in no event below the floor price of $2.25.

The Company reviewed the conversion option of the April 2019 Bridge Notes and determined that there was a beneficial conversion feature with a value of approximately $0.9 million which was recorded as a debt discount with an offset to additional paid in capital at the time of the Amendment No.2 Agreement. The Company also reviewed the redemption features of the April 2019 Bridge Notes and determined that there is a redemption feature (the "Bridge Notes Redemption Feature") that qualifies as an embedded derivative. The Company performed a valuation at the time of issuance which resulted in zero value, at that time, due to the high value of the conversion feature and a limited upside from the redemption premium.

Debt discounts and debt issuance costs related to the April 2019 Bridge Notes totaled $2.0 million. Since the costs exceeded the $1.0 million face amount of the debt at issuance, the Company recorded $1.0 million of debt discount and debt issuance costs as a reduction of the related debt in the accompanying consolidated balance sheet with the excess $1.0 million expensed as a loss on issuance of convertible notes in the consolidated statements of operations during the year ended December 31, 2019.

Pursuant to the Amendment No.2 Agreement, previously issued warrants were amended such that the exercise price of such warrants was amended from $7.50 to $5.40 and any warrant that had a one-year term was amended to have a five-year term. The Company reviewed the amendments to the warrants and determined that they will be treated as a

Table of Contents

modification of an outstanding equity instrument at the time of the Amendment No.2 Agreement. Management calculated the change in fair value due to the modifications to be an expense of approximately $1.1 million which is included in loss on modification of warrants in the consolidated statements of operations during the year ended December 31, 2019.

On May 14, 2019, the Company entered into a securities purchase agreement pursuant to which, the Company was provided with $1.0 million of gross proceeds for the issuance of notes with an aggregate principal of $1.1 million (the "May 2019 Bridge Notes") together with applicable warrants, with substantially the same terms and conditions as the previously issued Bridge Notes and related warrants. The 9% discount associated with the May 2019 Bridge Notes was approximately $0.1 million and was recorded as a debt discount. In connection with the May 2019 Bridge Note issuances, the Company issued to the investors 154,343 warrants to purchase shares of common stock of the Company with a five year term and exercise price of $9.56 (the "May 2019 Warrants"). The May 2019 Warrants had an initial value of approximately $0.9 million at the date of issuance and were recorded as a liability with an offset to debt discount. See Note 12 – Fair Value for further discussion. The May 2019 Bridge Notes were issued to investors that previously participated in the 2018 Note Agreement.

The conversion price of the May 2019 Bridge Notes is $7.12, provided that a) in the event the notes are not paid in full prior to 180 days after the original issue date or b) upon a registration statement (as defined in the purchase agreement) being declared effective, whichever occurs earlier, the conversion price shall be equal to 80% of the lowest VWAP in the 10 trading days prior to the date of the notice of conversion, but in no event below the floor price of $2.25.

The Company reviewed the conversion option of the May 2019 Bridge Notes and determined that there was a beneficial conversion feature with a value of approximately $0.9 million which was recorded as a debt discount with an offset to additional paid in capital at the time of issuance of the May 2019 Bridge Notes. The May 2019 Bridge Notes also contain the Bridge Notes Redemption Feature and the Company performed a valuation at the time of issuance which resulted in zero value, at that time, due to the high value of the conversion feature and a limited upside from the redemption premium.

Debt discounts and debt issuance costs related to the May 2019 Bridge Notes totaled $2.0 million. Since the costs exceeded the $1.1 million face amount of the debt, the Company recorded $1.1 million of debt discount and debt issuance costs as a reduction of the related debt in the accompanying consolidated balance sheet with the excess $0.9 million expensed as a loss on issuance of convertible notes in the consolidated statements of operations during the year ended December 31, 2019.

On March 26, 2020, the Company entered into an amendment agreement (the "March 2020 Amendment") amending the terms of that certain Amendment No. 2 Agreement dated April 16, 2019 and the securities purchase agreement dated May 14, 2019. As a result of the March 2020 Amendment, (i) the maturity date of the April 2019 Bridge Notes and the May 2019 Bridge Notes was extended three months from April 16, 2020 to July 16, 2020, (ii)

the floor price at which conversions may occur under the April 2019 Bridge Notes and the May 2019 Bridge Notes was amended from $2.25 to $0.40, and (iii) guaranteed interest on the April 2019 Bridge Notes and the May 2019 Bridge Notes was amended from twelve months to eighteen months.

The Company reviewed the modifications and concluded that the March 2020 Amendment will be treated as an extinguishment of the related April 2019 Bridge Notes and May 2019 Bridge Notes. The difference between the carrying value of the notes just prior to modification (the "Pre-modification Debt") and the fair value of the notes just after modification (the "Post-modification Debt") would be recorded as a gain or loss on extinguishment in the consolidated statements of operations. The Company removed the carrying value of the Pre-modification Debt which included $1.0 million of unamortized debt discounts and beneficial conversion features of $0.5 million. The Company calculated the fair value of the Post-modification Debt to be $2.6 million. The Company reviewed whether or not a beneficial conversion feature existed on the Post-modification Debt but the calculation resulted in zero intrinsic value so no new beneficial conversion feature was recorded. Management also reviewed the Bridge Notes Redemption Feature of the post-modification notes but their fair value was zero so no derivative liability was recorded at the time of modification, however this will be reassessed at the end of each reporting period. As a result, the Company recorded a debt premium on the Post-modification Debt of $0.8 million and a loss on extinguishment of convertible notes of $1.2 million in the consolidated statements of operations during the year ended December 31, 2020.

Table of Contents

During the years ended December 31, 2020 and 2019, $2.2 million and $4.8 million, respectively, of Bridge Notes, plus interest, were converted into 3,908,145 and 1,900,766 shares of common stock of the Company, respectively. As a result of the conversions, the Company wrote-off approximately $0.5 million of derivative liability, with an offset to additional paid-in capital, during the year ended December 31, 2019.

During the years ended December 31, 2020 and 2019, the change in Bridge Note debt discounts and debt premiums was as follows:

	For the Years Ended December 31,			
	2020		2019	
	Debt Discounts	Debt Premiums	Debt Discounts	Debt Premiums
Beginning balance at January 1	$ (1,796)	$ —	$ (1,111)	$ 647
Additions:	—	793	(2,088)	—
Deductions:				
Amortization (accretion) (1)	703	(385)	273	(167)
Write-off related to note conversions (2)	138	(408)	1,130	(480)
Write-off related to note extinguishment (3)	955	—	—	—
Balance at December 31	$ —	$ —	$ (1,796)	$ —

(1) Amortization/accretion is recognized as interest expense/income within the consolidated statements of operations based on the effective interest method.

(2) Write-offs associated with note conversions are recognized as an offset to additional paid-in capital at the time of the conversion.

(3) Write-offs associated with note extinguishment are recognized as a loss and included in loss on extinguishment of convertible notes in the consolidated statements of operations.

Convertible Promissory Notes – Exchange Notes.

During the years ended December 31, 2020 and 2019, zero and $0.6 million, respectively, of previously issued convertible promissory notes (the "Exchange Notes") were converted into zero and 155,351 shares of common stock of the Company, respectively. As of December 31, 2020 and 2019, the outstanding balance of the Exchange Notes, net of discounts, was zero, respectively.

There was no Exchange Note activity during the year ended December 31, 2020. During the year ended December 31, 2019, the change in Exchange Note debt discounts was as follows:

(Dollars in thousands)

	For the Year Ended December 31, 2019
Beginning balance at January 1	$ (83)
Deductions:	
Amortization (1)	2
Write-off related to note conversions (2)	81
Balance at December 31	$ —

Table of Contents

(1) Amortization is recognized as interest expense within the consolidated statements of operations based on the effective interest method.
(2) Write-offs associated with note conversions are recognized as an offset to additional paid-in capital at the time of the conversion.

As a result of the Exchange Note conversions, during the year ended December 31, 2019, the Company wrote-off less than $0.1 million of derivative liability with an offset to additional paid-in capital.

Convertible Promissory Notes – Crede Note.

On January 15, 2019, the Company and Crede Capital Group LLC ("Crede") entered into an amendment and restatement agreement (the "Crede Amendment Agreement") in order to enable the Company to provide Crede with an alternative means of payment of a previous settlement amount by issuing to Crede a convertible note in the amount of $1.45 million (the "Crede Note"). The conversion price of the Crede Note shall equal 90% of the closing bid price of the Company's common stock on the date prior to each conversion date. The Crede Note is payable by the Company on the earlier of (i) January 15, 2021 or (ii) upon the closing of a qualified offering in which the Company receives gross proceeds of at least $4.0 million. The Crede Note may not be converted if, after giving effect to the conversion, Crede together with its affiliates would beneficially own in excess of 4.99% of the outstanding shares of the Company's common stock. The Company, at its option, may redeem some or all of the then outstanding principal amount of the Crede Note for cash.

