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

FORM 10-K

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

For the fiscal year ended: December 31, 2019

Or

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

For the transition period from: _____ to _____

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

Delaware	**001-36305**	**26-1367393**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

911 Bern Court, Suite 110
San Jose, CA 95112
(Address of Principal Executive Office) (Zip Code)

(877) 774-4211
(Registrant's telephone number, including area code)

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

None

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

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	OTCQB

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant was approximately $171,150,529.52 as of June 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of the registrant's common stock outstanding as of February 28, 2020 was 6,534,076

DOCUMENTS INCORPORATED BY REFERENCE

None.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This annual report on Form 10-K contains forward-looking statements. Such forward-looking statements include those that express plans, anticipation, intent, contingency, goals, targets or future development and/or otherwise are not statements of historical fact. These forward-looking statements are based on our current expectations and projections about future events and they are subject to risks and uncertainties known and unknown that could cause actual results and developments to differ materially from those expressed or implied in such statements.

In some cases, you can identify forward-looking statements by terminology, such as “expects,” “anticipates,” “intends,” “estimates,” “plans,” “believes,” “seeks,” “may,” “should,” “continue,” “could” or the negative of such terms or other similar expressions. Accordingly, these statements involve estimates, assumptions and uncertainties that could cause actual results to differ materially from those expressed in them. Any forward-looking statements are qualified in their entirety by reference to the factors discussed throughout this annual report on Form 10-K.

You should read this annual report on Form 10-K and the documents that we reference herein and therein and have filed as exhibits, completely and with the understanding that our actual future results may be materially different from what we expect. You should assume that the information appearing in this annual report on Form 10-K is accurate as of the date on the front cover of this annual report only. Because the risk factors referred to herein could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us or on our behalf, you should not place undue reliance on any forward-looking statements. These risks and uncertainties, along with others, are described under the heading “Risk Factors.” Further, any forward-looking statement speaks only as of the date on which it is made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. We qualify all of the information presented in this annual report on Form 10-K, and particularly our forward-looking statements, by these cautionary statements.

This annual report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

2019 ANNUAL REPORT ON FORM 10-K

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PART I

ITEM 1. BUSINESS

General

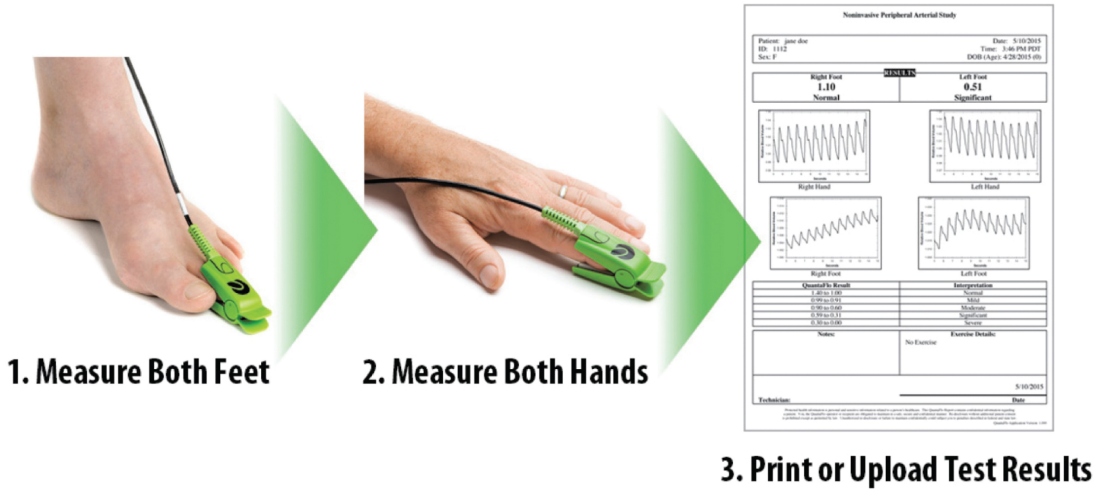
We are a company providing technology solutions to improve the clinical effectiveness and efficiency of healthcare providers. Our mission is to develop, manufacture and market innovative proprietary products and services that assist our customers in evaluating and treating chronic diseases. In 2011, we began commercializing our first patented and U.S. Food and Drug Administration, or FDA, cleared product, which measured arterial blood flow in the extremities to aid in the diagnosis of peripheral arterial disease, or PAD. In March 2015, we received FDA 510(k) clearance for the next generation version of our product, QuantaFlo®, which we began commercializing in August 2015. We believe our products and services position us to provide valuable information to our customer base, which in turn permits them to better guide patient care.

In the year ended December 31, 2019, we had total revenues of $32,767,000 and net income of $15,084,000 compared to total revenues of $21,491,000 and net income of $5,014,000, in 2018. We had an income tax benefit of $4,383,000 in 2019, primarily due to the release of a tax valuation allowance in the third quarter, as compared to income tax expense of $26,000 in 2018. Our pre-tax net income was $10,701,000 in 2019 compared to $5,040,000 in 2018.

Our Products and Services

We currently market only one patented and FDA-cleared vascular-testing product, QuantaFlo®, to our customers, who include insurance plans, physician groups and risk assessment groups.

QuantaFlo® is a four-minute in-office blood flow test. Healthcare providers can use blood flow measurements as part of their examinations of a patient's vascular condition, including assessments of patients who have vascular disease. The following diagram illustrates the use of QuantaFlo®:



QuantaFlo® features a sensor clamp that is placed on the toe or finger much like current pulse oximetry devices. Infrared light emitted from the clamp on the dorsal surface of the digit is scattered and reflected by the red blood cells coursing through the area of illumination. Returning light is 'sensed' by the sensor. A blood flow waveform is instantaneously constructed by our proprietary software algorithm. Both index fingers and both large toes are interrogated, which takes about 30 seconds for each. A hardcopy report form is generated that displays four waveforms and the ratio of each leg measurement compared with the arms. Results are classified as Flow Obstruction or No Flow Obstruction.

We have primarily developed a license model rather than an outright sales model for QuantaFlo®. This license model eliminates the need to make a capital equipment sale. Consequently, we generally require no down payment or long-term commitment from our customers. QuantaFlo® has an expected average lifetime of at least three years. We intend to reevaluate the monthly price periodically in consideration of the revenue generation associated with QuantaFlo®. To date, we roughly estimate that routine office usage of the QuantaFlo® has ranged from a few tests per week up to 10 tests per day. We also offer contracts in which we invoice on a per test basis for use of QuantaFlo®.

We have placed our QuantaFlo® product with healthcare insurance plans, integrated delivery networks, independent physician groups and companies contracting with the healthcare industry such as risk assessment groups, in addition to doctors' offices. Our largest customer is a U.S. diversified healthcare company and its affiliated plans, and in the year ended December 31, 2019, it accounted for 49.4% of our revenues.

Other Blood Flow Testing Methods

Blood flow is the amount of blood delivered to a given region per unit time, whereas blood pressure is the force exerted by circulating blood on the walls of arteries. Given a fixed resistance, blood flow and blood pressure are proportional. The traditional ankle brachial index, or ABI, with Doppler test uses a blood pressure cuff to measure the systolic blood pressure in the lower legs and in the arms. A blood pressure cuff is inflated proximal to the artery in question. Using a Doppler device, the inflation continues until the pulse in the artery ceases. The blood pressure cuff is then slowly deflated. When the artery's pulse is re-detected through the Doppler probe the pressure in the cuff at that moment indicates the systolic pressure of that artery. The test is repeated on all four extremities. Well-established criteria for the ratio of the blood pressure in a leg compared to the blood pressure in the arms are used to assess the presence or absence of flow obstruction. Generally, these tests take 15 minutes to perform and require a vascular technician to be done properly. Like QuantaFlo®, the traditional analog ABI test with Doppler is a non-invasive physiologic measurement that may be abnormal in the presence of PAD. Alternatively, primary care physicians may palpate the pedal pulses to assess blood flow in the lower extremities. However, pulse palpation is generally not sensitive for the detection of vascular disease. Other options to detect arterial obstructions are imaging systems that use ultrasound, x-ray technology or magnetic resonance to obtain anatomic information about blood vessels in the legs. However, as compared to QuantaFlo®, imaging tests are much more expensive and are performed by specialists in special laboratories or offices.

Market Opportunity

Fee-for-service is a payment model where services are unbundled and paid for separately. In health care, it gives an incentive for physicians to provide more treatments because payment is dependent on the quantity of care, rather than quality of care. Capitation is a payment arrangement that pays a physician or group of physicians a set amount for each enrolled person assigned to them, per period of time, whether or not that person seeks care. The amount of remuneration is based on the average expected healthcare utilization of that patient, with greater payment for patients with significant medical history. For Medicare Advantage patients, the Centers for Medicare & Medicaid Services, or CMS, pays a fee per patient, also known as capitation. CMS uses risk adjustment to adjust capitation payments to health plans, either higher or lower, to account for the differences in expected health costs of individuals. Accordingly, under CMS guidelines, risk factor adjustments per patient will provide payment that is higher for sicker patients who have conditions that are codified. Accordingly, there is a financial incentive to identify those Medicare Advantage patients that are sicker, including those that have undiagnosed ailments such as PAD.

The coding system used by CMS for the Medicare Advantage program is a hierarchical condition category, or HCC, diagnostic classification system that begins by classifying over 14,000 diagnosis codes into 805 diagnostic groups, or DXGs. Each code maps to exactly one DXG, which represents a well-specified medical condition, such as DXG 96.01 pre-cerebral or cerebral arterial occlusion with infarction. DXGs are further aggregated into 189 condition categories, or CCs. CCs describe a broader set of similar diseases. Diseases within a CC are related clinically and with respect to cost. An example is CC96 Ischemic or Unspecified Stroke, which includes DXGs 96.01 and 96.02 acute but ill-defined cerebrovascular disease. We believe that quality of care measured by completeness and wellness is an economic benefit. These changes are already in place for the approximately 19 million participants in the Medicare Advantage program and are expected to expand to more types of insured patients as healthcare reform is deployed.

Undiagnosed vascular disease of the legs has been called a major under-diagnosed health problem in the United States by the National Institute of Health and the Wall Street Journal. We believe vascular disease in leg arteries is undiagnosed in 75% of cases, which is about 12 million Americans. Known as PAD, this condition is a common and deadly cardiovascular disease that is often undiagnosed. PAD develops when the arteries in the legs become clogged with plaque — fatty deposits — that limit blood flow to the legs. As with clogged arteries in the heart, clogged arteries in the legs place patients at an increased risk of heart attack and stroke. Published studies have shown that persons with PAD are four times more likely to die of heart attack, and two to three times more likely to die of stroke. According to a study by P.G. Steg published in the JAMA, patients with PAD have a 21% event rate of cardiovascular death, heart attack, stroke or cardiovascular hospitalization within 12 months. The SAGE Group has estimated that as many as 20 million people are affected with PAD in the United States alone and A.T. Hirsch et al. in a JAMA published article further estimate that only 11% have claudication (pain on exertion), a classic symptom of PAD. One can lower the risks associated with PAD if the disease is detected, with early detection providing the greatest benefit.

Many people affected with PAD do not have noticeable symptoms. When symptoms of PAD are present, they often include fatigue, heaviness, cramping or pain in the legs during activity, leg or foot pain, sores, wounds or ulcers on the toes, feet, or legs, which are slow to heal. Persons with PAD may become disabled and not be able to work and can even lead to amputations. According to the National Limb Loss Information Center, an estimated 2 million Americans are amputees and the main causes are vascular disease in 54% of this population.

Risk factors for developing PAD include:

- Age (over 50 years);
- Race (African-American);
- History of smoking;
- Diabetes;
- High blood pressure;
- High blood cholesterol; and
- Personal history of vascular disease, heart attack, or stroke.

We believe medical personnel who care for those older than 50 years are the target market for QuantaFlo®, along with those insurance plans that have a high number of Medicare Advantage patients. Based on U.S. Census data, we believe there are more than 80 million older Americans who could be evaluated for the presence of PAD.

According to the National Center for Health Workforce Analysis, there are over 275,000 medical professionals practicing primary care in the United States. In addition, based on American Heart Association data, there are over 20,000 cardiologists and 7,500 vascular and cardiovascular surgeons. Also, there are millions of diabetic patients seen routinely by endocrinologists. Many podiatrists who see patients with these problems and orthopedic surgeons may see value in screening patients for circulation issues prior to leg procedures. Neurologists may need a tool to differentiate leg pain from vascular versus neurologic etiology. Nephrologists see patients with kidney disease, who have a higher frequency of PAD. Wound care centers need to know the adequacy of limb perfusion. We expect that each physician will have many patient visits annually from people older than 50 years. While it is standard practice to ask about symptoms of PAD and to feel for diminished pulses on physical exam, we believe that it is often the case in busy practices that the questions go unasked.

Generally speaking, individual products are not specifically approved by name under a third-party payor code. Physicians who seek reimbursement for PAD testing procedures are likely to use codes that describe non-invasive physiologic testing of extremities. We do not track directly how physicians code for and receive payment for such procedures.

Strategy

Our mission is to develop, manufacture and market proprietary products and services that assist healthcare providers in evaluating and treating chronic diseases. We intend to do this by:

- ***Targeting customers with patients at risk of developing PAD.*** Healthcare providers use blood flow measurements as part of their assessment of a patient's vascular condition. Our strategy is to keep marketing QuantaFlo® on a recurrent revenue model to insurance plans and medical personnel who care for those older than 50 years, including cardiologists, internists, nephrologists, endocrinologist, podiatrists, and family practitioners. Specifically, we believe there are more than 300,000 physicians and other potential customers in the United States alone, many of whom care for patients will be more than 50 years old and at increased risk of developing PAD. Based on U.S. Census data, the evaluable patient population for QuantaFlo® is estimated to be more than 80 million patients in the United States annually.
- ***Expanding the tools available to internists and non-peripheral vascular experts.*** Our intention is to provide a tool to internists and non-peripheral vascular experts, for whom it was previously impractical to conduct a blood flow measurement unless in a specialized vascular laboratory. For vascular specialists, QuantaFlo® does not require the use of blood pressure cuffs (which should not be used on some breast cancer patients), and measures without blood pressure in obese patients and patients with non-compressible, hard, calcified arteries. Currently, these patients often are unable to be measured satisfactorily with traditional analog ABI devices.
- ***Developing additional product and service offerings that allow healthcare providers to deliver cost-effective wellness and receive increased compensation for their services.*** In March 2015, we received FDA 510(k) clearance of our product, QuantaFlo®, reflecting several updates and modifications to the original model that were developed in conjunction with our consultant engineering groups. We are also exploring potential new product and service offerings. These product and service offerings are designed to provide cost-effective wellness solutions for our growing, established customer base. Our goal is to achieve a reputation for outstanding service and the provision of cost-effective wellness solutions, while leveraging our gains in the marketplace for such product and service offerings.

Sales and Marketing

We provide our QuantaFlo® product to our customers through our salespersons and our co-exclusive distributor, Bard Peripheral Vascular, Inc., or Bard. Bard, a large medical device company with a worldwide presence in both interventional cardiology and dialysis, was acquired by Becton, Dickinson and Company in December 2017. We began a co-exclusive supply and distribution arrangement with Bard in late 2012 in an effort to increase our sales and marketing reach, which arrangement accounted for less than 4% of our revenues in each of 2018 and 2019. With certain exceptions, we appointed Bard on a co-exclusive basis to license QuantaFlo® to certain customers, and we retained the right to license directly to such customers as well. In addition to our co-exclusive distributor, we have direct sales and marketing representatives, who have experience selling products and services to our anticipated market.

We deliver our vascular testing product directly to our customers, and in-service training to the customer is provided either on-line or in person. Because QuantaFlo® is relatively easy to use training can generally be accomplished in less than one day.

Customers who have licensed our QuantaFlo® product may pay by credit card or check generally on the 15th of each month as an advance for usage during the next 30 days. In some cases, customers prefer an annual license paid in advance. We provide technical support daily, coupled directly to the manufacturing operation so that replacement products, if needed, can be shipped overnight directly to the customer. The majority of the support is over the telephone and focuses on software and connectivity issues, rather than hardware. We plan to upgrade QuantaFlo® operating systems as appropriate by direct shipments.

In addition to the license model with a fixed monthly fee, we also have contracts that charge a variable monthly fee, in which we invoice based on the number of tests performed with QuantaFlo®. In addition to licensing the QuantaFlo® software, we have sold QuantaFlo® equipment and accessories.

Manufacturing

We manufacture our product, QuantaFlo®, in the United States through independent contractors whom we pay for finished goods. Our contracts provide for subassemblies, product final assembly, test, serialization, finished goods, inventory and shipping operations. Our current contracts will remain in force until terminated by us upon three months written notice, or until terminated by either party for cause. Although we believe we have a good working relationship with our current contract manufacturers, there are many such qualified contract manufacturers available around the country should we need to replace them or if they are not able to meet demand as we grow our business as anticipated. While our current independent contract manufacturers source some supplies from China, we believe QuantaFlo® is relatively easy to manufacture, and should we encounter issues due to supply chain disruptions as a result of the current coronavirus, we believe alternative sources should be available. We employ a consultant vendor qualification expert to monitor and test the quality controls and quality assurance procedures of our contract manufacturer.

Competition

The principal competitor for QuantaFlo® is the standard blood pressure cuff ABI device. QuantaFlo® does not include a blood pressure cuff. There are several companies that manufacture the traditional ABI device, which range in price from $2,500 to $20,000. Some of these companies are much larger than us and have more financial resources and their own distributor network. The traditional ABI devices are differentiated by the degree of automation designed into each product. ABI devices that rely more heavily on operator assessment (*i.e.*, listening to the return of pulse while decreasing cuff pressure), are thought to have less objectivity in their measurement. Because standard ABI devices require a better trained operator, the products are usually sold to specialized vascular labs that are supervised by a vascular surgeon, with the tests performed by a licensed vascular technician. It is not uncommon for such ABI devices to be marketed to the offices of internists, podiatrists, endocrinologists or most cardiologists.

Our intention is to provide a tool to internists and non-peripheral vascular experts, for whom it was previously impractical to conduct a blood flow measurement unless in a specialized vascular laboratory. For vascular specialists, QuantaFlo® does not require the use of blood pressure cuffs (which should not be used on some breast cancer patients), and measures without blood pressure in obese patients and patients with non-compressible, hard, calcified arteries. Currently, these patients often are unable to be measured with traditional analog ABI devices.

We are not aware of another approved product that performs “digital ABI” without the use of a blood pressure cuff. As our market share continues to grow, we believe that competitors may try to market competing digital devices to our customers.

Research and Development Program

We have dedicated engineering consultants that are well integrated into our overall business, ranging from customer requirements to technical support. The engineering group uses our in-house quality system as its framework for new product development and release. The majority of the engineering is circuit design and software development. We are currently developing several updates and modifications to QuantaFlo® in conjunction with our consultant engineering groups, as well as exploring potential new product and service offerings. These product and service offerings are being designed to provide cost-effective wellness solutions for our growing, established customer base. The new products and service offerings under development or that may be developed may incorporate some of our current technology or new technology. We are also directing much of our activity to building our trade secrets and protecting proprietary positions.

We have sponsored several studies of our blood flow measurement products or provided data to authors on the use of our products for review and publication. One of these studies, the results of which were compiled in 2012 and published in a peer reviewed journal in 2013, sought to determine the frequency of finding undiscovered vascular disease in primary care practices using our vascular testing product. In the study of 632 patients at 19 office practices, the frequency of flow obstruction was 12% and of these patients, 75% did not have classic symptoms of PAD. Among other limitations of the study, the publication mentions the

study's retrospective design, no direct comparison to other vascular tests and passive data collection such that 8% of patients had one or more missing data fields.

Another study we sponsored was designed to assess the side by side performance of our vascular testing product compared with traditional analog ABI with Doppler measurements in medical practices. In the study of 181 limbs from 121 patients at 5 medical practices during 2012 and 2013, three techniques were used on all limbs: our test, traditional analog ABI with Doppler, and Duplex ultrasound imaging as a gold standard. Traditional analog ABI with Doppler was unable to perform a conclusive study in 8.7% of limbs. In the remaining limbs, our vascular testing product and the ABI with Doppler measurements were in agreement, or in other words concordant, in 78% of limbs. Among the discordant limbs, Duplex imaging judged that the true positive rate of our vascular testing product was significantly higher than that of ABI with Doppler by a 2 to 1 margin. The results of the study are available as a white paper that may be shown to potential customers or other interested parties. Among other limitations of the study, the study had a small sample size, was conducted at specialty practices not primary care practices, had a retrospective design with incomplete collection of demographic information and clinical characteristics of the population, was not peer reviewed and was sponsored by us.

Another study also was designed to assess the side by side performance of our vascular testing product compared with traditional analog ABI with Doppler measurements in medical practices. In this prospective study at five medical practices during 2013 through 2015, 360 limbs from 180 patients were examined with three techniques: Our vascular testing product, traditional analog ABI with Doppler, and Duplex ultrasound imaging as a gold standard. Results demonstrated that our test demonstrated greater sensitivity, greater accuracy and equivalent specificity compared to ABI with Doppler measurements. The results of the study are available as a white paper. Among limitations of the study are that it had a small sample size, was conducted at a mix of primary care and specialty practices, had no formal tracking of consecutive patients, and was sponsored by us.

Another study, the results of which were compiled and published in a peer reviewed journal in 2018, reported an analysis of a registry of screening PAD testing with our product between January 2017 and July 2017. In this study, 226,565 patients were tested and 31.3% had moderate to severe flow impairment in the lower extremities. Further analysis of a subset of 26,459 patients for whom clinical characteristics were recorded showed that 95% were asymptomatic. The authors concluded that earlier recognition of PAD may lead to earlier secondary preventive measures and improved outcomes for a population with a high-risk of cardiovascular mortality and morbidity. Among other limitations of the study, the publication mentions the study's retrospective design and that clinical factors were recorded for only approximately 10% of patients.

A retrospective case series compiled and published in a peer reviewed journal in 2018 reported on 48 patients that were tested with our product and subsequently had a contrast angiography procedure for clinical indications. Using contrast angiography as the gold standard for determining PAD, the author concluded the data supports the use of our product as an aid for practicing physicians to accurately diagnose PAD in combination with clinical judgment. Among other limitations of the study, the sample size was small, tests were performed at specialty centers, and the analysis was done retrospectively.

Certain racial and economic groups in the United States are underserved by the medical community with limited access to specialists, a lack of early detection programs and inadequate preventive disease management. There is abundant evidence that certain ethnic populations are more at risk for cardiovascular disease and suffer sequelae of untreated PAD. A study was compiled and published in a peer reviewed journal in 2018 that presented a retrospective analysis of 1,901 patients tested with our product at 22 medical practices that serve predominately lower-income, non-white populations. The author concluded that our product can be effectively utilized by primary care clinicians in poor and underserved communities to identify PAD. The author posited that identifying PAD earlier in the disease process can be an important step towards filling the unmet need of higher intensity vascular care for minority populations. Limitations of the study include that it was a retrospective analysis and that there was no protocol to unveil the identity or ethnicity of any of the individual patients.

Women may lack early detection programs and have inadequate preventive disease management. A study was compiled and published in a peer reviewed journal in 2019 that presented a retrospective analysis of 68,402 female patients tested with our product at primary care medical practices in the United States. The

author concluded that our product was an efficient means to aid in the diagnosis of PAD in vulnerable women who are currently underserved by their health care providers. Limitations of the study include that it was a retrospective analysis with self-reporting of clinical characteristics.

Patents and Licenses

We have been issued one patent for our apparatus, U.S. Patent No. 7,628,760, which expires December 11, 2027.

Governmental Regulation

Our vascular testing product received FDA 510(k) clearance in February 2010 as a Class II Medical Device. Advanced Vascular Technologies, or AVD, an entity formerly affiliated with our co-founder and honorary Chairman Emeritus, Dr. Herbert J. Semler, applied for and obtained for the 510(k) clearance. However, any interests it may have had in such 510(k) clearance were subsequently assigned to us and AVD did not manufacture any products for our company. In March 2015, we received FDA 510(k) clearance for the next generation version of this product, QuantaFlo®. The Class II Medical Device designation means that QuantaFlo® is subject to the FDA's general controls, and any other special controls as deemed necessary by the FDA to provide reasonable assurance of the safety and effectiveness of the device. Pre-market review and clearance by the FDA for Class II devices are generally accomplished through the 510(k) pre-market notification procedure.

As our business is subject to extensive federal, state, local and foreign regulations, we currently employ an established regulatory consultant specializing in medical devices to maintain our regulatory filings, monitor our on-going activities, and ensure compliance with all federal and state regulations, which are subject to change. Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business.

U.S. Food and Drug Administration Regulation

QuantaFlo® is a medical device subject to extensive regulation by the FDA and other federal, state, local and foreign regulatory bodies. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

- product design and development;
- product testing;
- product manufacturing;
- product safety;
- post-market adverse event reporting;
- post-market surveillance;
- product labeling;
- product storage;
- record keeping;
- pre-market clearance or approval;
- post-market approval studies;
- advertising and promotion; and
- product sales and distribution.

FDA's Pre-market Clearance and Approval Requirements

To commercially distribute QuantaFlo® or any future medical device we develop requires or will require either prior 510(k) clearance or prior approval of a pre-market approval, or PMA, application from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a pre-market notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in class III, requiring approval of a PMA application. Both pre-market clearance and PMA applications are subject to the payment of user fees, paid at the time of submission for FDA review. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

510(k) Clearance Pathway

To obtain 510(k) clearance, a medical device manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMA applications. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is completed, but it can take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new pre-market submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to QuantaFlo® we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite PMA application(s). We have made and plan to continue to make minor additional product enhancements that we believe do not require new 510(k) clearances.

Pre-market Approval Pathway

A PMA application must be submitted if the device cannot be cleared through the 510(k) clearance process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. Accordingly, a PMA application must be supported by extensive data including, but not limited to, technical information regarding device design and development, preclinical and clinical trials, data and manufacturing and labeling to support the FDA's determination that the device is safe and effective for its intended use. After a PMA application is complete, the FDA begins an in-depth review of the submitted information, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with Quality System Regulations, or QSRs, which impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the

loss or withdrawal of the approval. New PMA applications or PMA application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, regardless of its classification or pre-market pathway, numerous regulatory requirements apply. These include, but are not limited to:

- establishment registration and device listings with the FDA;
- Quality System Regulations, which require manufacturers to follow stringent design, testing, process control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for uncleared or unapproved, *i.e.*, "off-label," uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, that may present a risk to health; and
- requirements to conduct post-market surveillance studies to establish continued safety data.

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or pre-market approval of new products;
- withdrawing 510(k) clearance or pre-market approvals that are already granted; and
- criminal prosecution.

We are subject to unannounced device inspections by the FDA and the California Food and Drug Branch. These inspections may include our suppliers' facilities.

Third-Party Coverage and Reimbursement

We cannot control whether or not providers who use QuantaFlo® will seek third-party coverage for such procedures or reimbursement. If providers intend to seek third-party coverage or reimbursement for use of QuantaFlo®, the success of our product could become dependent on the availability of coverage and reimbursement from third-party payors, such as governmental programs including Medicare and Medicaid, private insurance plans and managed care programs. Reimbursement is contingent on established coding for a given procedure, coverage of the codes by the third-party payors and adequate payment for the resources used.

Physician coding for procedures is established by the American Medical Association. CMS, the agency responsible for administering Medicare and Medicaid, and the National Center for Health Statistics, are

jointly responsible for overseeing changes and modifications to billing codes used by hospitals for reporting inpatient procedures, and many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. All physician and hospital coding is subject to change, which could impact coverage and reimbursement and physician practice behavior. We do not track denial of requests for reimbursement made by the users of QuantaFlo®. It is our belief that such denials have occurred and might occur in the future with more or less frequency. We are not in the business of performing QuantaFlo® measurements that require us to seek reimbursement from third-party payors. Many of our customers are third-party payors who pay us directly for use of our product and services.

Independent of the coding status, third-party payors may deny coverage based on their own criteria, such as if they believe that the clinical efficacy of a device or procedure is not well established and is deemed experimental or investigational, is not the most cost-effective treatment available, or is used for an unapproved indication. We will continue to provide the appropriate resources to patients, physicians, hospitals and insurers in order to promote the best in patient care and clarity regarding reimbursement and work to obtain appropriate coverage policies. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. As the portion of the U.S. population over the age of 65 and eligible for Medicaid continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. National and regional coverage policy decisions are subject to unforeseeable change and have the potential to impact physician behavior. For example, if CMS decreases the monthly payment for a 65-year-old patient, then the provider will have to decide which steps to eliminate from his or her routine office visits in order to maintain a profitable business model. If the time of an office visit will need to be reduced to maintain a profitable business, a provider may decide to eliminate certain services or conducting certain procedures, such as deciding not to use a thermometer, take someone's blood pressure or use a QuantaFlo® to run an ABI test. Thus, reimbursement limitations imposed by CMS on providers may affect their decision making about which services to provide during an office visit, which could affect our company.

Particularly in the United States, third-party payors carefully review, have undertaken cost-containment initiatives, and increasingly challenge, the prices charged for procedures and medical products as well as any technology that they, in their own judgment, consider experimental or investigational. In addition, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval or pre-authorization of the services that a member will receive. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined amount per member per month. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

There can be no assurance that third-party coverage and reimbursement will be available or adequate, or that future legislation, regulation, or coverage and reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. The unavailability or inadequacy of third-party payor coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

Healthcare Fraud and Abuse

Our operations may be subject to federal and state healthcare laws and regulations including fraud and abuse laws, such as anti-kickback and false claims laws, data privacy and security laws and transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals.