In accordance with the terms of the Crede Amendment Agreement, during the period commencing on the date of issuance of the Crede Note and ending on the date Crede no longer beneficially owns any portion of the Crede Note, Crede shall not sell, on any given trading day, more than the greater of (i) $10,000 of common stock (subject to adjustment for any stock splits or combinations, stock dividends, recapitalizations or similar event after the date hereof) and (ii) 10% of the daily average composite trading volume of the Company's common stock as reported by Bloomberg, LP (subject to adjustment for any stock splits or combinations, stock dividends, recapitalizations or similar event after the date hereof) for such trading day.

During the year ended December 31, 2019, the Company made no payments on the Crede Note. On April 16, 2019, the entire outstanding amount of $1.45 million was converted into 270,699 shares of common stock of the Company and as of December 31, 2020 and 2019 the remaining amount due on the Crede Note was zero.

Convertible Promissory Notes – Leviston Note

On February 8, 2018, the Company entered into an equity purchase agreement (the "2018 Purchase Agreement") with Leviston Resources LLC ("Leviston"). On January 29, 2019, the Company entered into a settlement agreement (the "Leviston Settlement") with Leviston pursuant to which the Company issued to Leviston a convertible note in the amount of $0.7 million (the "Leviston Note") in full satisfaction of certain obligations to Leviston.

In addition to the Leviston Settlement and the Leviston Note, the Company and Leviston have each executed a release pursuant to which each of the Company and Leviston agreed to release the other party from their respective obligations arising from or concerning the Obligations.

During the year ended December 31, 2019, the Company made cash payments of less than $0.1 million on the Leviston Note and $0.7 million of the Leviston note was converted into 184,357 shares of common stock of the Company.

The remaining amount due on the Leviston Note was zero as of December 31, 2020 and 2019, respectively.

Table of Contents

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES.

Accrued expenses at December 31, 2020 and 2019 are as follows:

(dollars in thousands)	2020	2019
Accrued expenses	$ 1,332	$ 1,268
Accrued compensation	685	247
Accrued interest	19	124
	$ 2,036	$ 1,639

The Company was able to reduce certain accrued expense and accounts payable amounts through negotiations with certain vendors to settle outstanding liabilities and reversed certain accrued expenses based on statute

of limitations for collections being met. The Company recorded these amounts as gains which are included in gain on settlement of liability, net in the consolidated statements of operations. During the years ended December 31, 2020 and 2019, approximately $0.1 million and $1.4 million, respectively, was recorded as a gain.

8. LEASES

On January 1, 2019, the Company recorded initial ROU assets and corresponding operating lease liabilities of approximately $750,000 and a reversal of deferred rent and prepaid expenses of approximately $6,000 resulting in no cumulative effect adjustment upon adoption of Topic 842. The Company leases administrative facilities and laboratory equipment through operating lease agreements. In addition we rent various equipment used in our diagnostic lab and in our administrative offices through finance lease arrangements. Our operating leases include both lease (e.g., fixed payments including rent) and non-lease components (e.g., common area or other maintenance costs). The facility leases include one or more options to renew, from 1 to 5 years or more. The exercise of lease renewal options is typically at our sole discretion, therefore, the renewals to extend the lease terms are not included in our ROU assets and lease liabilities as they are not reasonably certain of exercise. We regularly evaluate the renewal options and, when they are reasonably certain of exercise, we include the renewal period in our lease term. As our leases do not provide an implicit rate, we use our collateralized incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

Operating leases result in the recognition of ROU assets and lease liabilities on the balance sheet. ROU assets represent our right to use the leased asset for the lease term and lease liabilities represent our obligation to make lease payments. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Lease expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The primary leases we enter into with initial terms of 12 months or less are for equipment.

Upon the adoption of Topic 842, our accounting for finance leases, previously referred to as capital leases, remains substantially unchanged from prior guidance.

Table of Contents

The balance sheet presentation of our operating and finance leases is as follows:

(dollars in thousands)	**Classification on the Consolidated Balance Sheet**	**December 31, 2020**	**December 31, 2019**
Assets:			
Operating lease assets	Operating lease right-of-use assets, net	$ 335	$ 519
Finance lease assets	Property and equipment, net	175	184
Total lease assets		$ 510	$ 703
Liabilities:			
Current:			
Operating lease obligations	Current maturities of operating lease liabilities	$ 225	$ 209
Finance lease obligations	Current maturities of finance lease liabilities	48	52

Noncurrent:			
Operating lease obligations	Operating lease liabilities, less current maturities	92	317
Finance lease obligations	Finance lease liabilities, less current maturities	116	119
Total lease liabilities		$ 481	$ 697

As of December 31, 2020, the estimated future minimum lease payments, excluding non-lease components, are as follows:

(dollars in thousands)	**Operating Leases**	**Finance Leases**	**Total**
2021	$ 241	$ 61	$ 302
2022	48	49	97
2023	35	38	73
2024	17	28	45
2025	—	13	13
Thereafter	—	—	—
Total lease obligations	341	189	530
Less: Amount representing interest	(24)	(25)	(49)
Present value of net minimum lease obligations	317	164	481
Less, current portion	(225)	(48)	(273)
Long term portion	$ 92	$ 116	$ 208

Other information as of December 31, 2020 and 2019:

	December 31, 2020	**December 31, 2019**
Weighted-average remaining lease term (years):		
Operating leases	1.9	2.8
Finance leases	3.6	4.3
Weighted-average discount rate:		
Operating leases	8.00%	8.00%
Finance leases	8.28%	7.25%

During the years ended December 31, 2020 and 2019, operating cash flows from operating leases was $0.2 million, respectively. During the years ended December 31, 2020 and 2019, ROU assets obtained in exchange for operating lease liabilities was zero and $0.8 million, respectively, and ROU assets obtained in exchange for financing lease liabilities was less than $0.1 million and zero, respectively.

Table of Contents

Operating Lease Costs

Operating lease costs were $0.2 million and $0.3 million during the years ended December 31, 2020 and 2019, respectively. These costs are primarily related to long-term operating leases for the Company’s facilities and

laboratory equipment. Short-term and variable lease costs were less than $0.1 million for the years ended December 31, 2020 and 2019, respectively.

Finance Lease Costs

Finance leases are included in property and equipment, net and finance lease liabilities, less current maturities on the consolidated balance sheets. The associated amortization expense and interest included in the consolidated statements of operations for the years ended December 31, 2020 and 2019 is less than $0.1 million, respectively.

9. COMMITMENTS AND CONTINGENCIES

PURCHASE COMMITMENTS

The Company has entered into purchase commitments for reagents from suppliers. These agreements started in 2011 and run through 2025. The Company and the suppliers will true up the amounts on an annual basis. The future minimum purchase commitments under these and other purchase agreements are as follows:

Years ending December 31,	(dollars in thousands)
2021	$ 1,068
2022	228
2023	219
2024	170
2025	50
Thereafter	—
	$ 1,735

LITIGATIONS

The Company is delinquent on the payment of outstanding accounts payable for certain vendors and suppliers who have taken or have threatened to take legal action to collect such outstanding amounts. See below for a discussion on these matters.

CPA Global provides us with certain patent management services. On February 6, 2017, CPA Global claimed that we owe approximately $0.2 million for certain patent maintenance services rendered. CPA Global has not filed claims against us in connection with this allegation. A liability of less than $0.1 million has been recorded and is reflected in accounts payable within the accompanying consolidated balance sheet at December 31, 2020 and 2019.

On February 17, 2017, Jesse Campbell (“Campbell”) filed a lawsuit individually and on behalf of others similarly situated against us in the District Court for the District of Nebraska alleging we had a materially incomplete and misleading proxy relating to a potential merger and that the merger agreement’s deal protection provisions deter superior offers. On June 21, 2019, the parties filed a stipulation of settlement, in which defendants are released from all claims and expressly deny that that they have committed any act or omission giving rise to any liability. The stipulation includes a settlement payment of $1.95 million. On July 10, 2019, the Court entered an order preliminarily approving the settlement. During the third quarter of 2019, both the Company and the insurance company paid their respective amounts of $0.27 million and $1.68 million, respectively, to an escrow account where the funds were held until they were approved for distribution. On June 3, 2020, the Court approved the settlement and entered an order of dismissal. As of the date the consolidated financial statements were issued, the escrow funds have been released and this matter is closed.