The federal Anti-Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The federal Anti-Kickback Law is subject to evolving interpretations. For example, the government has enforced the federal Anti-Kickback Law to reach large settlements with healthcare companies based on, among other things, inappropriate consultant arrangements with physicians or questionable joint venture arrangements. The majority of states also have anti-kickback laws, which establish similar prohibitions that may apply to

items or services reimbursed by any third-party payor, including commercial insurers. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Health Care Reform Law, among other things, amended the intent requirement of the federal Anti-Kickback Law and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Health Care Reform Law provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act and certain criminal healthcare fraud statutes.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. The federal government is using the civil False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare providers and suppliers throughout the country for a wide variety of Medicare billing practices and has obtained multi-million and multi-billion dollar settlements in addition to individual criminal convictions. In addition, off-label promotion has been pursued as a violation of the federal False Claims Act. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although physicians are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and suppliers' compliance with the healthcare reimbursement rules and fraud and abuse laws.

Additionally, the majority of states in which we market our products have similar fraud and abuse laws, such as anti-kickback, false claims, anti-fee splitting and self-referral laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and violations may result in substantial civil, criminal and administrative penalties.

The Health Care Reform Law also imposed new reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to physicians, as defined by such law, and teaching hospitals. Such information is now made publicly available in a searchable format, and device manufacturers are now required to report and disclose any investment interests held by physicians and their family members during the preceding calendar year. Failure to submit required information may result in significant civil monetary penalties for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Additionally, the commercial compliance environment is continually evolving in the healthcare industry as some states, including California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Our business operations may also be subject to certain federal and state laws regarding the use and disclosure of individually identifiable health information, such as the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which impose obligations on certain entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to an unprecedented level of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, the company may be required to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement.

The U.S. and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased U.S. government oversight and enforcement of the Foreign Corrupt Practices Act. Whenever a governmental authority concludes that we are not in compliance with applicable laws or regulations, that authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees and can recommend criminal prosecution. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of devices we distribute.

If a governmental authority were to conclude that we are not in compliance with applicable fraud and abuse laws and regulations, we and our officers and employees could be subject to severe penalties including, for example, civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and the results of our operations.

It is uncertain whether and how future legislation, whether domestic or foreign, could affect prospects for QuantaFlo® or what actions foreign, federal, state or private payors for health care treatment and services may take in response to any such health care reform proposals or legislation.

Employees

As of December 31, 2019, we had 67 employees, all of which were full-time employees. None of our employees is represented by a labor union, and we consider our relationship with our employees to be good. We also regularly engage consultants and subcontractors on an as-needed basis.

ITEM 1A. RISK FACTORS

Any investment in our securities involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this annual report on Form 10-K before deciding whether to purchase our common stock. Our business, financial condition or results of operations and trading price or value of our securities could be materially adversely affected by these risks if any of them actually occur. This annual report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this annual report on Form 10-K.

Risks Related to Our Business

If we do not successfully implement our business strategy, our business and results of operations will be adversely affected.

Our business strategy was formed based on assumptions about the PAD market and healthcare reform that might prove wrong. We believe that various demographics and industry-specific trends, including the aging of the general population, growth of capitated payment programs, numbers of undiagnosed patients with PAD and the importance of codifying vascular disease will help drive growth in the PAD market and our risk assessment business. However, these demographics and trends, and our assumptions about them, are uncertain. Actual demand for our products and service offerings could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternatives to our products or other risk assessment service providers gain widespread acceptance.

In addition, we may not be able to successfully implement our business strategy. To implement our business strategy, we need to (among other things) find new applications for and improve our products and service offerings and educate healthcare providers and plans about the clinical and cost benefits of our products, all of which we believe could increase acceptance of our products by physicians. In addition, we are seeking to increase our sales and, in order to do so, might need to expand our direct and distributor sales forces in existing and new territories, all of which could result in our becoming subject to additional or different regulatory requirements, with which we may not be able to comply. Moreover, even if we successfully implement our business strategy, our operating results may not improve or may decline. We may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our products obsolete. Any delay or failure to implement our business strategy may adversely affect our business, results of operations and financial condition.

We currently actively market only one FDA-cleared product, a vascular testing product; vascular testing may not achieve broad market acceptance or be commercially successful.

We currently actively market only one product, QuantaFlo® and expect that revenues from our vascular testing product will account for the vast majority of our revenues for at least the next several years. Our vascular testing product may not gain broad market acceptance unless we continue to educate physicians and plans of its benefits. Moreover, even if physicians understand the benefits of vascular testing, they still may elect not to use our product for a variety of reasons, such as the familiarity of the physician with other devices and approaches. We may not be successful in gaining market acceptance of a technique measuring comparative blood flows using our proprietary algorithm to indicate flow obstruction as opposed to existing techniques that measure comparative blood pressures using well-accepted criteria to indicate flow obstruction, or imaging techniques that visualize anatomy of the arteries. Physicians may also object to renting an examining tool with on-going monthly payments rather than making a one-time capital purchase or be reluctant to pay monthly fees for tools in the examining room when they have many such tools, such as thermometer and stethoscope that only required one-time minimal purchases.

If physicians do not perceive our vascular testing product as an attractive alternative to other products, procedures and techniques, we will not achieve significant market penetration or be able to generate significant revenues. To the extent that our product is not commercially successful or is withdrawn from the market for any reason, our revenues will be adversely impacted, and our business, operating results and financial condition will be harmed.

Physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our products provides a safe and effective alternative to other existing ABI devices.

We believe that physicians will not widely adopt our vascular testing product or our other products in development unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of such product provides a safe and effective alternative to other existing ABI devices.

We cannot provide any assurance that the data collected from our past, current and any future clinical trials will be sufficient to demonstrate that our products are an attractive alternative to other ABI devices or procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other ABI devices that are available on the market, our ability to successfully market our products will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our vascular testing product and our other products in development will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published. Accordingly, there is a risk that our products may not be adopted by many physicians, which would negatively impact our business, financial condition and results of operations.

If healthcare providers are unable to obtain adequate coverage and reimbursement either for procedures performed using our product or patient care incorporating the use of our product, it is unlikely that our product will gain widespread acceptance.

Maintaining and growing revenues from our products and service offerings depends on the availability of coverage and adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Healthcare providers that use medical devices such as our vascular testing product to test their patients generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices, or to compensate them for their patient care services. The existence of coverage and adequate reimbursement for the procedures or patient care performed with our vascular testing product by third-party payors is central to the acceptance of our vascular testing product and any future products. During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring healthcare expenditures, and anti-fraud initiatives. We may not be able to achieve or maintain profitability if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Further, many private payors use coverage decisions and payment amounts determined by CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and/or hospitals. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures or patient care performed with our vascular testing product. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures or patient care performed with our vascular testing product if any payment is made at all. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures or patient care performed with our product will be reimbursed at a cost-effective level.

Our vascular testing product is generally but not specifically approved for reimbursement under any third-party payor codes; if third-party payors refuse to reimburse our customers for their use of our product, it could have a material adverse effect on our business.

Our vascular testing product is licensed by healthcare providers. They may bill various third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, private insurance

plans and managed care programs for procedures in which our vascular testing product is used. Reimbursement is a significant factor considered by healthcare providers in determining whether to license medical devices or systems such as our vascular testing product. We cannot control whether or not providers who use our vascular testing product will seek reimbursement. Therefore, our ability to successfully commercialize our vascular testing product could depend on the coverage and adequacy of reimbursement from these third-party payors.

Currently, our vascular testing product is generally but not specifically approved for any particular reimbursement code. Although most of our customers report being covered and reimbursed by third-party payors consistently for procedures using a variety of different reimbursement codes, there is a risk that third-party payors may disagree with the reimbursement under a particular code. In addition, some potential customers have deferred renting our product given the uncertainty regarding reimbursement. We do not track denial of requests for reimbursement made by the users of our product. It is our belief that such denials have occurred and might occur in the future with more or less frequency. Even if our product and procedures are often currently covered and reimbursed by third-party payors and Medicare, problems for customers to receive reimbursement or adverse changes in payors' coverage and reimbursement policies that affect our product could harm our ability to market our vascular testing product. Obtaining approval for a particular reimbursement code is time consuming and can be costly. Accordingly, at this time, and given the way we intend our vascular testing product to be used, we do not intend to pursue formal approval for our vascular testing product for any particular code.

Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our product will be justified and incorporated into the overall cost of the procedure.

We rely on a small number of employees in our direct sales force and face challenges and risk in managing and maintaining our distribution network and the parties who make up that network.

We face significant challenges and risks in managing our distribution network and retaining the parties who make up that network. We had only three dedicated direct sales employees and 19 account managers as of December 31, 2019. If any of our sales or marketing force were to resign, or if our co-exclusive distributor were to cease to do business with us, our sales could be adversely affected. Our co-exclusive distributor accounted for less than 4% of our revenues for each of the years ended December 31, 2019 and 2018. If our co-exclusive distributor were to cease to distribute our product, it would slow down our efforts to gain widespread market acceptance of our vascular testing product. While our contract automatically renews for one-year terms, our co-exclusive distributor has the right terminate our arrangement upon 90 days' notice prior to expiration. Even if not terminated, we may need to seek out alternatives, such as increasing our direct sales and marketing force or contracting with external independent sales representatives or enter another distributor relationship. There is no guarantee that we would be successful in our efforts to find independent sales representatives or another large distributor, or that we would be able to negotiate contract terms favorable to us. Failure to hire or retain qualified direct sales and marketing personnel or independent distributors would prevent us from expanding our business and generating revenues, which would have a material adverse effect on our ability to achieve or maintain profitability.

To adequately commercialize our products, we may need to increase our sales and marketing network, which will require us to hire, train, retain and supervise employees and other independent contractors.

We are currently exploring other sales models to generate revenues from our products in addition to the leasing model. As we increase our marketing efforts to pursue these new strategies and expand our efforts to target insurance plans that serve Medicare Advantage members, we may need to increase our sales and marketing network. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives, independent sales representatives or distributors with significant technical knowledge about our product, in addition to coordinating networks of contract medical assistants and other personnel to staff health and wellness fairs and physicians' offices in fee-for-service models. New hires and independent contractors require training, supervision and take time to achieve full

productivity. If we fail to train and supervise new hires adequately, or if we experience high turnover in our sales force or trained professionals in the future, we cannot be certain that we will maintain or increase our sales. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our vascular testing product or our other products and service offerings in development, which would adversely affect our business, results of operations and financial condition.

We do not require our customers to enter into long-term licenses or maintenance contracts for our products or services and may therefore lose customers on short notice.

Our business is primarily based on a leasing model rather than an outright sale of our products. Our pricing is based on data collected on use rates and third-party payment rates to physicians and facilities for the use of our product. We require no down payment, long-term commitment or maintenance contract or fees from our customers and replace damaged products free of charge in the service model. If we lose current customers on short notice, we may not be able to find new customers to replace them with in a timely manner and that could adversely affect our business, results of operations and financial condition. In addition, our business model of replacing damaged products free of charge may prove to be costly and affect the profitability of our service model.

We are exposed to risk as a significant portion of our revenues and accounts receivables are with a limited number of customers.

Three customers account for a significant portion of our revenues, accounts receivable. For the year ended December 31, 2019, three customers accounted for 49.4%, 13.2%, and 12.5% of our revenues, and as of December 31, 2019, three customers accounted for 55.9%, 17.6%, and 12.0% of our accounts receivable. If our largest customers were to cease using or stop payment for our vascular testing devices, it would have a material adverse effect on our revenues and/or our accounts receivable. This concentration of revenues and accounts receivable among a limited number of customers represents a significant risk.

We rely heavily upon the talents of a small number of key personnel, the loss of whom could severely damage our business.

Our performance depends to a large extent on a small number of key scientific, technical, managerial and marketing personnel. We do not maintain key man insurance for any of our personnel. The loss of the services of any of these key personnel could still severely damage our business prospects, which could have a material adverse effect on our financial condition and results of operations.

We rely on a small number of independent suppliers and facilities for the manufacturing of our vascular testing product. Any delay or disruption in the supply of the product or facility may negatively impact our operations.

We manufacture our vascular testing product through a small number of independent contractors based in the United States. The loss or disruption of our relationships with outside vendors could subject us to substantial delays in the delivery of our product to customers. Our current contractors source some supplies from China and should these outside vendors encounter issues due to supply chain disruptions as a result of the current coronavirus, we believe alternative suppliers should be available. However, significant delays in the delivery of our product could result in possible cancellation of orders and the loss of customers. Although we expect our vendors to comply with our contract terms, we do not have control over our vendors. Our inability to provide a product that meets delivery schedules could have a material adverse effect on our reputation in the industry, which could have a material adverse effect on our financial condition and results of operations.

Further, our vascular testing product is manufactured in the United States in a limited number of facilities. If an event occurred that resulted in material damage to these manufacturing facilities or our manufacturing contractors lacked sufficient labor to fully operate their facilities, we may be unable to transfer the manufacture of our vascular testing product to another facility or location in a cost-effective or timely manner, if at all. This potential inability to transfer production could occur for a number of reasons, including but not limited to a lack of necessary relevant manufacturing capability at another facility, or the regulatory requirements of the FDA or other governmental regulatory bodies. Even if there are many qualified

contract manufacturers available around the country and our product is relatively easy to manufacture, such an event could have a material adverse effect on our financial condition and results of operations.

Because we operate in an industry with significant product liability risk, and we may not be sufficiently insured against this risk, we may be subject to substantial claims against our product or services that we may provide.

The development, manufacture and sale, lease or use of products or provision of services in a medical setting entails significant risks of product liability or other negligence or malpractice claims. Although we maintain insurance to cover us in the event of liability claims, and as of the date of this this annual report on Form 10-K, no such claims have been asserted or threatened against us, our insurance may not be sufficient to cover all possible future liabilities regarding our product, or from performing tests with our product or other non-proprietary products. Accordingly, we may not be adequately protected from any liabilities, including any adverse judgments or settlements, we might incur in connection with the development, clinical testing, manufacture and sale, lease or use of our products or the provision of services. A successful product liability or negligence or medical malpractice claim or series of claims brought against us that result in an adverse judgment against or settlement by us in excess of any insurance coverage could seriously harm our financial condition or reputation. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations. In addition, product liability and other malpractice insurance is expensive and may not always be available to us on acceptable terms, if at all.

We may implement a product recall or voluntary market withdrawal or stop shipment of our product due to product defects or product enhancements and modifications, which would significantly increase our costs.

The manufacturing and marketing of our vascular testing product and any future products that we may develop involves an inherent risk that our products may prove to be defective. In that event, we may voluntarily implement a recall or market withdrawal or stop shipment or may be required to do so by a regulatory authority. A recall of our vascular testing product or one of our future products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall or as a result of the damage to our reputation for quality and safety. Further any product recall, voluntary market withdrawal or shipment stoppage of our product could significantly increase our costs and have a material adverse effect on our business.

If we fail to properly manage our anticipated growth, our business could suffer.

Our growth has placed, and will continue to place, a significant strain on our management and on our operational and financial resources and systems. Failure to manage our growth effectively could cause us to over-invest or under-invest and result in losses or weaknesses. Additionally, our anticipated growth will increase the demands placed on our supplier, resulting in an increased need for us to carefully monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

An information security incident, including a cybersecurity breach, could have a negative impact on our business or reputation.

To meet business objectives, we rely on both internal information technology systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research and patient data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these information technology systems and networks, and the confidentiality, integrity, and availability of our sensitive data. We continually assess these threats and make investments to increase internal protection, detection, and response capabilities, as well as ensure our third-party providers have required capabilities and controls, to address this risk. To date, we have not experienced any material impact to our business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for us to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

We will need to generate significant revenues to remain profitable.

We intend to increase our operating expenses substantially as we add sales and technical support representatives to increase our geographic coverage, increase our marketing capabilities, pursue research and new product and service offering development and increase our general and administrative functions to support our growing operations. We will need to generate significant sales to maintain profitability and we might not be able to do so. Even if we do generate significant sales, we might not be able to sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we anticipate or if our operating expenses exceed our expectations, our financial performance will likely be adversely affected.

Our future financial performance will depend in part on the successful improvements and software updates to our vascular testing product on a cost-effective basis.

Our future financial performance will depend in part on our ability to influence, anticipate, identify and respond to changing consumer preferences and needs and the technologies relating to the care and treatment of vascular problems. We can provide no assurances that our vascular testing product will achieve significant commercial success and that it will gain meaningful market share. We may not correctly anticipate or identify trends in consumer preferences or needs or may identify them later than competitors do. In addition, difficulties in manufacturing or in obtaining regulatory approvals may delay or prohibit improvements to our vascular testing product or our other products in development. Further, we may not be able to develop improvements and software updates to our vascular testing product at a cost that allows us to meet our goals for profitability. Service costs relating to our product may be greater than anticipated, rentals may be returned prior to the end of the license term, and we may be required to devote significant resources to address any quality issues associated with our vascular testing product.

Failure to successfully introduce improve or update our products on a cost-effective basis, or delays in customer decisions related to the evaluation of our products could cause us to lose market acceptance and could materially adversely affect our business, financial condition and results of operations.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products or service offerings could become obsolete or uncompetitive.

The market for medical systems, equipment and other devices and services is highly competitive. We compete with many medical service companies in the United States and internationally in connection with our vascular testing product and products under development. We face competition from numerous companies in the diagnostic area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our vascular testing product or any other future products, if and when they are approved for sale or license, or service offerings that we may develop. Our future success will depend largely upon our ability to anticipate and keep pace with developments and advances. Current or future competitors could develop alternative technologies or products or service offerings that are more effective, easier to use or more economical than what we or any potential licensee develop. If our

technologies or products or service offerings become obsolete or uncompetitive, our related revenues would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

One of our business strategies is developing additional products and service offerings that allow healthcare providers to deliver cost-effective wellness and receive increased compensation for their services. The development of new products and service offerings involves time and expense and we may never realize the benefits of this investment.

As part of our business strategy, we intend to develop additional products and service offerings that allow healthcare providers to deliver cost-effective wellness and receive increased compensation for their services. Such product and service offering development may require substantial investments and we may commit significant resources and time before knowing whether our efforts will translate into profits for our company. We may also choose to invest some of our cash resources in other entities that may have complementary technologies or product offerings, and may not realize the benefit of such investments. It is possible that our development efforts will not be successful and that we will not be able to develop new products or service offerings, either alone or in partnership with others, or if developed that we will obtain the necessary regulatory approvals for commercialization. Even if we receive necessary regulatory approvals, there is no guarantee that such approved products or any new service offerings will achieve market acceptance and we may never realize the benefits of any investment in this strategy.

Risks Related to Our Legal and Regulatory Environment

Our business is subject to many laws and government regulations governing the manufacture and sale of medical devices, including the FDA's 510(k) clearance process, and laws and regulations governing patient data and information, among others.

Our vascular testing product and any future medical devices that we may develop or services that we may offer are subject to extensive regulation in the United States by the federal government, including by the FDA. The FDA regulates virtually all aspects of a medical device's design, development, testing, manufacturing, labeling, storage, record keeping, adverse event reporting, sale, promotion, distribution and shipping. We must report to the FDA when evidence suggests that one of our devices may have caused or contributed to death or serious injury or has malfunctioned and the device or a similar device would be likely to cause or contribute to death or serious injury if the malfunction were to recur. If such adverse event occurred, we could incur substantial expense and harm to our reputation and our business and results of operations could be adversely affected.

Before a new medical device can be marketed in the United States, it must first receive either pre-market approval or 510(k) clearance from the FDA, unless an exemption exists. The same rule applies when a manufacturer plans to market a medical device for a new use. The process can be costly and time-consuming. The FDA is expected to respond to a section 510(k) notification in 90 days, but often takes much longer. The pre-market approval process usually takes six months to three years, but may take longer. We cannot assure that any new medical devices or new uses or modifications for our vascular testing product that we develop will be cleared or approved in a timely or cost-effective manner, if cleared or approved at all. Even if such clearances or approvals are received, they may not be for all indications. Because medical devices may only be marketed for cleared or approved indications, this could significantly limit the market for that product and may adversely affect our results of operations.

Our vascular testing product was initially cleared through the 510(k) clearance process in February 2010, and in March 2015 we received FDA clearance of the next generation version, QuantaFlo®. However, any further modification to a cleared 510(k) device that could significantly affect its safety or efficacy, or that would constitute a significant change in its intended use, will require a new clearance process. The FDA requires device manufacturers to make their own determination regarding whether a modification requires a new clearance; however, the FDA can review and invalidate a manufacturer's decision not to file for a new clearance. We cannot guarantee that the FDA will agree with our decisions not to seek clearances for particular device modifications or that we will be successful in obtaining 510(k) clearances for modifications. Any

such additional clearance processes with the FDA could delay our ability to market a modified product and may adversely affect our results of operations.

Moreover, as we explore other opportunities to generate revenues, which include performing risk assessment testing for physicians or insurance plans on their patient pools, we are subject to additional laws and regulations regarding the provision of such services. Although we intend to subcontract for qualified and licensed professionals to use our vascular testing product, among others, to provide risk assessment services to our customers' patients, the provision of such services is subject to a number of laws and regulations, including with respect to patient data and other information.

The FDA may change its policies, adopt additional regulations, or revise existing regulations, in particular relating to the 510(k) clearance process.

The FDA may change its policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay pre-market approval or 510(k) clearance of a device, or could impact our ability to market our currently cleared device. Future reforms could require us to file new 510(k) clearances and could increase the total number of 510(k) clearance to be filed. We cannot predict what effect these reforms will have on our ability to obtain 510(k) clearances in a timely manner. We also cannot predict the nature of other regulatory reforms and their resulting effects on our business.

Our business is subject to unannounced inspections by FDA to determine our compliance with FDA requirements.

FDA inspections can result in inspectional observations on FDA's Form-483, warning letters or other forms of more significant enforcement action. More specifically, if FDA concludes that we are not in compliance with applicable laws or regulations, or that our vascular testing product or any future medical device we develop is ineffective or pose an unreasonable health risk, the FDA could:

- require us to notify health professionals and others that our devices present unreasonable risk of substantial harm to public health;
- order us to recall, repair, replace or refund the cost of any medical device that we manufactured or distributed;
- detain, seize or ban adulterated or misbranded medical devices;
- refuse to provide us with documents necessary to export our product;
- refuse requests for 510(k) clearance or pre-market approval of new products or new intended uses;
- withdraw 510(k) clearances that are already granted;
- impose operating restrictions, including requiring a partial or total shutdown of production;
- enjoin or restrain conduct resulting in violations of applicable law pertaining to medical devices; and/or
- assess criminal or civil penalties against our officers, employees or us.

If the FDA concludes that we failed to comply with any regulatory requirement during an inspection, it could have a material adverse effect on our business and financial condition. We could incur substantial expense and harm to our reputation, and our ability to introduce new or enhanced products in a timely manner could be adversely affected.

Although part of our business strategy is based on payment provisions enacted under government healthcare reform, we also face significant uncertainty in the industry regarding the implementation, transformation or repeal and replacement of the Health Care Reform Law.

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The Health Care Reform Law brought a new way of doing business for providers and health insurance plans, shifting the focus from fee for service programs to capitated programs that pay a monthly fee per patient. The Health Care Reform law also provided for higher risk factor adjustment payments for sicker patients who have conditions that are codified, as well as economic benefits for achieving certain quality of care measurements.

There remain judicial and Congressional challenges to certain aspects of the Health Care Reform Law, as well as efforts by the Trump administration to repeal or replace certain aspects of the Health Care Reform Law. President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Health Care Reform Law or otherwise circumvent some of the requirements for health insurance mandated by the Health Care Reform Law. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Health Care Reform Law. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Health Care Reform Law such as removing penalties, starting January 1, 2019, for not complying with the Health Care Reform Law's "individual mandate" to carry health insurance, delaying the implementation of certain Health Care Reform Law-mandated fees, and increasing certain discounts owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Health Care Reform Law is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Health Care Reform Law are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allotted one hour for oral arguments. It is unclear when such oral arguments are to be held and when a decision is expected to be made. It is also unclear how such litigation and other efforts to repeal and replace the Health Care Reform Law will impact the Health Care Reform Law.

We believe that the Health Care Reform Law measures are mainly positive for our business given the ability of our vascular testing product to measure blood flow in an in-office setting, which can assist doctors and other providers to suspect PAD and other vascular diseases. However, we cannot predict what changes will now be made, and if these features will be repealed. If changes are made to the Health Care Reform Law, or it is repealed altogether without a comparable replacement, such that there are no incentives for identifying sicker patients, it would negatively affect our business prospects and strategy, and could materially adversely affect our business, financial condition and results of operations.

In addition, the Health Care Reform Law imposed a 2.3% excise tax on the sale, lease, rental or use of any taxable human medical device after December 31, 2012, subject to certain exclusions, by the manufacturer, producer or importer of such device. However, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Health Care Reform Law's mandated medical device excise tax. Further, the Health Care Reform Law encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, as well as other bundled payment initiatives, which may ultimately result in the reduction of medical device acquisitions and the consolidation of medical device suppliers used by hospitals. Changes to or repeal of the Health Care Reform Law could adversely affect our financial results and business.

The applicable healthcare fraud and abuse laws and regulations, along with the increased enforcement environment, may lead to an enforcement action targeting us, which could adversely affect our business.

We are subject to healthcare fraud and abuse laws and regulations including, but not limited to, the Federal Anti-Kickback Statute, state anti-kickback statutes, the Federal False Claims Act, and state false claims acts. Additionally, to the extent we maintain financial relationships with physicians and other healthcare providers, we may be subject to Federal and state physician payment sunshine laws and regulations, which require us to track and disclose these financial relationships. These and other laws regulate interactions amongst health care entities and with sources of referrals of business, among other things. The Federal Anti-Kickback Statute is a criminal statute that imposes substantial penalties on persons or entities that offer, solicit, pay or receive payments in return for referrals, recommendations, purchases or orders of items or services that are reimbursable by Federal healthcare programs. The Federal False Claims Act imposes liability on any person or entity that submits or causes to be submitted a claim to the Federal government that he or she knows (or should know) is false. Off-label promotion has been pursued as a violation of the Federal False Claims Act. The Health Care Reform Law further provides that a claim submitted for items or services, the provision of which resulted from a violation of the Anti-Kickback Statute, is "false" under the Federal False Claims Act and certain other false claims statutes. Our business operations may also be subject to certain federal and state laws regarding the use and disclosure of individually identifiable health information, such

as HIPAA and HITECH, which impose obligations on certain entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

We may be subject to liability under these laws and may also be subject to liability for any future conduct that is deemed by the government or the courts to violate these laws, including significant administrative, criminal and civil penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of operations.

Additionally, the government has continued to pursue an increasing number of enforcement actions. This increased enforcement environment may increase scrutiny of us, directly or indirectly, and could increase the likelihood of an enforcement action targeting us. We have entered into a supply and distribution agreement with Bard Peripheral Vascular, Inc., as well as purchase agreements with a number of our customers, and intend to start offering risk assessment services to our customers. These customers include parties that bill Federal healthcare programs for use of our product, all of whom may be subject to government scrutiny. Finally, to the extent that any of the agreements are breached or terminated, our business may experience a decrease in revenues. In addition, to the extent that our customers, many of whom are providers, may be affected by this increased enforcement environment, our business could correspondingly be affected. It is possible that a review of our business practices or those of our customers by courts or government authorities could result in a determination with an adverse effect on our business. We cannot predict the effect of possible future enforcement actions on our business.

Changes in, or interpretations of, tax rules and regulations may adversely affect our effective tax rates.

We are subject to income and other taxes in the United States. Significant judgment is required in evaluating our provision for income taxes. During the ordinary course of business, there are many transactions for which the ultimate tax determination is uncertain. For example, there could be changes in the valuation of our deferred tax assets and liabilities or changes in the relevant tax, accounting, and other laws, regulations, principles and interpretations. Although we believe our tax estimates are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. The results of an audit or litigation, or the effects of a change in tax policy in the United States, could have a material effect on our operating results in the period or periods for which that determination is made. In addition, new income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our earnings. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

For example, on December 22, 2017, President Trump signed into law U.S. federal income tax legislation, informally titled the Tax Cuts and Jobs Act, or the Tax Act, which significantly revised the Internal Revenue Code of 1986, as amended, or the Code. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation.

Our ability to use net operating loss, or NOL, carryforwards to offset future taxable income may be subject to limitations.

As of December 31, 2019, we had federal NOL carryforwards of $10.3 million. These NOL carryforwards, to the extent they arose prior to 2018, could expire unused and be unavailable to offset

future income tax liabilities. Under the Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have completed a formal Code Section 382 study for the period January 1, 2012 through June 30, 2019 and believed a change in ownership has occurred. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

We are currently a "smaller reporting company," and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are a "smaller reporting company," as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and will remain a smaller reporting company for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure; and
- reduced disclosure obligations regarding executive compensation.

We have taken advantage of reduced reporting burdens in this annual report on Form 10-K. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, we have incurred and will continue to incur increased costs, and our management has been and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices. Moreover, after we are no longer a smaller reporting company, we will incur additional significant legal, accounting and other expenses to address compliance and corporate governance. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, the currently applicable rules and regulations have already increased our legal and financial compliance costs and made some activities more time-consuming and costly. We will need to continue to dedicate internal resources, potentially engage outside consultants and continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

We currently have material weaknesses in our internal control over financial reporting. If we are not able to remedy these material weaknesses in our internal control over financial reporting, if we identify additional material weaknesses or significant deficiencies in the future, or if our former material weaknesses recur, it could have an adverse effect on our company.