LEGAL AND REGULATORY ENVIRONMENT

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not limited to, matters such as licensure, accreditation, government healthcare program participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

10. INCOME TAXES

The Company recorded a deferred tax liability of $0.1 million as of December 31, 2018, related to the acquisition of IPR&D through the Merger. This deferred tax liability was recorded to account for the book versus tax basis difference related to the IPR&D intangible asset. This deferred tax liability was excluded from sources of future taxable income, as the timing of its reversal cannot be predicted due to the indefinite life of this IPR&D. As such, this deferred tax liability cannot be used to offset the valuation allowance. As a result of the write-off of the IPR&D in 2019, the related deferred tax liability of $0.1 million was eliminated and is included in income tax benefit in the consolidated statements of operations for the year ended December 31, 2019.

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 net deferred tax assets relate primarily to its net operating loss carryforwards, allowance for doubtful accounts and stock-based compensation, offset by property and equipment and intangible assets. The Company has recorded a full valuation allowance to offset the net deferred tax assets, as it is more likely than not that the Company will not realize future benefits associated with these net deferred tax assets at December 31, 2020 and 2019.

At December 31, 2020 and 2019, the Company had net deferred tax assets of $13.5 million and $10.7 million, respectively, against which a full valuation allowance has been recorded. The increase in the valuation allowance for the years ended December 31, 2020 and 2019 is $2.8 million and $1.9 million, respectively, resulting from additional net operating losses generated in the year. The deferred tax liabilities associated with the book versus tax basis difference of

intangible assets are the result of an asset step-up pursuant to the Merger. Significant components of the Company's deferred tax assets at December 31, 2020 and 2019 are as follows:

	Dollars in Thousands	
	2020	2019
Deferred tax assets:		
Net operating loss and credit carryforwards	$ 15,941	$ 13,989
Allowance for doubtful accounts	986	666
Stock-based compensation	461	292
Other	39	—
Gross deferred tax assets	17,427	14,947
Deferred tax liabilities:		
Property and equipment	(94)	(95)
Intangible assets	(3,849)	(4,148)
IPR&D intangible assets	—	—
Gross deferred tax liabilities	(3,943)	(4,243)
Net deferred tax assets	13,484	10,704
Less valuation allowance	(13,484)	(10,704)
Net deferred liability	$ —	$ —

The Company's provision for income taxes for the years ended December 31, 2020 and December 31, 2019 relates to income taxes in states and other jurisdictions and differs from the amounts determined by applying the statutory federal income tax rate to the loss before income taxes for the following reasons:

	Dollars in Thousands	
	2020	2019
Benefit at federal rate	$ (2,231)	$ (2,796)
Increase (decrease) resulting from:		
State income taxes—net of federal benefit	(379)	(517)
Miscellaneous permanent differences	48	78
Warrant liability revaluation	(3)	(104)
Meals and entertainment	18	—
Impairment of in-process research and development	—	(70)
Change in valuation allowance	2,547	3,339
Total income tax benefit	$ —	$ (70)

The income tax expense consists of the following for the years ended December 31, 2020 and 2019.

	Dollars in Thousands	
	2020	2019
ederal:		
Current	$ —	$ —
Deferred	—	(70)
Total Federal	$ —	$ (70)
tate:		
Current	$ —	$ —
Deferred	—	—
Total State	$ —	$ —
oreign:		
Current	$ —	$ —
Deferred	—	—

Total Foreign	$ —	$ —
Total Tax Provision	$ —	$ (70)

Table of Contents

The Company had approximately $68 million and $61 million of available gross federal and state net operating loss ("NOL") carryforwards as of December 31, 2020 and 2019, respectively. Beginning in 2018, under the Act, federal loss carryforwards have an unlimited carryforward period, however such losses can only offset 80% of taxable income in any one year. Included in the total NOLs for 2020 are $39 million of federal losses that fall under these new rules. Section 382 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any one year may be limited. The Company reduced its tax attributes (NOLs and tax credits) and generated a limitation on utilization of such attributes resulting from the Merger.

At December 31, 2020 and 2019, and as a result of the limitations under Section 382 of the Internal Revenue Code, the Company had a total of unused federal tax net operating loss carryforwards with expiration dates as follows:

	Dollars in Thousands	
	2020	2019
2036	$13,470	$13,470
2037	13,641	3,441
Unlimited life	39,101	42,100
Total Federal	$66,212	$59,011

The Company has adopted guidance on accounting for uncertainty in income taxes which clarified the accounting for income taxes by prescribing the minimum threshold a tax position is required to meet before being recognized in the financial statements as well as guidance on de-recognition, measurement, classification and disclosure of tax positions. There are no material uncertain tax positions that would require recognition in the financial statements. The Company is obligated to file income tax returns in the U.S. federal jurisdiction and various U.S. states. Since the Company had losses in the past, all prior years that generated NOLs are open and subject to audit examination in relation to the NOL generated from those years. Our evaluation of uncertain tax positions was performed for the tax years ended December 31, 2014 and forward.

11. STOCKHOLDERS' EQUITY

Common Stock

Pursuant to our Third Amended and Restated Certificate of Incorporation, as amended, we currently have 150,000,000 shares of common stock authorized for issuance. On December 20, 2018, the Company's shareholders approved the proposal to authorize the Company's Board of Directors to, in its discretion, to amend the Company's

Third Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 150,000,000 shares to 250,000,000 shares. The Company has not yet affected this increase.

During the year ended December 31, 2019, the Company issued 310,200 shares of its common stock in connection with the exercise of 310,200 warrants. The warrant exercises resulted in net cash proceeds to the Company of approximately $1.6 million during the year ended December 31, 2019.

During the years ended December 31, 2020 and 2019, the Company issued 3,980,145 and 2,511,173 shares of its common stock, respectively, in connection with the conversion of convertible notes, plus interest, totaling $2.2 million and $7.6 million, respectively. See Note 6 – Convertible Notes.

LP Purchase Agreement

On September 7, 2018, the Company entered into the LP Purchase Agreement, pursuant to which Lincoln Park has agreed to purchase from the Company up to an aggregate of $10,000,000 of common stock of the Company (subject to certain limitations) from time to time over the term of the LP Purchase Agreement. Pursuant to the terms of the LP Purchase Agreement, on the agreement date, the Company issued 40,000 shares of its common stock to Lincoln Park as

Table of Contents

consideration for its commitment to purchase shares of common stock of the Company under the LP Purchase Agreement (the "LP Commitment Shares"). Also on September 7, 2018, the Company entered into a registration rights agreement with Lincoln Park (the "LP Registration Rights Agreement"), pursuant to which on September 14, 2018, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, 466,667 shares of common stock, which includes the LP Commitment Shares, that have been or may be issued to Lincoln Park under the LP Purchase Agreement. The Form S-1 was declared effective by the SEC on September 28, 2018. As of January 16, 2019, all shares registered under this S-1 had been sold and/or issued to Lincoln Park. On February 1, 2019, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, an additional 1,000,000 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement. The Form S-1 was declared effective by the SEC on February 12, 2019. As of August 5, 2019, all shares registered under this S-1 had been sold and/or issued to Lincoln Park. On August 9, 2019, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, an additional 1,800,000 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement. As of January 9, 2020, all shares registered under this S-1 had been sold and/or issued to Lincoln Park. On January 14, 2020, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, an additional 920,654 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement. As of April 6, 2020, all of the additional 920,654 shares registered under this S-1 had been sold and/or issued to Lincoln Park.

Under the LP Purchase Agreement, the Company may, from time to time and at its sole discretion, on any single business day on which the closing price of its common stock is not less than the Floor Price, defined as the lower of (i) $1.50 per share (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction as provided in the LP Purchase Agreement) and (ii) $0.10 per share, direct Lincoln Park to purchase shares of its common stock in amounts up to 30,000 shares, which amounts

may be increased to up to 36,666 shares depending on the market price of its common stock at the time of sale and subject to a maximum commitment by Lincoln Park of $1,000,000 per single purchase, which the Company refers to as "regular purchases", plus other "accelerated amounts" and/or "additional accelerated amounts" under certain circumstances. The Company will control the timing and amount of any sales of its common stock to Lincoln Park. The purchase price of the shares that may be sold to Lincoln Park in regular purchases under the LP Purchase Agreement will be based on the market price of the common stock of the Company preceding the time of sale as computed under the LP Purchase Agreement. The purchase price per share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the business days used to compute such price. The Company may at any time in its sole discretion terminate the LP Purchase Agreement without fee, penalty or cost upon one business day notice. There are no restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the LP Purchase Agreement or LP Registration Rights Agreement, other than a prohibition on the Company entering into certain types of transactions that are defined in the LP Purchase Agreement as "Variable Rate Transactions". Lincoln Park may not assign or transfer its rights and obligations under the Purchase Agreement.