In connection with their evaluation of our internal control over financial reporting for the year ended December 31, 2019, our management identified material weaknesses in our control activities, information

and communication and monitoring activities. Namely, we had insufficient segregation of duties, oversight of work performed and ineffective compensating controls in our finance and accounting functions due to limited personnel; certain of our information technology and change management controls were not designed effectively to provide an adequate audit trail; we have sufficient controls to validate the completeness and accuracy of underlying data; we did not design sufficient protocols and procedures to retain adequate documentary evidence related to the timely review and approval of manual journal entries; and we did not sufficiently design and retain adequate documentary evidence supporting the design and operating effectiveness of certain important management review controls. While we have implemented a remediation plan, which we commenced in 2019, there is no guarantee that we will successfully remediate these material weaknesses. In prior years, we have identified certain other deficiencies and material weaknesses in connection with management's evaluation of our internal control over financial reporting that we have remedied. These weaknesses have included issues arising from our size and inability to segregate duties, as well as, even more recently, a lack of controls to identify and analyze related party transactions and a lack of technical accounting competence, and inadequate procedures and controls to appropriately comply with, and account for, certain payroll tax withholdings and related expenses.

Although we implemented measures to remedy former material weaknesses, we are now in the process of implementing measures to address the recently identified material weaknesses. We cannot assure you that we have identified all material weaknesses or that we will not in the future have additional deficiencies or material weaknesses in our internal control over financial reporting. If we have additional significant deficiencies or material weaknesses in our internal control over financial reporting in the future, it could have an adverse effect on our company.

Risks Related to Our Intellectual Property

Our success largely depends on our ability to obtain and protect the proprietary information on which we base our product.

Our success depends in large part upon our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to license from others' patents and patent applications necessary to develop our product. If our patent or any future patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our product was to be limited, our ability to continue to manufacture and market our product could be adversely affected. In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors.

As of December 31, 2019, we have been issued, or have rights to, one U.S. patent. The patent we hold may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on this patent. These risks are also present for the process we use for manufacturing our product. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our product, either in the United States or in international markets. The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. We may institute, become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product or force us to cease some of our business operations, which could

materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. The defense and prosecution of intellectual property suits, USPTO proceedings and related legal and administrative proceedings are both costly and time consuming. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our vascular testing product or any future products. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Although we try to ensure that we and our employees and independent contractors 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 that these employees or independent contractors have used or disclosed intellectual property in violation of the rights of others. These claims may cover a range of matters, such as challenges to our trademarks, as well as claims that our employees or independent contractors are using trade secrets or other proprietary information of any such employee's former employer or independent contractors. Although we do not expect the resolution of the proceeding to have a material adverse effect on our business or financial condition, litigation to defend ourselves against claims can be both costly and time consuming, and divert management's attention away from growing our business.

In addition, while it is our policy to require our employees and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party infringed a patent or illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Common Stock

Our executive officers, directors and significant stockholders, if they choose to act together, have the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and significant stockholders beneficially own in the aggregate shares representing approximately 53.2% of our common stock as of February 29, 2020. If these stockholders choose to act together, they are able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, can control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and the board of directors; or
- impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- allow for a classified board of directors;
- establish advance notice requirements for stockholders proposal that can be acted on at stockholder meeting and nominations to our board of directors; and
- limit who may call stockholder meetings.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our common stock was delisted from the Nasdaq Capital Market and is trading on the over-the-counter markets, which may negatively impact the price of our common stock and our ability to access the capital markets.

The Nasdaq Stock Market suspended trading of our common stock on the Nasdaq Capital Market in August 2016, and in November 2016, our common stock was delisted. Our common stock is currently trading on the over-the-counter markets, which could adversely affect the liquidity of our common stock. Stocks traded on the over-the-counter market generally have limited trading volume and exhibit a wider spread between the bid/ask quotation, as compared to securities listed on a national securities exchange. Consequently, you may not be able to liquidate your investment in the event of an emergency or for any other reason.

Some significant material adverse consequences of trading on the over-the-counter markets may include:

- a limited availability of market quotations for our common stock;
- a reduced amount of news and analyst coverage for us;
- a decreased ability to issue additional securities or obtain additional financing in the future;
- reduced liquidity for our stockholders;
- potential loss of confidence by partners and employees; and
- loss of institutional investor interest and fewer business development opportunities.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for smaller medical device companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. This volatility is even more prevalent in the over-the-counter markets. As a result of this volatility, you may not be able to sell your common stock. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products, services or technologies;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the medical device sector;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock

price, we may be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

There is no assurance of an established public trading market.

A regular market for our common stock may not be sustained in the future. The OTCQB is an inter-dealer, over-the-counter market that provides significantly less liquidity than the Nasdaq Capital Market. Quotes for stocks included on the OTCQB are not listed in the financial sections of newspapers. As such, investors and potential investors may find it difficult to obtain accurate stock price quotations, and holders of our common stock may be unable to resell their securities at or near their original offering price or at any price. Market prices for our common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to a future offering;
- change in interest rates;
- competitive development, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for our common stock;
- investor perceptions of our company and medical device industry generally; and
- general economic and other national conditions.
- the issuance of new equity securities pursuant to a future offering;
- change in interest rates;

We may not be able to achieve secondary trading of our common stock in certain states because our common stock is not nationally traded.

Because our common stock is not listed for trading on a national securities exchange, our common stock is subject to the securities laws of the various states and jurisdictions of the United States in addition to federal securities law. Such regulations cover any primary offering we might attempt and all secondary trading by our stockholders. If we fail to take appropriate steps to register our common stock or qualify for exemptions for our common stock in certain states or jurisdiction of the United States, the investors in those jurisdictions where we have not taken such steps may not be allowed to purchase our common stock and those who presently hold our common stock may not be able to resell their shares without substantial effort and expense. These restrictions and potential costs could be significant burdens on our stockholders.

If we fail to remain current on our reporting requirements, we could be removed from the OTCQB, which would limit the ability of broker-dealers to sell our securities and the ability of stockholders to sell their securities in the secondary market.

Companies trading on the OTCQB, such as we, must be reporting issuers under Section 12 of the Exchange Act and must be current in their reports under Section 13 in order to maintain price quotation privileges. If we fail to remain current on our reporting requirements, we could be removed from the OTCQB. As a result, the market liquidity of our securities could be severely adversely affected by limiting the ability of broker-dealers to sell our securities and the ability of our stockholders to sell their securities in the secondary market.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital or pursue strategic acquisition opportunities, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in such an offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

The price per share at which we sell or issue additional shares of our common stock or other securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price at which you purchased your shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Because we outsource our manufacturing to “turn-key” manufacturers and have a geographically dispersed sales force and distributor arrangement, we have minimal needs for office space to conduct our day-to-day business operations. Our headquarters are located in San Jose, CA, where we lease an operations fulfillment space that also serves as our corporate headquarters address.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently a party to any litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business, operating results, cash flows or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock has traded on the OTCQB under the symbol "SMLR" since August 11, 2016. From February 21, 2014 until August 11, 2016, our common stock was traded on the Nasdaq Capital Market under the symbol "SMLR." The following tables set forth, for the periods indicated, the high and low bid prices, reflecting inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions, when listed on the OTCQB, for each period indicated.

	High	Low
Fiscal Year 2019		
First Quarter	$43.99	$32.00
Second Quarter	$49.00	$34.07
Third Quarter	$54.50	$40.00
Fourth Quarter	$50.00	$35.26

	High	Low
Fiscal Year 2018		
First Quarter	$ 9.60	$ 6.45
Second Quarter	$15.99	$ 7.72
Third Quarter	$36.00	$14.80
Fourth Quarter	$40.00	$25.50

Holders

On February 28, 2020, the closing sale price of a share of our common stock was $53.00 per share and there were 6,534,076 shares of our common stock outstanding. On that date, our shares of common stock were held by approximately 27 stockholders of record. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

Dividends

We have not declared or paid any cash dividends on our common stock, and we do not anticipate declaring or paying cash dividends for the foreseeable future. We are not subject to any legal restrictions respecting the payment of dividends, except that we may not pay dividends if the payment would render us insolvent. Any future determination as to the payment of cash dividends on our common stock will be at our board of directors' discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this annual report on Form 10-K.

Recent Sales of Unregistered Securities

Not applicable.

Purchases of Equity Securities

During the quarter ended June 30, 2019, we repurchased a warrant to acquire 65,542 shares of our common stock from the family trust of our Chief Executive Officer, Dr. Douglas Murphy-Chutorian,

which warrant had an exercise price equal to $4.50 per share and an expiration date of July 31, 2023, at an aggregate purchase price of $2,687,222. The purchase price reflects the difference between the aggregate exercise price of the warrant and the aggregate fair market value of the shares underlying the warrant, based on the last trade price of our common stock on May 3, 2019, the date of the warrant repurchase agreement. Following this repurchase, the warrant was cancelled and is no longer issued and outstanding.

During the quarter ended December 31, 2019, we repurchased warrants to acquire an aggregate of 93,797 shares of our common stock from the family trust of our Chief Executive Officer, Dr. Douglas Murphy-Chutorian, which warrants had exercise prices ranging from $2.00 to $4.50 per share and an expiration date of July 31, 2023, at an aggregate purchase price of $3,945,696. The purchase price reflects the difference between the aggregate exercise price of the warrants and the aggregate fair market value of the shares underlying the warrants, based on the last trade price of our common stock on November 6, 2019, the date of the warrant repurchase agreement. Following the repurchase, the warrants were cancelled and are no longer issued and outstanding.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

The following discussion and analysis should be read together with our financial statements and the related notes appearing elsewhere in this annual report on Form 10-K. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. See "Forward-Looking Statements" for a discussion of the uncertainties, risks and assumptions associated with these statements. Actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under "Risk Factors" and elsewhere in this annual report on Form 10-K.

Overview

We are a company providing technology solutions to improve the clinical effectiveness and efficiency of healthcare providers. Our mission is to develop, manufacture and market innovative proprietary products and services that assist our customers in evaluating and treating chronic diseases. In 2011, we began commercializing our first patented and U.S. Food and Drug Administration, or FDA, cleared product, which measured arterial blood flow in the extremities to aid in the diagnosis of peripheral arterial disease, or PAD. In March 2015, we received FDA 510(k) clearance for the next generation version of our product, QuantaFlo®, which we began commercializing in August 2015. We believe our products and services position us to provide valuable information to our customer base, which in turn permits them to better guide patient care.

In the year ended December 31, 2019, we had total revenues of $32,767,000 and net income of $15,084,000 compared to total revenues of $21,491,000 and net income of $5,014,000 in 2018. We had an income tax benefit of $4,383,000 in 2019, primarily due to the release of a tax valuation allowance in the third quarter, as compared to income tax expense of $26,000 in 2018. Our pre-tax net income was $10,701,000 in 2019 compared to $5,040,000 in 2018. In the three months ended December 31, 2019, we had net income of $2,833,000 compared to net income of $1,387,000 for the three months ended December 31, 2018.

Sources of Revenues and Expenses

Revenues

We generate revenues primarily from the rental or license of our vascular testing product. We recognize revenues from the licensing of our vascular testing product pursuant to agreements that normally automatically renew each month with revenues recognized on a daily convention basis. Our arrangements with customers for our vascular testing product are normally on a month-to-month basis with fees billed at the rates established in our customer agreements, which are either fixed fees, or variable fees based on usage. We also recognize revenue for hardware and supplies sales as of the date of shipment.

Cost of revenues

Our cost of revenues for our vascular testing product consists primarily of five components: the depreciation expense of our vascular testing product for lease; the write-off of the residual value of our vascular testing products retired from active leasing; manufacturing oversight personnel costs; the cost of hardware and supplies sold; and other miscellaneous items, such as freight, that are not directly related to product production. Each vascular testing product unit has a depreciation schedule based on the cost of the unit. The cost of each unit is depreciated on a straight-line basis over 36 months. Each unit has its own cost of production, which varies from time to time. We believe that the cost of each unit is a function of manufacturing efficiencies, supply costs and fixed overhead expense as affected by volume of units produced, which change from time to time. When cost of production is lower, the new units have a lower monthly depreciation and decrease the average depreciation per unit per month, which means our cost of revenues is lower. Similarly, if cost of production is higher, the new units will have a higher monthly depreciation and increase the average depreciation per unit per month, which means our cost of revenues is higher. We believe growth in the number of monthly depreciation charges is predominately due to our sales and marketing efforts, which add new customers to an established customer base. The retirement of units from active leasing

is primarily a function of the aggregate number of vascular testing units rented and the occurrence from time to time of system upgrades. The cost of hardware or supplies sold are the cost of production for the item sold. The other costs of revenue vary primarily as a function of the aggregate number of vascular testing units rented and changes in operations such as manufacturing, delivery or maintenance.

Engineering and product development expense

Our engineering and product development expense consists of costs associated with the design, development, testing and enhancement of our vascular testing product and other products in development. We also include salaries and related employee benefits, research-related overhead expenses and fees paid to external service providers in our engineering and product development expense.

Sales and marketing expense

Our sales and marketing expense consists primarily of sales commissions and support costs, salaries and related employee benefits, travel, education, trade show and marketing costs.

General and administrative expense

Our general and administrative expense consists primarily of salaries and related employee benefits, professional service fees, associated travel costs and depreciation and amortization expense.

Total other expense

Our total other income expense primarily reflects other taxes and fees as well as interest income and expense.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements. Critical accounting policies are those accounting policies that may be material due to the levels of subjectivity and judgment necessary to account for highly uncertain matters or the susceptibility of such matters to change, and that have a material impact on financial condition or operating performance. While we base our estimates and judgments on our experience and on various other factors that we believe to be reasonable under the circumstances, actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies used in the preparation of our financial statements require significant judgments and estimates. For additional information relating to these and other accounting policies, see Note 2 to our audited financial statements, appearing elsewhere in this this annual report on Form 10-K.

Revenue Recognition

We recognize revenue from the licensing of our vascular testing product pursuant to agreements that automatically renew each month with revenue recognized on a daily convention basis. Our arrangements with customers for our vascular testing product are normally on a month-to-month basis with fees billed at the rates established in the customer agreement, which are either fixed fees or variable fees based on usage. We also recognize revenue for hardware and supplies sales as of the date of shipment.

Stock-Based Compensation

We recognize compensation expense in an amount equal to the estimated grant-date fair value of each option grant, or stock award over the estimated period of service and vesting. Although we calculate the fair value under the Black Scholes option pricing model, which is a standard option pricing model, this model still requires the use of numerous assumptions, including, among others, the expected life (turnover), volatility of the underlying equity security, a risk-free interest rate and expected dividends. The model and assumptions also attempt to account for changing employee behavior as the stock price changes and capture

the observed pattern of increasing rates of exercise as the stock price increases. The use of different values by management in connection with these assumptions in the Black Scholes option pricing model could produce substantially different results.