Under applicable rules of The Nasdaq Capital Market, in no event may the Company issue or sell to Lincoln Park under the LP Purchase Agreement more than 19.99% of the shares of its common stock outstanding immediately prior to the execution of the LP Purchase Agreement (which is 308,590 shares based on 1,543,724 shares outstanding immediately prior to the execution of the LP Purchase Agreement), which limitation the Company refers to as the Exchange Cap, unless (i) the Company obtains stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of the Company's common stock to Lincoln Park under the LP Purchase Agreement equals or exceeds $7.05 (which represents the closing consolidated bid price of the Company's common stock on September 7, 2018, plus an incremental amount to account for the issuance of the LP Commitment Shares to Lincoln Park), such that issuances and sales of the Company's common stock to Lincoln Park under the LP Purchase Agreement would be exempt from the Exchange Cap limitation under applicable NASDAQ rules. In any event, the LP Purchase Agreement specifically provides that the Company may not issue or sell any shares of its common stock under the LP Purchase Agreement if such issuance or sale would breach any applicable NASDAQ rules. The Company received shareholder approval on December 20, 2018.

Table of Contents

The LP Purchase Agreement also prohibits the Company from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of the Company's common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of the Company's common stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder, which limitation the Company refers to as the Beneficial Ownership Cap as defined in the LP Agreement.

As of the date the consolidated financial statements were issued, we have already received an aggregate of $9.4 million from the sale of common stock to Lincoln Park under the LP Purchase Agreement, including approximately: $1.4 million from the sale of 328,590 shares of common stock during 2018; $6.6 million from the sale of 2,778,077 shares of common stock during 2019; and $1.4 million from the sale of 1,040,654 shares of common stock during 2020. As of April 6, 2020, all registered shares relating to the LP Purchase Agreement had been sold and/or issued to Lincoln Park. The LP Purchase Agreement terminated during our second fiscal quarter of 2020.

Effective April 13, 2020, the Company became eligible to sell additional shares to Lincoln Park pursuant to the LP 2020 Purchase Agreement, as discussed below.

LP 2020 Purchase Agreement

On March 26, 2020, the Company entered into a purchase agreement (the "LP 2020 Purchase Agreement") and a registration rights agreement (the "LP 2020 Registration Rights Agreement") with Lincoln Park pursuant to which Lincoln Park has agreed to purchase from us, from time to time, up to $10,000,000 of our common stock, subject to certain limitations, during the 24 month term of the LP 2020 Purchase Agreement. Pursuant to the terms of the LP 2020 Purchase Agreement, on the agreement date, the Company issued 250,000 shares of its common stock to Lincoln Park as consideration for its commitment to purchase shares of common stock of the Company under the LP Purchase Agreement (the "LP 2020 Commitment Shares"). Pursuant to the terms of the LP 2020 Registration Rights Agreement, on March 27, 2020, as amended on April 8, 2020, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, 1,770,000 shares of common stock, which includes the LP 2020 Commitment Shares, that have been or may be issued to Lincoln Park under the LP 2020 Purchase Agreement. The Form S-1 was declared effective by the SEC on April 13, 2020. As of June 22, 2020, all shares registered under this S-1 had been sold and/or issued to Lincoln Park. On June 26, 2020, the Company filed with the SEC a registration statement on Form S-1 to register for resale under the Securities Act of 1933, as amended, or the Securities Act, an additional 4,500,000 shares of common stock that have been or may be issued to Lincoln Park under the LP Purchase Agreement. The Form S-1 was amended twice on July 7, 2020 and declared effective by the SEC on July 7, 2020. As of December 31, 2020, 2,960,000 shares registered under this S-1 had been sold and/or issued to Lincoln Park.

Under the LP 2020 Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 50,000 shares of our common stock on any such business day, which we refer to as a Regular Purchase in the LP 2020 Purchase Agreement, provided, however, that (i) the Regular Purchase may be increased to up to 80,000 shares, provided that the closing sale price is not below $1.00 on the purchase date and (ii) the Regular Purchase may be increased to up to 100,000 shares, provided that the closing sale price is not below $1.50 on the purchase date. In each case, the maximum amount of any single Regular Purchase may not exceed $1,000,000 per purchase. Lincoln Park has no right to require the Company to sell any shares of common stock to Lincoln Park, but Lincoln Park is obligated to make purchases as we direct, subject to certain conditions. The purchase price for Regular Purchases shall be equal to the lesser of: (i) the lowest sale price of the common shares during the purchase date, or (ii) the average of the three (3) lowest closing sale prices of the common shares during the ten (10) business days prior to the purchase date.

Under applicable rules of The Nasdaq Capital Market, in no event may we issue or sell to Lincoln Park under the LP 2020 Purchase Agreement more than 19.99% of the shares of our common stock outstanding immediately prior to the execution of the LP 2020 Purchase Agreement (which is 1,774,024 shares, based on 8,870,129 shares outstanding immediately prior to the execution of the LP 2020 Purchase Agreement), which limitation we refer to as the Exchange Cap, unless (i) we obtain stockholder approval to issue shares of common stock in excess of the Exchange Cap or (ii) the average price of all applicable sales of our common stock to Lincoln Park under the LP 2020 Purchase Agreement equals or exceeds $0.7306 (which represents the closing consolidated bid price of our common stock on March 25, 2020, plus an incremental amount to account for our issuance of the Commitment Shares to Lincoln Park), such that the transactions contemplated by the LP 2020 Purchase Agreement are exempt from the Exchange Cap limitation under applicable Nasdaq

rules. In any event, the LP 2020 Purchase Agreement specifically provides that we may not issue or sell any shares of our common stock under the LP 2020 Purchase Agreement if such issuance or sale would breach any applicable rules or regulations of The Nasdaq Capital Market.

The LP 2020 Purchase Agreement also prohibits us from directing Lincoln Park to purchase any shares of common stock if those shares, when aggregated with all other shares of our common stock then beneficially owned by Lincoln Park and its affiliates, would result in Lincoln Park and its affiliates having beneficial ownership, at any single point in time, of more than 4.99% of the then total outstanding shares of our common stock, as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 13d-3 thereunder, which limitation we refer to as the Beneficial Ownership Cap.

As of the date of issuance of this Annual Report on Form 10-K, we have already received an aggregate of $8.8 million from the sale of common stock to Lincoln Park under the LP 2020 Purchase Agreement, including approximately $7.5 million from the sale of 4,480,000 shares of common stock during 2020 and $1.3 million from the sale of 500,000 shares of common stock to Lincoln Park which were sold from January 1, 2021 through the date of issuance of this Annual Report on Form 10-K.

Preferred Stock

The Company's Board of Directors is authorized to issue up to 15,000,000 shares of preferred stock in one or more series, from time to time, with such designations, powers, preferences and rights and such qualifications, limitations and restrictions as may be provided in a resolution or resolutions adopted by the Board of Directors. The authority of the Board of Directors includes, but is not limited to, the determination or fixing of the following with respect to shares of such class or any series thereof: (i) the number of shares; (ii) the dividend rate, whether dividends shall be cumulative and, if so, from which date; (iii) whether shares are to be redeemable and, if so, the terms and amount of any sinking fund providing for the purchase or redemption of such shares; (iv) whether shares shall be convertible and, if so, the terms and provisions thereof; (v) what restrictions are to apply, if any, on the issue or reissue of any additional preferred stock; and (vi) whether shares have voting rights. The preferred stock may be issued with a preference over the common stock as to the payment of dividends. We have no current plans to issue any additional preferred stock. Classes of stock such as the preferred stock may be used, in certain circumstances, to create voting impediments on extraordinary corporate transactions or to frustrate persons seeking to effect a merger or otherwise to gain control of the Company. For the foregoing reasons, any additional preferred stock issued by the Company could have an adverse effect on the rights of the holders of the common stock.

Series B Preferred Stock

The Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock ("Series B Preferred Stock") with the State of Delaware which designates 6,900 shares of our preferred stock as Series B Preferred Stock. The Series B Preferred Stock has a stated value of $1,000 per share and a par value of $0.01 per share. The Series B Preferred Stock includes a beneficial ownership blocker but has no dividend rights (except to the extent dividends are also paid on the common stock). On August 28, 2017, the Company completed an underwritten public offering (the "August 2017 Offering") consisting of the Company's Series B Preferred Stock and warrants.

The conversion price of the Series B Preferred Stock contains a down round feature. The Company will recognize the effect of the down round feature when it is triggered. At that time, the effect would be treated as a deemed dividend and as a reduction of income available to common shareholders in our basic earnings per share calculation.

The March 2020 Amendment, see Note 6 – Convertible Notes, triggered the down round feature of the Series B Preferred Stock and, as a result, the conversion price of the Company's Series B Convertible Preferred Stock was automatically adjusted from $2.25 per share to $0.40 per share. In connection with the down round adjustment, the Company calculated an incremental beneficial conversion feature of approximately $3.3 million which was recognized as a deemed dividend at time of the down round adjustment ("Deemed Dividend A").

Table of Contents

There were no conversions of Series B Preferred Stock during the years ended December 31, 2020 and 2019, respectively. At December 31, 2020 and 2019, the Company had 6,900 shares of Series B designated and issued and 47 shares of Series B outstanding.

Liquidation Preferences

The following is the liquidation preferences for the Company's preferred stock;

Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary, the holders shall be entitled to receive out of the assets of the Corporation an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of Preferred Stock before any distribution or payment shall be made to the holders of the Common Stock, and if the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the holders shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares. If all amounts were paid in full; and thereafter, the holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation the same amount that a holder of Common Stock would receive if the Preferred Stock were fully converted to Common Stock which amount shall be paid pari passu with all holders of Common Stock.

Table of Contents

Common Stock Warrants

The following represents a summary of the warrants outstanding as of December 31, 2020:

	Issue Year	Expiration	Underlying Shares	Exercise Price
Warrants				
(1)	2016	January 2021	596	$ 544.50
(2)	2017	June 2022	2,540	$ 41.25
(2)	2017	June 2022	500	$ 7.50
(3)	2017	June 2022	6,095	$ 105.00
(4)	2017	August 2022	25,201	$ 0.40
(5)	2017	August 2022	4,000	$ 46.88

(6)	2017	August 2022	47,995	$	150.00
(6)	2017	August 2022	9,101	$	7.50
(7)	2017	August 2022	16,664	$	0.40
(7)	2017	August 2022	7,335	$	0.40
(8)	2017	October 2022	666	$	0.40
(9)	2018	October 2022	7,207	$	112.50
(10)	2018	April 2023	69,964	$	5.40
(10)	2018	April 2023	121,552	$	5.40
(11)	2018	October 2022	15,466	$	11.25
(12)	2018	July 2023	14,671	$	5.40
(12)	2018	July 2023	14,672	$	5.40
(12)	2018	August 2023	36,334	$	5.40
(12)	2018	August 2023	36,334	$	5.40
(12)	2018	September 2023	19,816	$	5.40
(12)	2018	September 2023	20,903	$	5.40
(13)	2018	November 2023	75,788	$	5.40
(13)	2018	December 2023	51,282	$	5.40
(14)	2019	April 2024	147,472	$	5.40
(15)	2019	May 2024	154,343	$	9.56
			906,497		

(1) These warrants were issued in connection with an offering which was completed in January 2016. Of the remaining outstanding warrants as of December 31, 2020, 357 warrants are recorded as liability, See Note 12 – Fair Value for further discussion, and 239 warrants are treated as equity.
(2) These warrants were issued in connection with the Merger.
(3) These warrants were issued in connection with the Merger.
(4) These warrants were issued in connection with an underwritten public offering completed on August 28, 2017 (the "August 2017 Offering") and are the August 2017 Offering Warrants discussed below.
(5) These warrants were issued in connection with the August 2017 Offering.
(6) These warrants were issued in connection with the conversion of our Series A Senior stock, at the time of the closing of the August 2017 Offering.
(7) These warrants were issued in connection with the conversion of convertible bridge notes, at the time of the closing of the August 2017 Offering, and are the Note Conversion Warrants discussed below.
(8) These warrants were issued in connection with a waiver of default the Company received in the fourth quarter of 2017 in connection with certain convertible promissory notes and are the Convertible Promissory Note Warrants discussed below.
(9) These warrants were issued in connection with the Debt Obligation settlement agreements and are the Creditor Warrants discussed below.
(10) These warrants were issued in connection with the 2018 Note Agreement and are the April 2018 Warrants discussed below.

Table of Contents

(11) These warrants were issued in connection with the 2018 Note Agreement and are the Advisor Warrants discussed below.

(12) These warrants were issued in connection with the 2018 Note Agreement and are the Q3 2018 Warrants discussed below.
(13) These warrants were issued in connection with the 2018 Note Agreement, and subsequent Amendment Agreement, and are the Q4 2018 Warrants discussed below.
(14) These warrants were issued in connection with the 2018 Note Agreement and subsequent Amendment No. 2 Agreement and are the April 2019 Warrants discussed below.
(15) These warrants were issued in connection with the May 2019 Bridge Notes and are the May 2019 Warrants discussed below.

During the year ended December 31, 2020, 2,692 warrants expired. These warrants had been issued in connection with transactions which were completed between October 2014 and July 2015.

August 2017 Offering Warrants

In connection with the August 2017 Offering, the Company issued 178,666 warrants at an exercise price of $45.00, which contain a down round provision. The August 2017 Offering Warrants were exercisable immediately and expire 5 years from date of issuance.

As a result of the March 2020 Amendment, the exercise price of the August 2017 Offering Warrants was adjusted from the previously amended $2.25 to $0.40. At the time the exercise price was adjusted, the Company calculated the fair value of the down round provision on the warrants to be approximately $6,000 and recorded this as a deemed dividend ("Deemed Dividend B").

There were 6,800 August 2017 Offering Warrants exercised during the year ended December 31, 2019 for proceeds to the Company of approximately $15,000. During the year ended December 31, 2019, the intrinsic value of the August 2017 Offering Warrants exercised was approximately $36,000.

Note Conversion Warrants

Upon the closing of the August 2017 Offering, the Company issued 23,999 warrants to purchase the Company's common stock (the "Note Conversion Warrants"). The Note Conversion Warrants have an exercise price of $45.00 per share, a five year term and contain a down round provision.

As a result of the March 2020 Amendment, the exercise price of the Note Conversion Warrants was adjusted from the previously amended $2.25 to $0.40. At the time the exercise price was adjusted, the Company calculated the fair value of the down round provision on the warrants to be approximately $5,000 and recorded this as a deemed dividend ("Deemed Dividend C").

Convertible Promissory Note Warrants

The Convertible Promissory Note Warrants had an original exercise price of $45.00 per share and contain a down round provision.

As a result of the March 2020 Amendment, the exercise price of the Convertible Promissory Note Warrants was adjusted from the previously amended $2.25 to $0.40. At the time the exercise price was adjusted, the Company calculated the fair value of the down round provision on the warrants to be less than $1,000 and recorded this as a deemed dividend ("Deemed Dividend D").

Series C Warrants

In connection with a Series C preferred stock offering during 2017, the Company issued 130,857 warrants at an exercise price of $24.45, which contain a down round provision.

There were 25,037 Series C Warrants exercised during the year ended December 31, 2019 for proceeds to the Company of approximately $56,000 and, as a result, there were no Series C Warrants outstanding at December 31, 2020 and 2019, respectively. During the year ended December 31, 2019, the intrinsic value of the Series C Warrants exercised was approximately $43,000.

Creditor Warrants

In the fourth quarter of 2017, the Company entered into Settlement Agreements with the Creditors pursuant to which the Company agreed to issue, to certain of its Creditors, warrants to purchase 7,207 shares of the Company's common stock at an exercise price of $112.50 per share. The Creditor Warrants were issued in February 2018.

April 2018 Warrants

In connection with the issuance of Bridge Notes in April 2018, the Company issued 243,224 warrants at an exercise price of $11.25 at time of issuance. At issuance, half of these April 2018 Warrants had a five-year term and half had a one-year term.

In April 2019, as a result of the Amendment No.2 Agreement, the exercise price of the April 2018 Warrants was adjusted from the previously amended $7.50 to $5.40 and all April 2018 Warrants that had a one-year term were amended to have a five-year term. Due to these modifications, the change in fair value of the April 2018 Warrants was calculated to be an expense of approximately $0.7 million which is included in loss on modification of warrants in the consolidated statements of operations for the year ended December 31, 2019.

During the year ended December 31, 2019, 51,708 April 2018 Warrants were exercised for proceeds to the Company of $279,000. During the year ended December 31, 2019, the intrinsic value of the April 2018 Warrants exercised was approximately $128,000.

Advisor Warrants

At the time of the 2018 Note Agreement, the Company issued 15,466 warrants with an exercise price of $11.25 to a financial advisor.

Q3 2018 Warrants

In connection with the issuance of Bridge Notes during the third quarter of 2018, the Company issued 196,340 warrants with an exercise price of $11.25 at time of issuance (the "Q3 2018 Warrants"). At the time of issuance, half of these Q3 2018 Warrants had a five-year term and half had a one-year term. In September 2018, the exercise price was modified to $7.50.

In April 2019, as a result of the Amendment No.2 Agreement, the exercise price of the Q3 2018 Warrants was adjusted from the previously amended $7.50 to $5.40 and all Q3 2018 Warrants that had a one-year term were amended to have a five-year term. Due to these modifications, the change in fair value of the Q3 2018 Warrants was calculated to be an expense of approximately $0.4 million which is included in loss on modification of warrants in the consolidated statements of operations for the year ended December 31, 2019.