Accounting for Income Taxes

Deferred income taxes result primarily from temporary differences between financial and tax reporting. Deferred tax assets and liabilities are determined based on the difference between the financial statement basis and tax basis of assets and liabilities using enacted tax rates. Future tax benefits are subject to a valuation allowance when management is unable to conclude that our deferred tax assets will more-likely-than-not be realized from the results of operations. Our estimate for the valuation allowance for deferred tax assets requires management to make significant estimates and judgments about projected future operating results. If actual results differ from these projections or if management's expectations of future results change, it may be necessary to adjust the valuation allowance.

Factors Affecting Future Results

We have not identified any factors that have a recurring effect that are necessary to understand period to period comparisons as appropriate, nor any one-time events that have an effect on the financials.

Results of Operations

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Revenues

We had revenues of $32,767,000 for the year ended December 31, 2019, an increase of $11,276,000, or 52.5%, compared to $21,491,000 in 2018. Our revenues are primarily from fees charged to customers for use of our vascular testing products and from sale of accessories used with these products. We recognized revenues of $31,840,000 from fees for our vascular testing products in 2019, an increase of $10,735,000 compared to $21,105,000 in 2018. The remainder was from other equipment/supply sales of accessories, which were $927,000 in 2019 as compared to $386,000 in 2018.

Revenues from fees for vascular testing products are recognized monthly for each unit installed with a customer, usually billed as a fixed monthly fee or as a variable monthly fee dependent on usage. The primary reason for the increase in revenues was growth in the number of installed units from both new customers and established customers, which we believe is the result of our sales and marketing efforts.

Operating expenses

We had total operating expenses of $22,059,000 for the year ended December 31, 2019, an increase of $5,910,000, or 36.6%, compared to $16,149,000 in 2018. The primary reason for this change was overall growth in our business, increased compensation of the sales team and increased headcount of field sales and technical support personnel to service the expanding number of customers. As a percentage of revenues, operating expenses decreased to 67.3% in 2019, as compared to 75.1% in 2018. The changes in the various components of our operating expenses are described below.

Cost of revenues

We had cost of revenues of $3,661,000 for the year ended December 31, 2019, an increase of $958,000, or 35.4%, from $2,703,000 for 2018. The primary reason for this change was increased costs due to increased sales volume of, placement of and technical support for installations in the field. These increases were partially offset by lower depreciation per unit per month as a greater percentage of installations were software and sensor only rather than laptop, software and sensor, as well as lower residual value for retired units. As a percentage of revenues, cost of revenues decreased to 11.2% in 2019, as compared to 12.6% in 2018.

Engineering and product development expense

We had engineering and product development expense of $2,479,000 for the year ended December 31, 2019, an increase of $394,000, or 18.9%, compared to $2,085,000 in 2018. The increase was primarily due to

timing of consultant costs, personnel and other costs associated with our product development and customization efforts. As a percentage of revenues, engineering and product development expense decreased to 7.6% in 2019, as compared to 9.7% in 2018.

Sales and marketing expense

We had sales and marketing expense of $8,965,000 for the year ended December 31, 2019, an increase of $1,763,000, or 24.5%, compared to $7,202,000 in 2018. The increase was primarily due to higher sales compensation and personnel expense and the continued expansion of existing customer orders, marketing activities and increased headcount and associated expense as compared to the prior year period. As a percentage of revenues, sales and marketing expense decreased to 27.4% in 2019, as compared to 33.5% in 2018.

General and administrative expense

We had general and administrative expense of $6,954,000 for the year ended December 31, 2019, an increase of $2,795,000, or 67.2%, compared to $4,159,000 in 2018. The increase was primarily due to the growth in our business, higher professional fees and higher expenses for personnel and our board of directors. As a percentage of revenues, general and administrative expense was 21.2% in 2019, as compared to 19.4% in 2018.

Other expense

We had other expense of $7,000 for 2019, a decrease of $295,000, or 97.7%, compared to $302,000 in 2018. The decrease was primarily due to lower interest expense associated with retirement of notes payable.

Provision for taxes

In 2019, we recorded a tax benefit of $4,383,000, compared to a tax expense of $26,000 in 2018. The decrease in income tax expense was primarily due to an income tax benefit recognized in 2019 relating to the release of the entire valuation allowance against deferred tax assets. The valuation allowance was released in the third quarter of 2019 due to our recent history of eight straight quarters of positive income before income taxes, resulting in an income tax benefit. Due to full release of the valuation allowance in the third quarter of 2019, income in future periods may also result in income tax expense. As of December 31, 2019, we had federal NOL carryforwards of $10.3 million.

Net income

For the foregoing reasons, we had a net income of $15,084,000 for the year ended December 31, 2019, an increase of $10,070,000, or 200.8%, compared to a net income of $5,014,000 for the year ended December 31, 2018.

Liquidity and Capital Resources

We had cash of $7,741,000 at December 31, 2019, compared to cash of $3,284,000 at December 31, 2018, and total current liabilities of $5,207,000 at December 31, 2019, compared to $3,512,000 at December 31, 2018. As of December 31, 2019, we had working capital of approximately $6,236,000.

Our cash is held in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper and money market accounts. In addition, we may also choose to invest some of our cash resources in other entities that may have complementary technologies or product offerings.

Operating activities

We generated $12,728,000 of net cash from operating activities for the year ended December 31, 2019, compared to $4,697,000 of net cash in operating activities for the year ended December 31, 2018. The improvement was primarily due to changes in net income, as well as both non-cash adjustments and operating

assets and liabilities, which occurred due to growth in our business. Non-cash adjustments to reconcile net income to net cash from operating activities were $3,250,000 in the year ended December 31, 2019. These non-cash adjustments primarily reflect the deferred tax asset of $4,501,000, partially offset by depreciation of assets for lease of $483,000, stock-based compensation expense of $365,000, loss on disposal of assets for lease of $206,000, fixed assets depreciation and amortization of $149,000 and allowance for doubtful accounts of $48,000. Changes in operating assets and liabilities provided $894,000 of net cash. These changes in operating assets and liabilities included cash provided by accrued expenses of $1,113,000, deferred revenue of $520,000 and accounts payable of $58,000, partially offset by cash used by trade accounts receivable of $734,000 and prepaid expenses of $63,000.

Investing activities

We used $1,698,000 of net cash in investing activities for the year ended December 31, 2019, primarily attributable to purchase of assets for lease of $1,524,000 and additions to property and equipment of $174,000, to support our growing business.

We used $843,000 of net cash in investing activities for the year ended December 31, 2018, primarily attributable to purchase of assets for lease of $706,000 and additions to property and equipment of $137,000, to support our growing business.

Financing activities

We used $6,573,000 of net cash from financing activities during the year ended December 31, 2019, primarily due to cash used in payments for purchases of warrants of $6,633,000, partially offset by proceeds from exercise of stock options of $60,000.

We used $2,027,000 of net cash from financing activities during the year ended December 31, 2018, primarily due to cash used in payments of loans payable of $2,897,000, partially offset by proceeds from issuance of common stock of $870,000 (including $456,000 from exercise of stock options and $414,000 from exercise of warrants).

Description of Indebtedness

We do not currently have any outstanding material indebtedness.

Off-Balance Sheet Arrangements

As of each of December 31, 2019 and 2018, we had no off-balance sheet arrangements.

Commitments and Contingencies

As of each of December 31, 2019 and 2018, other than employment/consulting agreements with our executive officers and our San Jose lease, we had no material commitments other than the liabilities reflected in our financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data required by this item are included in Part IV, Item 15 of this annual report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure material information required to be disclosed in our reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance, as appropriate, to allow timely decisions regarding required financial disclosure. In designing and evaluating the disclosure controls and procedures, we recognized that a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. 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 a company have been detected. Management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision of and with the participation of our management, including our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2019. Based upon that evaluation, our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance concluded that, because of the material weaknesses in our internal control over financial reporting described below, our disclosure controls and procedures were not effective for the reasons described below. Notwithstanding the material weaknesses described below, our management, including our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance, has concluded that the consolidated financial statements included in this Annual Report on Form 10-K are fairly stated, in all material respects, in accordance with generally accepting accounting principles in the United States for each of the periods presented herein.

During the year ended December 31, 2019, we identified material weaknesses in our internal control over financial reporting, as described below. A "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2019, our material weaknesses in internal control over financial reporting were:

a. Insufficient segregation of duties, oversight of work performed and ineffective compensating controls in our finance and accounting functions due to limited personnel;

b. Our information technology general controls related to user access security and change management controls related to our enterprise resource planning system were not designed effectively to provide an adequate audit trail for system change management controls and for the periodic review and testing of user access rights and permissions.

c. We did not sufficiently design and effectively implement controls to validate the completeness and accuracy of underlying data used in the performance of various controls over accounting transactions and disclosures;

d. We did not design sufficient protocols and procedures to retain adequate documentary evidence related to the timely review and approval of manual journal entries including the review of the underlying information at a sufficient level of detail; and

e. We did not sufficiently design and retain adequate documentary evidence supporting the design and operating effectiveness of certain important management review controls including the precision of review and evidence of procedures performed.

Each of the material weaknesses described above, combined with ineffective compensating financial close and review controls, had a pervasive impact on our activity level cycles and accounts and creates a reasonable possibility that a material misstatement of the consolidated financial statements will not be prevented or detected on a timely basis. Accordingly, management concluded that our disclosure controls and procedures were not effective as of December 31, 2019.

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 Exchange Act Rules 13a-15(f) and 15d-15(f). We maintain internal control over financial reporting designed to provide reasonable, but not absolute, 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. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2019. In making their assessment of internal control over financial reporting, our management used the criteria described in the 2013 Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our evaluation included documenting, evaluating and testing of the design and operating effectiveness of our internal control over financial reporting. Based on this evaluation, and due to the material weaknesses described above, we concluded that we did not maintain effective control over financial reporting as of December 31, 2019.

Remediation Plan

We are currently taking actions to remediate the material weaknesses in our internal control over financial reporting and are implementing additional processes, procedures, policies, and controls designed to address the underlying causes associated with the above-mentioned deficiencies. We are committed to remediating the deficiencies described above. Our internal control remediation efforts include the following:

- We are adding additional accounting resources to support the objectives of proper segregation of duties within our finance and accounting functions including controls over segregation of duties over the initiation of transactions, the recording of transactions, and the custody of assets.
- We are in the process of reassessing and formalizing the design of certain accounting and information technology policies relating to security and change management controls.
- We engaged an outside firm to assist management with (i) reviewing our current processes, procedures and systems and assessing the design of controls to identify opportunities to enhance the design of controls that would address relevant risks identified by management, and (ii) enhancing and implementing protocols to retain sufficient documentary evidence of operating effectiveness of such controls.

In addition to implementing and refining the above activities, we expect to engage in additional activities in fiscal year 2020, including:

- Continuing to enhance and formalize our accounting, business operations, and information technology policies, procedures, and controls to achieve complete, accurate, and timely financial accounting, reporting and disclosures.

- Designing and implementing controls that address the completeness and accuracy of underlying data used in the performance of controls over accounting transactions and disclosures.
- Enhancing policies and procedures to retain adequate documentary evidence for certain management review controls over certain business processes including precision of review and evidence of review procedures performed to demonstrate effective operation of such controls.
- Developing monitoring controls and protocols that will allow us to timely assess the design and the operating effectiveness of controls over financial reporting and make necessary changes to the design of controls, if any.

We will continue to report regularly to the audit committee on the progress and results of the remediation plans, including the identification, status and resolution of internal control deficiencies.

Attestation Report of Independent Registered Public Accounting Firm

BDO USA LLP, an independent registered public accounting firm, as auditors of our consolidated financial statements, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2019. BDO USA LLP's report, which expresses an adverse opinion on the effectiveness of our internal control over financial reporting due to material weaknesses, is included herein.

Changes in Internal Control over Financial Reporting

Other than in connection with executing upon the implementation of the remediation plan outlined above, there were no changes in our internal control over financial reporting during the year-ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors and Executive Officers

The following are our directors and executive officers and their respective ages and positions as of the date of this annual report on Form 10-K:

Name	Age	Position	Director Since	Term Expires
Douglas Murphy-Chutorian, M.D.	65	Chief Executive Officer and Director	September 2012	2021
Andrew B. Weinstein	55	Senior Vice President, Finance and Accounting	N/A	N/A
Daniel E. Conger	43	Vice President, Finance	N/A	N/A
Arthur “Abbie” Leibowitz, M.D., F.A.A.P.	73	Director	June 2014	2020
Wayne T. Pan, M.D., Ph.D.	56	Director	May 2014	2022

Board of Directors

Douglas Murphy-Chutorian, M.D. — Dr. Douglas Murphy-Chutorian has served as a member of our board of directors since September 2012 and as our chief executive officer since October 31, 2012. Dr. Murphy-Chutorian has had broad, diverse career experience in healthcare over the past 30 years, stretching from clinician, academician, inventor, entrepreneur, chief executive officer, chairman of the board, and consultant to financial firms. Since April 15, 2005, he has been managing director of Select Healthcare Capital, LLC. Dr. Murphy-Chutorian is a named inventor on more than 30 patents, and has guided more than 50 products through various regulatory approval processes. His business career has included extensive involvement in all facets of the medical industry from financial, research and development, manufacturing, marketing and sales, regulatory, reimbursement, and clinical trials. His breadth of healthcare experience includes all major sectors of the industry: medical devices, health services, pharmaceuticals, biotechnology and managed care. He received his B.A. and M.D. from Columbia University. He completed his internal medicine residency at New York University/Bellevue Medical Center and his fellowship in cardiology at Stanford University Medical Center. He has served as a faculty member in interventional cardiology at both Stanford and Montefiore Medical Center. Dr. Murphy-Chutorian’s experience as a cardiologist, inventor and executive, in particular serving as our Chief Executive Officer, qualify him to be a director of our company.