There were 53,610 Q3 2018 Warrants exercised during the year ended December 31, 2019 for proceeds to the Company of approximately $290,000. During the year ended December 31, 2019, the intrinsic value of the Q3 2018 Warrants exercised was approximately $133,000.

Table of Contents

Q4 2018 Warrants

In connection with the issuance of the Bridge Notes during the fourth quarter of 2018, the Company issued 300,115 warrants with an exercise price of $5.40 at time of issuance and a five-year term (the "Q4 2018 Warrants").

There were 173,045 Q4 2018 Warrants exercised during the year ended December 31, 2019 for proceeds to the Company of $935,000. During the year ended December 31, 2019, the intrinsic value of the Q4 2018 Warrants exercised was approximately $489,000.

April 2019 Warrants

In connection with the issuance of the April 2019 Bridge Notes, the Company issued 147,472 warrants with an exercise price of $5.40 and a five-year term.

May 2019 Warrants

In connection with the issuance of the May 2019 Bridge Notes, the Company issued 154,343 warrants with an exercise price of $9.56 and a five-year term.

Deemed Dividends

As discussed above, certain of our preferred stock and warrant issuances contain down round provisions which require us to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS.

There were no deemed dividends recorded in 2019. The following represents a summary of the dividends recorded for the year ended December 31, 2020:

Deemed Dividends	**Amount Recorded** (in thousands)
Dividends resulting from the March 2020 Amendment	
Deemed Dividend A	$ 3,333
Deemed Dividend B	6
Deemed Dividend C	*
Deemed Dividend D	5
For the year ended December 31, 2020	**$ 3,344**

* Represents less than one thousand dollars

12. FAIR VALUE

FASB guidance on fair value measurements, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements for our financial assets and liabilities, as well as for other assets and liabilities that are carried at fair value on a recurring basis in our consolidated financial statements.

FASB guidance establishes a three-level fair value hierarchy based upon the assumptions (inputs) used to price assets or liabilities. The three levels of inputs used to measure fair value are as follows:

Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities;

Table of Contents

Level 2—Observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets or liabilities in inactive markets; and

Level 3—Unobservable inputs reflecting our own assumptions and best estimate of what inputs market participants would use in pricing the asset or liability.

Common Stock Warrant Liabilities.

Certain of our issued and outstanding warrants to purchase shares of common stock do not qualify to be treated as equity and, accordingly, are recorded as a liability. We are required to record these instruments at fair value at each reporting date and changes are recorded as a non-cash adjustment to earnings. The gains or losses included in earnings are reported in other income (expense) in our consolidated statement of operations.

2016 Warrant Liability

The Company has a warrant liability related to warrants issued in January 2016 (the "2016 Warrant Liability") and it represents the fair value of such warrants, of which, 357 warrants remain outstanding as of December 31, 2020.

In March 2018, a portion of the 2016 Warrant Liability was part of a settlement agreement pursuant to a lawsuit that was filed against the Company by one of the warrant holders. As such, approximately $0.4 million of the warrant liability, representing 1,347 warrants, was canceled on the date of the settlement agreement.

The 2016 Warrant Liability is considered a Level 3 financial instrument and was valued using the Black Scholes model. As of December 31, 2020, assumptions and inputs used in the valuation of the 2016 Warrant Liability include: remaining life to maturity of less than one month; annual volatility of 135%; and a risk-free interest rate of 0.08%. As of December 31, 2019, assumptions and inputs used in the valuation of the 2016 Warrant Liability include: remaining life to maturity of one year; annual volatility of 140%; and a risk-free interest rate of 1.59%. The 2016 Warrant Liability matured and was settled for cash of approximately $0.1 million in January 2021. The balance of the 2016 Warrant Liability was zero as of the date of issuance of this Form 10-K.

Bridge Note Warrant Liabilities

During 2019 and 2018, the Company issued warrants in connection with the issuance of Bridge Notes. All of these warrants issuances were classified as warrant liabilities (the "Bridge Note Warrant Liabilities"). See Note 6 - Convertible Notes for further discussion.

The Bridge Note Warrant Liabilities are considered Level 3 financial instruments and were valued using the Black Scholes model. As of December 31, 2020, assumptions used in the valuation of the Bridge Note Warrant Liabilities include: remaining life to maturity of 1.3 to 3.4 years; annual volatility of 162% to 201%; and risk free rate of 0.10% to 0.17%. As of December 31, 2019, assumptions used in the valuation of the Bridge Note Warrant Liabilities include: remaining life to maturity of 2.3 to 4.4 years; annual volatility of 141% to 163%; and risk free rate of 1.58% to 1.65%.

Table of Contents

During the years ended December 31, 2020 and 2019, the change in the fair value of the warrant liabilities measured using significant unobservable inputs (Level 3) were comprised of the following:

Dollars in Thousands

	Year Ended December 31, 2020		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at January 1	$ 70	$ 1,268	$ 1,338
Total gains:			
Revaluation recognized in earnings	60	(73)	(13)
Balance at December 31	$ 130	$ 1,195	$ 1,325

	Year Ended December 31, 2019		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at January 1	$ 116	$ 1,016	$ 1,132
Additions:	–	1,858	1,858
Total (gains) losses:			
Revaluation recognized in earnings	(46)	(370)	(416)
Modification recognized in earnings	–	1,128	1,128
Deductions – warrant liability settlement	–	(2,364)	(2,364)
Balance at December 31	$ 70	$ 1,268	$ 1,338

Derivative Liabilities.

Certain of our issued and outstanding convertible notes contain features that are considered derivative instruments and are required to bifurcated from the debt host and accounted for separately as derivative liabilities. The estimated fair value of the derivatives will be remeasured at each reporting date and any change in estimated fair value of the derivatives will be recorded as non-cash adjustments to earnings. The gains or losses included in earnings are reported in other income (expense) in our consolidated statement of operations.

Bridge Notes Redemption Feature

At the time of the Bridge Note issuances, the Company recorded derivative instruments and valued the derivatives using the "with and without" approach, whereby the Bridge Notes were valued both with the embedded derivative and without. Approximately $0.4 million of Bridge Notes Redemption Feature derivative liabilities were written off due to Bridge Note conversions during the year ended December 31, 2019.

Conversion Option

The Company recorded derivative liabilities related to the Conversion Option of the Exchange Notes and valued them using the Monte Carlo methodology. Approximately $0.1 million of Conversion Option derivative liabilities were written off due to Exchange Note conversions during the year ended December 31, 2019.

Table of Contents

During the year ended December 31, 2019, the change in the fair value of the derivative liabilities was comprised of the following:

(Dollars in thousands)	Year Ended December 31, 2019		
	Bridge Notes Redemption Feature	Conversion Option	Total Derivative Liabilities
Beginning balance at January 1	$ 30	$ 32	$ 62
Deductions - write-off in conjunction with convertible note conversions	(438)	(39)	(477)
Total loss:			
Revaluation recognized in earnings	408	7	415
Balance at December 31	$ —	$ —	$ —

13. EQUITY INCENTIVE PLAN

The Company currently issues stock awards under its 2017 Stock Option and Incentive Plan, as amended (the "2017 Plan") which will expire on June 5, 2027. Per the terms of the 2017 Plan, the shares authorized for issuance under the 2017 Plan were 913,586 at December 31, 2020, of which 90,682 remain available for future grant. The shares authorized under the 2017 Plan are subject to annual increases on January 1 by 5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or such lessor number of shares determined by the Company's Board of Directors or Compensation Committee. During the year ended December 31, 2020, the shares authorized for issuance increased by 394,905 shares.

The Plan is administered by the Compensation Committee of the Board of Directors (the "Committee"), which has the authority to set the number, exercise price, term and vesting provisions of the awards granted under the Plan, subject to the terms thereof. Either incentive or non-qualified stock options may be granted to employees of the Company, but only non-qualified stock options may be granted to non-employee directors and advisors. However, in either case, the Plan requires that stock options must be granted at exercise prices not less than the fair market value

of the common stock on the date of the grant. Options issued under the plan vest over periods as determined by the Committee and expire 10 years after the date the option was granted.

Stock Options.

The Company accounts for all stock-based compensation payments to employees and directors, including grants of employee stock options, at fair value at the date of grant and expenses the benefit in operating expense in the consolidated statements of operations over the service period of the awards. The Company records the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date. The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option pricing model, which requires various assumptions including estimating stock price volatility, expected life of the stock option, risk free interest rate and estimated forfeiture rate.

During the year ended December 31, 2020, the Company granted stock options to employees and directors to purchase up to 433,550 shares of common stock at a weighted average exercise price of $2.01. These awards have vesting periods of up to four years and had a weighted average grant date fair value of $1.85. The fair value calculation of options granted during 2020 used the follow assumptions: risk free interest rates of 0.40% to 1.73%, based on the U.S. Treasury yield in effect at the time of grant; expected life of six years; and volatility of 138% to 163% based on historical volatility of the Company's common stock over a time that is consistent with the expected life of the option.