Arthur “Abbie” Leibowitz, M.D., F.A.A.P. — Dr. Arthur “Abbie” Leibowitz has served as a member of our board of directors since June 2014. Dr. Leibowitz has over 50 years of experience in healthcare, with more than 30 years in leading positions with several healthcare companies. From 2001 to 2015, Dr. Leibowitz was chief medical officer and executive vice president at Health Advocate, Inc., a health advocacy and assistance company he co-founded that provides support and helps consumers navigate the healthcare system. In June 2014, Health Advocate, Inc. became a wholly owned subsidiary of the West Corporation, a publicly traded telecommunications and health services company. West Corporation was in turn acquired and taken private by Apollo Global Management, LLC in October 2017. Dr. Leibowitz continues with West Corporation as West Health Advocate Solutions, Inc.’s chief medical officer and president emeritus. Health Advocate Inc.’s clients include more than 12,000 small, medium, and large sized companies, not-for-profit organizations and associations, schools, colleges and universities, unions, health plans, and third-party administrators across the United States. Prior to his role at Health Advocate, Inc., Dr. Leibowitz served as executive vice president of digital health strategies and a member of the board of directors at Medicologic, Inc., where he was responsible for developing healthcare data, information services and strategies targeted at users of the company’s electronic medical record system, as well as data customers including payors, pharmaceutical companies, employers, regulatory and government agencies. Dr. Leibowitz served as vice president, medical delivery systems and chief medical officer at Aetna U.S. Healthcare, from 1996 to 2000, where he directed medical affairs and policies for one of the largest health benefits companies in the nation. In this role he was responsible for clinical policy development, technology assessment,

patient management activities, and quality improvement programs. From 1993 to 1996, Dr. Leibowitz was the vice president, health delivery, corporate medical director at U.S. Healthcare, where he coordinated the expansion of medical programs regionally into eight new markets. Dr. Leibowitz had also served as vice president, health delivery, and a network medical director at U.S. Healthcare, from 1987 to 1993. From 1975 to 1987, Dr. Leibowitz was the senior physician at Drexel Hill Pediatric Associates, where he established seven physician pediatric group practice serving a large and diverse urban/suburban patient population. Dr. Leibowitz has authored many articles in the medical literature and including revising his chapter on Health System Navigation in the recently published Second Edition of Population Health, Creating a Culture of Wellness, edited by David Nash and others. Dr. Leibowitz received both his B.A. and M.D. degrees from Temple University. We believe Dr. Leibowitz's extensive background, experience and knowledge of the healthcare industry qualify him to be a director of our company.

Wayne T. Pan, M.D., Ph.D., MBA — Dr. Wayne T. Pan has served as a member of our board of directors since May 2014. Dr. Pan has over 20 years of broad healthcare industry experience from clinical medicine, to managed care, and health information technology. Dr. Pan is currently a medical director in Global Medical Affairs at BioMarin Pharmaceutical Inc., functioning as the Global Medical Lead for products in development and marketed products treating the mucopolysaccharidoses (MPS) diseases, Morquio A (MPS IVA), Maroteaux-Lamy (MPS VI) and Sanfilippo B (MPS IIIB) syndromes. He is also a part-time associate medical director at San Francisco Health Plan, responsible for utilization management, appeals and grievances and the care transitions program. From April 2016 to February 2018, he was a medical director in Quality of Care and Health Economics and Outcomes Research, US Medical Affairs at Genentech, Inc., a biotechnology company based in South San Francisco. From April 2015 to April 2016, Dr. Pan served as the chief medical officer at Applied Research Works, a healthcare software technology company based in Palo Alto, offering health plans and integrated delivery systems, a cloud-based platform providing timely, actionable clinical data to providers at the point of care. From October 2014 to April 2015, Dr. Pan served as medical director in the technology group of Clover Health Labs, a start-up integrated healthcare delivery system based on the East Coast that includes a hospital system, a medical group and affiliated independent physicians, and a Medicare and Medicaid health plan. From June 2014 to April 2015 he served as the Chief Medical Officer at Santa Clara County IPA (SCCIPA), a large independent physician association in Santa Clara County, California with 800 multi-specialty physicians with 80,000 covered lives in commercial (HMO/ACO) and Medicare Advantage (HMO/ACO) programs. From August 2012 to May 2014 Dr. Pan served as chief medical officer at Thrasys, Inc., a global healthcare technology company that provides a cloud-based platform upon which healthcare delivery systems and provider organizations can build high quality, person-centered accountable care communities. Between October 2010 and July 2012, Dr. Pan was concurrently the chief medical informatics officer for Health Access Solutions, a health care software development company and chief medical officer of Pacific Partners Management Services, Inc., a medical management services company serving medical groups in northern California with over 50,000 covered lives. Prior to that, between September 2009 and February 2010, he served as chief medical officer for Affinity Medical Solutions, LLC, a medical management services organization serving independent physicians association clients and managing commercial and Medicare Advantage members. Dr. Pan has also served as chief medical officer between June 2008 and August 2009 for Alameda Alliance for Health, a local initiative health plan with Medicaid, Medicare Advantage Dual Eligible SNP and IHSS plans, and as an advisory chief medical officer at a data analytics start-up focused on big data issues in healthcare in 2007-2008. Dr. Pan holds an M.B.A. from The Wharton School, University of Pennsylvania, and an M.D. and Ph.D. from the Mt. Sinai School of Medicine, and a B.S. in Biology from Johns Hopkins University. We believe Dr. Pan's extensive healthcare-related business experience qualifies him to be a director of our company.

Other than as described above in the biographies, there are no family relationships among any of our directors or executive officers.

Executive Officers

Andrew B. Weinstein — Mr. Weinstein has served as our Senior Vice President, Finance and Accounting since October 2018. He previously served as the Vice President of Accounting since joining our company in March 2017. From May 2006 until joining our company, Mr. Weinstein served as Vice President, Controller and member of senior management at Health Advocate, Inc., a health advocacy and assistance company that provides support and helps consumers navigate the healthcare system. During his tenure at Health Advocate,

Mr. Weinstein was responsible for all accounting, finance, payroll, benefits and financial reporting activities of the company and its four subsidiaries, leading a team of eighteen people. He also served as a director of two of Health Advocate's subsidiaries. Mr. Weinstein received a B.S. in Accounting from Pennsylvania State University and is a Certified Public Accountant (Pennsylvania).

Daniel E. Conger — Mr. Daniel E. Conger has served as our Vice President of Finance since October 2010. From September 2008 until joining our company, Mr. Conger worked at Bacchus Vascular and its acquirer Covidien, Inc., a medical device, supplies and pharmaceuticals company, where he was the Plant Controller for the San Jose plant. At Covidien, Mr. Conger was responsible for creation of a $130 million annual budget, leading a team of six people. He had responsibility for preparation of monthly and quarterly financial statements, and presented quarterly results to executive management of the global business unit. Mr. Conger has been working in the medical device, start-up and biotechnology industries since 2006, and has experience designing internal control systems, implementing such systems, and running finance in a business centered manner. He received his B.S. in Business Administration from Humboldt State University in May 2001 and an MBA-Accounting Option from California State University East Bay in June 2010.

Director Independence

The Nasdaq suspended trading in our shares effective at the open of business on August 11, 2016 and filed a Form 25 Notification of Delisting with the Securities and Exchange Commission on November 11, 2016. Nevertheless, our board of directors has elected to continue to adhere to Nasdaq rules regarding director independence in anticipation of possibly relisting our common stock on the Nasdaq if and when such relisting becomes available to us.

Our board of directors consults with our outside counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his family members and our company, our senior management and our independent auditors, our board of directors has affirmatively determined that the following two directors are independent directors within the meaning of the applicable Nasdaq listing standards: Drs. Leibowitz and Pan. In making this determination, the board of directors found that neither of these directors had a material or other disqualifying relationship with our company.

In making such determinations, our board of directors considered the relationships that each such director has with our company, including the relationships and transactions described in the section of this annual report on Form 10-K captioned "Certain Relationships And Related Transactions, And Director Independence," and all other facts and circumstances that our board of directors deemed relevant in determining his independence, including the beneficial ownership of our capital stock by each director.

Changes to Procedures for Recommending Nominees to Board of Directors

None.

Audit Committee

Our board of directors has established a separately designated standing audit committee, which is currently comprised solely of Dr. Pan, who serves as both sole member and Chairman. We do not have any current board members who qualify as an "audit committee financial expert," and accordingly, our audit committee does not have an "audit committee financial expert". The nominating committee of the board of directors expects to identify suitable candidates for the board of directors prior to any potential relisting on Nasdaq, if not sooner, including an individual who can serve on the audit committee and who qualifies as an audit committee financial expert within the meaning of the SEC's rules.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of

ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the year ended December 31, 2019, all Section 16(a) filing requirements applicable to our officers, directors and greater than ten percent beneficial owners were in compliance.

Code of Ethics

We have adopted a code of ethics that applies to our principal executive officer (our chief executive officer), our principal accounting officer (our vice president of finance) and other officers performing similar functions, which we refer to as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http://www.semlercientific.com under the Corporate Governance section of the Investors portion of our website. Our Code of Business Conduct and Ethics is designed to meet the requirements of Item 406 of Regulation S-K. We will promptly disclose on our website (i) the nature of any amendment to the Code of Business Conduct and Ethics that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Business Conduct and Ethics that is granted to one of the covered persons.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the information as to compensation paid to or earned by our (i) principal executive officer and (ii) the two most highly compensated executive officers other than our principal executive officer. These individuals are referred to in this annual report on Form 10-K as our named executive officers, and were our only executive officers during the year ended December 31, 2019. As none of our named executive officers received any stock awards or nonqualified deferred compensation earnings during the years ended December 31, 2019 and 2018, we have omitted those columns from the table.

Name and Principal Position	Fiscal Year	Salary ($)	Bonus ($)	Option Award(s) ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
Douglas Murphy-Chutorian, M.D., director and chief executive officer	2019	$400,000	$ 0	$ 0	$744,708	$25,545	$1,170,253
	2018	$367,500	$ 0	$746,250	$448,642	$15,975	$1,578,367
Andrew B. Weinstein senior vice president, finance and accounting	2019	$265,625	$55,000	$ 0	$ 0	$ 1,686	$ 322,311
	2018	$230,000	$46,000	$ 0	$ 0	$ 979	$ 276,979
Daniel E. Conger, vice president, finance	2019	$200,000	$40,000	$ 0	$ 0	$23,058	$ 263,058
	2018	$200,000	$40,000	$ 0	$ 0	$22,024	$ 262,024

(1) Represents aggregate grant date fair value computed in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. For more information regarding assumptions used for computation of fair value, see Note 11 to our audited financial statements included elsewhere in this annual report on Form 10-K.

(2) Represents annual bonus earned under our incentive compensation plan. The amounts represent performance-based cash incentives earned by Dr. Murphy-Chutorian based on the achievement of certain company goals and his target incentive compensation amount. Incentive compensation awards are paid annually, based on the achievement of the objectives set by the compensation committee of our board of directors at the beginning of the fiscal year.

(3) For Dr. Murphy-Chutorian and Mr. Conger, represents payment of health insurance premiums pursuant to the terms of employment agreements.

Named Executive Officer Compensation Arrangements

We enter into individually negotiated compensation arrangements with each of our named executive officers. Our named executive officers may receive salary, bonus and other benefits, such as the payment of health insurance premiums or other individually negotiated health benefits pursuant to the terms of their negotiated compensation package. We may also grant our named executive officers awards under our equity incentive plans.

Douglas Murphy-Chutorian, M.D.

At the time he joined our company as a director, and subsequently as our chief executive officer, Dr. Murphy-Chutorian did not have a formal employment agreement with our company. We engaged Dr. Murphy-Chutorian as an independent contractor, and he received sales commissions, and then later, a monthly stipend of $16,000, in addition to such sales commissions. In September 2012, Dr. Murphy-Chutorian became a director and, effective October 31, 2012, our chief executive officer. On November 11, 2013, we entered into an at-will employment agreement with Dr. Murphy-Chutorian. Under the terms of this agreement, Dr. Murphy-Chutorian can be terminated at any time and his job titles, salaries and benefits may be modified from time to time as we deem necessary.

In 2019, Dr. Murphy-Chutorian's base salary was $400,000, with target incentive equal to 50% of base salary. Effective January 1, 2020, Dr. Murphy-Chutorian's base salary is $400,000, with target incentive equal to 75% of base salary.

Andrew B. Weinstein

On March 14, 2017, we entered into an at-will employment agreement with Mr. Weinstein, our senior vice president, finance and accounting. Under the terms of the agreement, Mr. Weinstein can be terminated at any time and his job titles, salaries and benefits may be modified from time to time as we deem necessary. At the start of 2019, Mr. Weinstein's base salary was $230,000, with a discretionary bonus equal to 20% of base salary. Effective March 15, 2019, Mr. Weinstein's base salary is $275,000, with a discretionary bonus equal to 20% of base salary. Effective March 1, 2020, Mr. Weinstein's base salary is $300,000, with a discretionary e bonus of $60,000.

Daniel E. Conger

On October 18, 2010, we entered into an at-will employment agreement with Mr. Conger, our vice president of finance. Under the terms of the agreement, Mr. Conger can be terminated at any time and his job titles, salaries and benefits may be modified from time to time as we deem necessary. In 2019, Mr. Conger's base salary was $200,000, with a discretionary bonus of $40,000. Effective January 1, 2020, Mr. Conger's base salary is $210,000, with a discretionary bonus of $40,000.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information about the number of outstanding equity awards held by our named executive officers at December 31, 2019. We have omitted certain columns from the table as we do not have any outstanding stock awards.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Douglas Murphy-Chutorian[1]	20,000	0	$0.52	11/21/2022
Douglas Murphy-Chutorian[1]	85,000	0	$2.10	11/08/2024
Douglas Murphy-Chutorian[1]	75,000	0	$1.96	12/31/2024
Douglas Murphy-Chutorian[1]	180,000	0	$3.44	07/20/2025
Douglas Murphy-Chutorian[1]	60,000	0	$2.59	12/31/2025
Douglas Murphy-Chutorian[2]	122,569	2,431	$2.23	02/17/2026
Douglas Murphy-Chutorian[2]	93,316	31,684	$1.72	01/19/2027
Douglas Murphy-Chutorian[2]	63,281	61,719	$8.00	12/31/2027
Andrew B. Weinstein[2]	21,271	8,729	$3.15	03/14/2027
Daniel E. Conger[1]	10,000	0	$3.44	07/20/2025
Daniel E. Conger[1]	3,000	0	$2.59	12/31/2025

(1) The option is fully vested.

(2) The option is subject to monthly vesting over four years (1/48 per month) such that it will be vested in full on the four-year anniversary of its grant date.

Director Compensation

The following table shows the compensation earned in the year ended December 31, 2019 by our non-employee directors. Our non-employee directors received only director fees in 2019, so we have omitted certain columns from the table. The compensation information for Dr. Murphy-Chutorian, our chief executive officer and a director, is set forth in "— Summary Compensation Table."

Name	Fees Earned or Paid in Cash ($)	Total ($)
Arthur "Abbie" Leibowitz, M.D., F.A.A.P.	$67,500	$67,500
Wayne T. Pan, M.D., Ph.D.	$70,500	$70,500

Non-Employee Director Compensation Policy

Prior to the adoption of our non-employee director compensation program in July 2014, we did not have a formal compensation plan for our directors. We did not pay our directors attendance fees or grant them equity or other compensation for service on our board.

Our non-employee director compensation program is currently as follows:

All non-employee directors are entitled to receive an annual $45,000 retainer for service as a board member ($82,500 for non-employee chairman of the board, if any) and an annual retainer for each committee on which they serve as a member:

- $22,500 per year for service as chairman of the audit committee or $11,250 per year for service as a member of the audit committee;

- $15,000 per year for service as chairman of the compensation committee or $7,500 per year for service as a member of the compensation committee;
- $7,500 per year for service as chairman of the nominating committee or $3,000 per year for service as a member of the nominating committee;

Cash payments to non-employee directors are to be paid quarterly and will be pro-rated for directors who join the board or a board committee mid-year. We no longer provide equity compensation to our non-employee directors for service on our board.