Table of Contents

The following table summarizes stock option activity under our plans during the year ended December 31, 2020:

	Number of Options	Weighted-Average Exercise Price
utstanding at January 1, 2020	490,330	$ 8.30
Granted	433,550	2.01
Forfeited	(100,888)	12.64
utstanding at December 31, 2020	822,992	$ 4.46
xercisable at December 31, 2020	337,155	$ 6.59

As of December 31, 2020, there were 701,533 options that were vested or expected to vest with an aggregate intrinsic value of $0.1 million and a remaining weighted average contractual life of 8.4 years.

During the year ended December 31, 2019, there were 292,604 options granted with a weighted average exercise price of $2.36 and 27,169 options forfeited with a weighted average exercise price of $6.03.

During the years ended December 31, 2020 and 2019, we recorded compensation expense for all stock awards of $0.7 million, respectively, within operating expense in the accompanying statements of operations. As of

December 31, 2020, the unrecognized compensation expense related to unvested stock awards was $1.6 million, which is expected to be recognized over a weighted-average period of 1.7 years.

14. SALES SERVICE REVENUE, NET AND ACCOUNTS RECEIVABLE

ASC Topic 606, "Revenue from contracts with customers"

The Company follows the guidance for the recognition of revenue from contracts with customers to transfer goods and services. The Company performed a comprehensive review of its existing revenue arrangements following the five-step model:

Step 1: Identification of the contract with the customer. Sub-steps include determining the customer in a contract; Initial contract identification and determine if multiple contracts should be combined and accounted for as a single transaction.

Step 2: Identify the performance obligation in the contract. Sub-steps include identifying the promised goods and services in the contract and identifying which performance obligations within the contract are distinct.

Step 3: Determine the transaction price. Sub-steps include variable consideration, constraining estimates of variable consideration, the existence of a significant financing component in the contract, noncash consideration and consideration payable to a customer.

Step 4: Allocate transaction price. Sub-steps include assessing the amount of consideration to which the Company expects to be entitled in exchange for transferring the promised goods or services to the customer.

Step 5: Satisfaction of performance obligations. Sub-steps include ascertaining the point in time when an asset is transferred to the customer and the customer obtains control of the asset upon which time the Company recognizes revenue.

Nature of Contracts and Customers

The Company's contracts and related performance obligations are similar for its customers and the sales process for all customers starts upon the receipt of requisition forms from the customers for patient diagnostic testing and the execution of contracts for biomarker testing and clinical research. Payment terms for the services provided are 30 days, unless separately negotiated.

Table of Contents

Diagnostic testing

Control of the laboratory testing services is transferred to the customer at a point in time. As such, the Company recognizes revenue for laboratory testing services at a point in time based on the delivery method (web-portal access or fax) for the patient's laboratory report, per the contract.

Clinical research grants

Control of the clinical research services are transferred to the customer over time. The Company will recognize revenue utilizing the "effort based" method, measuring its progress toward complete satisfaction of the performance obligation.

Biomarker testing and clinical project services

Control of the biomarker testing and clinical project services are transferred to the customer over time. The Company utilizes an "effort based" method of assessing performance and measures progress towards satisfaction of the performance obligation based upon the delivery of results.

The Company generates revenue from the provision of diagnostic testing provided to patients, biomarker testing provided to bio-pharma customers and clinical research grants funded by both bio-pharma customers and government health programs.

Disaggregation of Revenues by Transaction Type

We operate in one business segment and, therefore, the results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Service revenue, net for the years ended December 31, 2020 and 2019 was as follows:

(dollars in thousands)	**Diagnostic Testing**		**Biomarker Testing**		**Total**	
	2020	**2019**	**2020**	**2019**	**2020**	**2019**
Medicaid	$ 53	$ 28	$ —	$ —	$ 53	$ 28
Medicare	2,882	1,669	—	—	2,882	1,669
Self-pay	408	34	—	—	408	34
Third party payers	3,442	1,725	—	—	3,442	1,725
Contract diagnostics	—	—	426	595	426	595
Service revenue, net	$ 6,785	$ 3,456	$ 426	$ 595	$ 7,211	$ 4,051

Revenue from the Medicare and Medicaid programs account for a portion of the Company's patient diagnostic service revenue. Laws and regulations governing those programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount in the near term.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience. The Company does not typically enter arrangements where multiple contracts can be combined as the terms regarding services are generally found within a single agreement/requisition form. The Company derives its revenues from three types of transactions: diagnostic testing ("Diagnostic"), revenues from the Company's ICP technology and bio-pharma projects encompassing genetic diagnostics (collectively "Biomarker") and other revenues from clinical research grants from state and federal research programs and other product sales.

Deferred revenue

Deferred revenue, or unearned revenue, refers to advance payments for products or services that are to be delivered in the future. The Company records such prepayment of unearned revenue as a liability, as revenue that has not yet been earned, but represents products or services that are owed to a customer. As the product or service is delivered over time, the Company recognizes the appropriate amount of revenue from deferred revenue. As of December 31, 2020 and 2019, the deferred revenue was $6,000 and $35,000, respectively.

Contractual Allowances and Adjustments

We are reimbursed by payers for services we provide. Payments for services covered by payers average less than billed charges. We monitor revenue and receivables from payers and record an estimated contractual allowance for certain revenue and receivable balances as of the revenue recognition date to properly account for anticipated differences between amounts estimated in our billing system and amounts ultimately reimbursed by payers. Accordingly, the total revenue and receivables reported in our consolidated financial statements are recorded at the amounts expected to be received from these payers. For service revenue, the contractual allowance is estimated based on several criteria, including unbilled claims, historical trends based on actual claims paid, current contract and reimbursement terms and changes in customer base and payer/product mix. The billing functions for the remaining portion of our revenue are contracted and fixed fees for specific services and are recorded without an allowance for contractual discounts. The following table presents our revenues initially recognized for each associated payer class during the years ended December 31, 2020 and 2019.

(dollars in thousands)	**Gross Revenues**		**Contractual Allowances and adjustments**		**Revenues, net of Contractual Allowances and adjustments**	
	2020	**2019**	**2020**	**2019**	**2020**	**2019**
Medicaid	$ 53	$ 31	$ —	$ (3)	$ 53	$ 28
Medicare	2,882	1,686	—	(17)	2,882	1,669
Self-pay	411	34	(3)	—	408	34
Third party payers	11,891	5,785	(8,449)	(4,060)	3,442	1,725
Contract diagnostics	426	595	—	—	426	595
	15,663	8,131	(8,452)	(4,080)	7,211	4,051
Clinical research grants and other	220	44	—	—	220	44
	$15,883	$8,175	$ (8,452)	$ (4,080)	$ 7,431	$ 4,095

Allowance for Doubtful Accounts

The Company provides for a general allowance for collectability of services when recording net sales. The Company has adopted the policy of recognizing net sales to the extent it expects to collect that amount. Reference

FASB 954-605-45-5 and ASU 2011-07, Health Care Entities: Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debt, and the Allowance for Doubtful Accounts. The change in the allowance for doubtful accounts is directly related to the increase in patient service revenues. The following table presents our reported revenues net of the collection allowance and adjustments for the years ended December 31, 2020 and 2019.

(dollars in thousands)	Revenues, net of Contractual Allowances and adjustments		Allowances for doubtful accounts		Total	
	2020	2019	2020	2019	2020	2019
Medicaid	$ 53	$ 28	$ (53)	$ (28)	$ —	$ —
Medicare	2,882	1,669	(387)	(251)	2,495	1,418
Self-pay	408	34	—	—	408	34
Third party payers	3,442	1,725	(899)	(689)	2,543	1,036
Contract diagnostics	426	595	—	—	426	595
	7,211	4,051	(1,339)	(968)	5,872	3,083
Clinical research grants and other	220	44	—	—	220	44
	$ 7,431	$ 4,095	$ (1,339)	$ (968)	$ 6,092	$ 3,127

Costs to Obtain or Fulfill a Customer Contract

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in operating expenses in the consolidated statements of operations.

Shipping and handling costs are comprised of inbound and outbound freight and associated labor. The Company accounts for shipping and handling activities related to contracts with customers as fulfillment costs which are included in cost of sales in the consolidated statements of operations.

Accounts Receivable

The Company has provided an allowance for potential credit losses, which has been determined based on management's industry experience. The Company grants credit without collateral to its patients, most of who are insured under third party payer agreements.

The following summarizes the mix of receivables as of December 31, 2020 and 2019:

(dollars in thousands)	2020	2019
Medicaid	$ 131	$ 107
Medicare	1,054	814
Self-pay	276	88
Third party payers	3,373	2,203
Contract diagnostic services	53	36
	$ 4,887	$ 3,248
Less allowance for doubtful accounts	(4,013)	(2,674)
Accounts receivable, net	$ 874	$ 574

The following table presents the roll-forward of the allowance for doubtful accounts for the year ended December 31, 2020:

(dollars in thousands)		Allowance for Doubtful Accounts
Balance, January 1, 2020		$ (2,674)
Collection Allowance:		
Medicaid	$ (53)	
Medicare	(387)	
Third party payers	(899)	
	(1,339)	
Bad debt expense	$ —	
Total charges		(1,339)
Balance, December 31, 2020		$ (4,013)

Customer Revenue and Accounts Receivable Concentration

Customer revenue and accounts receivable concentration amounted to the following for the identified periods.

	Net sales		Accounts receivable, as of	
	Years Ended December 31,			
	2020	2019	December 31, 2020	December 31, 2019
Customer A	*	19 %	*	*
Customer B	*	11 %	*	17 %
Customer C	*	*	*	12 %

* represents less than 10%

15. SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2020 through the date the consolidated financial statements were issued.

Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers;

On March 1, 2021 the Board accepted the resignation of Mr. Rimer as a member of the Board, Audit Committee and Compensation Committee, effective March 1, 2021. The Board accepted that Mr. Rimer become an observer, and in such capacity Mr. Rimer will attend, in a non-voting observer capacity, all meetings of the Board.

On March 1, 2021, the Company elected Mr. Ron A. Andrews to fill the vacancy left by Mr. Rimer's resignation and to serve as a class III director of the Company, effective March 1, 2021, and until the Company's 2021 annual meeting of stockholders or his earlier resignation, retirement or removal.

On March 1, 2021, the Board appointed Mr. Sandberg as Chairman of the Board and Dr. Douglas Fisher as a member of the Audit Committee.

Table of Contents

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

None.

Item 9A. Controls and Procedures

(a) ***Evaluation of Disclosure Controls and Procedures***

We maintain a system of disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) ("Disclosure Controls") will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We monitor our Disclosure Controls and make modifications as necessary; our intent in this regard is that the Disclosure Controls will be modified as systems change and conditions warrant.

An evaluation of the effectiveness of the design and operation of our Disclosure Controls was performed as of the end of the period covered by this Report. This evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based on this evaluation, we concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2020.

(b) ***Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). In order to evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002, our management, with the participation of our principal executive officer and principal financial officer has conducted an assessment, including testing, using the criteria in Internal Control – Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission ("*COSO*") (2013). Our system of internal control over financial reporting is designed 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation.

Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2020.

Table of Contents

(c) ***Changes in internal control over financial reporting***

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2020, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a smaller reporting company, the Company is not required to include in this Annual Report a report on the effectiveness of internal control over financial reporting by the Company's independent registered public accounting firm.

Item 9B. Other Information

None.

Table of Contents

Part III

Item 10. Directors, Executive Officers and Corporate Governance

We intend to file with the Securities and Exchange Commission a definitive Proxy Statement, which we refer to herein as the 2021 Proxy Statement, not later than 120 days after the close of the fiscal year ended December 31, 2020. The information required by this item is incorporated herein by reference to the 2021 Proxy Statement. The information required by this item related to the executive officers can be found in the section captioned "Executive Officers of the Registrant" under Part I, "Item 1. Our Business" of this Annual Report on Form 10-K, and is also incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020.

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

The information required by this item is incorporated herein by reference to the 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020.

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

The information required by this item is incorporated herein by reference to the 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to the 2021 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2020.

Table of Contents

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this report:

1 **Financial Statements. The following financial statements of the Registrant are included in response to Item 8 of this report:**

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets of the Registrant and Subsidiary as of December 31, 2020 and 2019.

Consolidated Statements of Operations of the Registrant and Subsidiary for the years ended December 31, 2020 and 2019.

Consolidated Statements of Stockholders' Equity of the Registrant and Subsidiary for the years ended December 31, 2020 and 2019.

Consolidated Statements of Cash Flows of the Registrant and Subsidiary for the years ended December 31, 2020 and 2019.

Notes to Consolidated Financial Statements of the Registrant and Subsidiary.

2 Financial Statement Schedules.

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

3 Exhibits. The following exhibits are filed as required by Item 15(a)(3) of this report. Exhibit numbers refer to the paragraph numbers under Item 601 of Regulation S-K:

2.1 Agreement and Plan of Merger, dated October 12, 2016 by and among Transgenomic, Inc., New Haven Labs Inc. and Precipio Diagnostics, LLC (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on October 13, 2016).
2.2 First Amendment to Agreement and Plan of Merger, dated as of February 3, 2017 by and among Transgenomic, Inc., New Haven Labs Inc. and Precipio Diagnostics, LLC (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on February 2, 2017).
2.3 Second Amendment to Agreement and Plan of Merger, dated as of June 27, 2017 by and among Transgenomic, Inc., New Haven Labs Inc. and Precipio Diagnostics, LLC (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on June 30, 2017).
3.1 Third Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Company's 8-K filed on June 30, 2017).
3.2 Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K filed on June 30, 2017).
3.3 Certificate of Elimination (incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filed on June 30, 2017).
3.4 Certificate of Designation for Series B Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on August 31, 2017).
3.5 Certificate of Designation for Series C Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on November 6, 2017).
3.6 Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation, dated April 25, 2019 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on April 26, 2019).

Table of Contents

4.1	Form of Certificate of the Company's Common Stock (incorporated by reference to Exhibit 4 of the Company's Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
4.2	Form of Offering Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on August 23, 2017).
4.3	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K filed on August 23, 2017).
4.4	Form of Conversion Warrant (incorporated by reference to Exhibit 4.3 of the Company's Form 8-K filed on August 23, 2017).
4.5	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on November 6, 2017).
4.6	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on November 13, 2017).
4.7	Description of Securities of the Registrant (incorporated by reference to Exhibit 4.7 of the Company's Form 10-K filed on March 27, 2020).
10.1	License Agreement between the Company and Dana-Farber Cancer Institute dated October 8, 2009 (incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on November 5, 2009).
10.2†	Amended and Restated 2017 Stock Option and Incentive Plan (incorporated by reference to Annex D of the Company's Definitive Proxy Statement on Schedule 14A filed on December 29, 2017).
10.3†	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on June 28, 2017).
10.4†	Form of Non-Qualified Stock Option Agreement for Company Employees (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on June 28, 2017).
10.5†	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on June 28, 2017).
10.6	Form of New Bridge Warrant (incorporated by reference to Exhibit 10.6 of the Company's Form 8-K filed on June 30, 2017).
10.7	Form of Side Warrant (incorporated by reference to Exhibit 10.7 of the Company's Form 8-K filed on June 30, 2017).
10.8#	Amended and Restated Pathology Services Agreement, dated March 21, 2017, by and between the Company and Yale University (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K/A filed on July 31, 2017).
10.9	Lease, dated July 11, 2017, by and between the Company and Science Park Development Corporation (incorporated by reference to Exhibit 10.2 of the Company's Form 8K/A filed on July 31, 2017).
10.10	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on April 23, 2018).
10.11	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on December 3, 2018).
10.12	Form of Warrant to Purchase Common Stock relating to Amendment No. 2 Agreement (incorporated by reference to Exhibit 10.45 of the Company's Form 10-K filed on April 16, 2019).
10.13	Form of Warrant to Purchase Common Stock dated May 14, 2019 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed on May 16, 2019).
21.1	Subsidiaries of the Company.
23.1	Consent of Marcum LLP.
31.1	Certification of Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1*	Certification of Principal Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
32.2*	Certification of Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

Table of Contents

101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Registrant specifically incorporates it by reference.

\# Confidential treatment has been requested or granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

† Indicates a management contract or any compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

None.

Table of Contents

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 on this 29th day of March 2021.

Precipio, Inc.

By: /s/ ILAN DANIELI
Ilan Danieli,
Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ilan Danieli **Ilan Danieli**	Director and Chief Executive Officer (Principal Executive Officer)	March 29, 2021
/s/ Carl Iberger **Carl Iberger**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2021
/s/ Richard Sandberg **Richard Sandberg**	Chairman of the Board of Directors	March 29, 2021
/s/ Kathleen LaPorte **Kathleen LaPorte**	Director	March 29, 2021
/s/ Ronald Andrews **Ronald Andrews**	Director	March 29, 2021
/s/ Douglas Fisher, M.D. **Douglas Fisher, M.D.**	Director	March 29, 2021
/s/ Jeffrey Cossman, M.D. **Jeffrey Cossman, M.D.**	Director	March 29, 2021
/s/ David Cohen **David Cohen**	Director	March 29, 2021