Compensation-Related Risk

Our board of directors is responsible for the oversight of our risk profile, including compensation-related risks. Our compensation committee monitors our compensation policies and practices as applied to our employees to ensure that these policies and practices do not encourage excessive and unnecessary risk-taking. Our management, together with the compensation committee, reviews of our compensation programs, including our executive compensation program, to determine if such programs create risks that are likely to have a material adverse effect on our company. Based on this review, our board of directors believes that the level of risk associated with our compensation programs is not reasonably likely to have a material adverse effect on our company.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of February 29, 2020 of:

- each person who is known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock and is based on 6,534,076 shares of common stock issued and outstanding as of February 29, 2020. Shares of our common stock subject to options or warrants that are currently exercisable or exercisable within 60 days after February 29, 2020 are considered outstanding and beneficially owned by the person holding the options or warrants for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in the following table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Information with respect to beneficial ownership by 5% stockholders has been based on information filed with the SEC pursuant to Section 13(d) or Section 13(g) of the Exchange Act, as well as our records. Except as otherwise set forth in the footnotes to the following table, the address of each beneficial owner is c/o Semler Scientific, Inc., 911 Bern Court, Suite 110, San Jose, CA 95112.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders:		
William H.C. Chang[(1)]	1,292,323	19.8%
Park West Asset Management, LLC[(2)]	600,000	9.2%
Eric Semler	568,221	8.7%
Executive Officers and Directors:		
Dr. Arthur N. Leibowitz[(3)]	50,000	*
Dr. Douglas Murphy-Chutorian[(4)]	862,877	11.8%
Dr. Wayne T. Pan[(5)]	52,474	*
Andrew B. Weinstein[(6)]	23,771	*
Daniel E. Conger[(7)]	13,000	*
All directors and officers as a group (5 persons)	1,002,122	13.4%

* less than 1%

(1) Includes (a) 392,323 shares of our common stock held by the Chang Family Trust U/A DTD 10/23/2006, or the Chang Family Trust, for which Mr. and Mrs. Chang are co-Trustees and share voting and investment control, (b) 450,000 shares of our common stock held in six separate grantor retained annuity trusts, or GRATs, for which Mr. Chang acts as sole Trustee and has voting and investment control and (c) 450,000 shares of our common stock held in six separate GRATs for which Mrs. Chang acts as sole Trustee and has voting and investment control. The address for the Chang Family Trust, Mr. Chang and Mrs. Chang is 520 El Camino Real, 9th Floor, San Mateo, CA 94402.

(2) Includes (a) 543,174 shares of our common stock held by Park West Investors Master Fund, Limited, a Cayman Islands exempted company, or PWIMF, and (b) 56,826 shares of our common stock held by Park West Partners International, Limited, a Cayman Islands exempted company, or PWPI, and, collectively with PWIMF, the PW Funds. Park West Asset Management LLC, a Delaware limited

liability company, or PWAM, is the investment manager to the PW Funds, and Peter S. Park is the sole member and manager of PWAM. PWAM and Mr. Park may be deemed to beneficially own the 600,000 shares of our common stock held in the aggregate by the PW Funds. The address of the PW Funds, PWAM and Mr. Park is 900 Larkspur Landing Circle, Suite 165, Larkspur, California 94939.

(3) Represents options to acquire 50,000 shares of our common stock.

(4) Includes (a) 63,571 shares of our common stock, (b) options to purchase an aggregate of 722,431 shares of our common stock and (c) warrants to purchase an aggregate of 76,875 shares of our common stock. Options are held by Dr. Murphy-Chutorian. Other securities are held in a family trust over which Dr. Murphy-Chutorian is co-Trustee with his spouse, and with whom he shares voting and investment power over such securities.

(5) Includes (a) 6,141 shares of our common stock and (b) options to purchase 46,333 shares of our common stock.

(6) Represents options to acquire 23,771 shares of our common stock.

(7) Represents options to acquire 13,000 shares of our common stock.

Equity Compensation Plan Information

The following table sets forth information about our equity compensation plans as of December 31, 2019. We do not have any equity compensation plans that have not been approved by securityholders.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (#)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights ($)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (#)
	(a)	(b)	(c)
Equity Compensation Plans Approved by Securityholders:			
2014 Stock Incentive Plan	1,468,582	3.30	997,163[(1)]
2007 Key Person Stock Option Plan	113,000	1.58	0
Total	1,581,582	3.23	997,163

(1) The amount of shares available under this plan automatically increases on January 1st of each year in an amount equal to 4% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. Accordingly, effective January 1, 2020, the number of securities remaining available for issuance increased by 262,249 shares.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following includes a summary of transactions since January 1, 2018 to which we have been a party in which the amount involved exceeded or will exceed the lesser of (x) $120,000 or (y) 1% of our average total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Management — Summary Compensation Table — Named Executive Officer Compensation Arrangements." We also describe below certain other transactions with our directors, executive officers and stockholders.

Financings

On August 16, 2018, we issued 12,943 shares of our common stock to Glenn Krevlin, a significant stockholder at such time, as payment in full of an aggregate $294,453 of outstanding principal and interest on a promissory note in lieu of cash payment.

Warrant Repurchases

On May 3, 2019, we entered into a warrant purchase agreement, or the May Repurchase Agreement, with the Murphy-Chutorian Family Trust U/D/T dated January 13, 1997, or the Murphy-Chutorian Family Trust, of which Dr. Murphy-Chutorian, our director and chief executive officer is co-Trustee with his spouse and of which he is a beneficiary. Pursuant to the May Repurchase Agreement, we repurchased a warrant to acquire 65,542 shares of our common stock, or the May Repurchase Warrant, held by the Murphy-Chutorian Family Trust, which warrant had an exercise price equal to $4.50 per share and an expiration date of July 31, 2023, at an aggregate purchase price of $2,687,222. The purchase price reflects the difference between the aggregate exercise price of the May Repurchase Warrant and the aggregate fair market value of the shares underlying the May Repurchase Warrant, based on the last trade price of our common stock on May 3, 2019, the date of the May Repurchase Agreement. Following this repurchase, the May Repurchased Warrant was cancelled and is no longer issued and outstanding.

On November 6, 2019, we entered into a warrant purchase agreement, or the November Repurchase Agreement, with the Murphy-Chutorian Family Trust. Pursuant to the November Repurchase Agreement, we repurchased warrants to acquire an aggregate of 93,797 shares of our common stock, or collectively, the November Repurchase Warrants, held by the Murphy-Chutorian Family Trust, which warrants had exercise prices ranging from $2.00 to $4.50 per share and an expiration date of July 31, 2023, at an aggregate purchase price of $3,945,696. The purchase price reflects the difference between the aggregate exercise price of the November Repurchase Warrants and the aggregate fair market value of the shares underlying the November Repurchase Warrants, based on the last trade price of our common stock on November 6, 2019, the date of the November Repurchase Agreement. Following this repurchase, the November Repurchased Warrants were cancelled and are no longer issued and outstanding.

Review, Approval or Ratification of Transactions with Related Persons

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 (or if we are a "smaller reporting company' at such time, the lesser of (x) $120,000 or (y) 1% of our average total assets at year-end for the last two completed fiscal years) and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether

the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents fees for professional audit services rendered by BDO USA, LLP, or BDO, for the audit of our consolidated financial statements for the years ended December 31, 2019 and 2018. In addition to retaining BDO to conduct an audit of the financial statements, we engage the firm from time to time to perform other services. The following table sets forth all fees incurred in connection with professional services rendered to us by BDO during each of the last two fiscal years.

	Year Ended December 31,	
Fee Type	**2019**	**2018**
Audit Fees	$402,000	$200,650
Audit-Related Fees	0	0
Tax Fees	27,000	0
Total	$429,000	$200,650

Audit Fees. This category consists of the annual audit of our financial statements, the interim reviews of the quarterly financial statements, and services performed in conjunction with our registration statements. For 2019 this category also included an audit of our internal controls over financial reporting.

Audit-Related Fees. None.

Tax Fees. This category consists of services related to Internal Revenue Code Section 382 study.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee charter provides that the audit committee will approve the fees and other significant compensation to be paid to our independent auditors, and pre-approve all audit services and all non-audit services of independent auditors permitted under applicable law. The charter also provides that the audit committee may establish other pre-approval policies and procedures for the engagement of independent auditors to render services to us, including without limitation policies that would allow the delegation of pre-approval authority to one or more members of the audit committee, provided that any pre-approval decision is reported to the audit committee at its next scheduled meeting. The audit committee has approved all audit and audit-related work covered by the audit fees, tax fees and all other fees.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements and Financial Statement Schedules

(1) Financial Statements:

Financial statements are shown in the Index to Financial Statements included in Part II, Item 8 of this annual report on Form 10-K.

(2) Financial Statement Schedules:

Financial statement schedules have been omitted because either they are not applicable or the required information is included in the financial statements or the notes thereto.

(3) Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on November 2, 2015).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on October 21, 2016).
4.1	Specimen Common Stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 of our Form S-1 Registration Statement filed with the Securities and Exchange Commission on December 6, 2013).
4.2	Description of Capital Stock.
10.1	Form of Series A, Series A-1 and Series A-2 Preferred Stock Warrant (incorporated by reference to Exhibit 10.1 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.2†	Warrant Amendment (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 21, 2015).
10.3†	2007 Key Person Stock Option Plan (incorporated by reference to Exhibit 10.3 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.4†	Form of 2007 Key Person Stock Option Plan Option Grant Notice and Option Agreement (incorporated by reference to Exhibit 10.2 of our Form 10-Q filed with the Securities and Exchange Commission on November 3, 2015).
10.5†	At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between Semler Scientific, Inc. and Douglas Murphy-Chutorian, M.D., dated November 11, 2013 (incorporated by reference to Exhibit 10.6 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.6†	At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between Semler Scientific, Inc. and Daniel E. Conger, dated October 18, 2010 (incorporated by reference to Exhibit 10.5 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.7†	At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between Semler Scientific, Inc. and Andrew B. Weinstein, dated March 14, 2017 (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the Securities and Exchange Commission on October 5, 2018).
10.8†	2014 Stock Incentive Plan, dated August 26, 2014 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 2, 2014).

Exhibit No.	Description
10.9†	Form of 2014 Stock Incentive Plan Stock Option Grant Notice and Option Agreement (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed with the Securities and Exchange Commission on November 3, 2015).
10.10	Form of Indemnification Agreement, approved and entered into between the Company and each of the Company's directors and executive officers as of July 24, 2014 (incorporated by referenced to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on July 29, 2014).
10.11	Service & Supply Agreement between Semler Scientific, Inc. and Phoenix DeVentures, Inc. dated as of April 28, 2011(incorporated by reference to Exhibit 10.8 to Amendment No. 1 of our Form S-1 Registration Statement filed with the Securities and Exchange Commission on December 6, 2013).
10.12	Warrant Repurchase Agreement between Semler Scientific, Inc. and Murphy-Chutorian Family Trust U/D/T dated January 13, 1997, dated May 3, 2019 (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 7, 2019).
10.13	Warrant Repurchase Agreement between Semler Scientific, Inc. and Murphy-Chutorian Family Trust U/D/T dated January 13, 1997, dated November 6, 2019 (incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 8, 2019).
14.1	Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
23.1*	Consent of BDO USA, LLP dated March 9, 2020.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*(+)	Certification of Principal Executive Officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(+)	Certification of Principal Financial Officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement

(+) The certifications attached as Exhibit 32.1 and 32.2 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

ITEM 16. FORM 10-K SUMMARY

None.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Semler Scientific, Inc.
San Jose, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Semler Scientific, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of income, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated March 9, 2020 expressed an adverse opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

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

/s/ BDO USA, LLP

We have served as the Company's auditor since 2013
New York, NY
March 9, 2020

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Semler Scientific, Inc.
San Jose, California

Opinion on Internal Control over Financial Reporting

We have audited Semler Scientific, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We do not express an opinion or any other form of assurance on management's statements referring to any corrective actions taken by the Company after the date of management's assessment.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the balance sheets of the Company as of December 31, 2019 and 2018, the related statements of operations, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as "the financial statements") and our report dated March 9, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses regarding management's failure to design and maintain controls are identified and described in management's assessment. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the December 31, 2019 financial statements, and this report does not affect our report dated March 9, 2020 on those financial statements.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit

preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ BDO USA, LLP

New York, NY
March 9, 2020

Semler Scientific, Inc.

Balance Sheets

(In thousands of U.S. Dollars, except share and per share data)

	As of December 31	
	2019	**2018**
Assets		
Current Assets:		
Cash	$ 7,741	$ 3,284
Trade accounts receivable, net of allowance for doubtful accounts of $36 and $52 respectively	3,486	2,801
Prepaid expenses and other current assets	216	153
Total current assets	11,443	6,238
Assets for lease, net	2,079	1,243
Property and equipment, net	249	223
Long-term deposits	15	15
Long-term deferred tax assets	4,501	—
Total assets	$18,287	$ 7,719
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 338	$ 280
Accrued expenses	3,914	2,797
Deferred revenue	955	435
Total current liabilities	5,207	3,512
Long-term liabilities:		
Other long-term liabilities	7	11
Total long-term liabilities	7	11
Stockholders' equity:		
Common stock, $0.001 par value; 50,000,000 shares authorized; 6,556,221, and 6,349,985 shares issued, and 6,531,221 and 6,324,985 shares outstanding (treasury shares of 25,000 and 25,000, respectively)	7	6
Additional paid-in capital	19,400	25,608
Accumulated deficit	(6,334)	(21,418)
Total stockholders' equity	13,073	4,196
Total liabilities and stockholders' equity	$18,287	$ 7,719

(See accompanying notes to financial statements)

Semler Scientific, Inc.

Statements of Income

(In thousands of U.S. Dollars, except share and per share data)

	For the years ended December 31	
	2019	2018
Revenues	$ 32,767	$ 21,491
Operating expenses:		
Cost of revenues	3,661	2,703
Engineering and product development	2,479	2,085
Sales and marketing	8,965	7,202
General and administrative	6,954	4,159
Total operating expenses	22,059	16,149
Income from operations	10,708	5,342
Interest income (expense)	2	(59)
Related party interest expense	—	(239)
Other expense	(9)	(4)
Other expense	(7)	(302)
Pre-tax net income	10,701	5,040
Income tax (benefit) provision	(4,383)	26
Net income	$ 15,084	$ 5,014
Net income per share, basic	$ 2.34	$ 0.82
Weighted average number of shares used in computing basic income per share	6,440,724	6,079,326
Net income per share, diluted	$ 1.88	$ 0.66
Weighted average number of shares used in computing diluted income per share	8,029,909	7,629,523

(See accompanying notes to financial statements)

Semler Scientific, Inc.

Statements of Stockholders' Equity

(In thousands of U.S. Dollars, except share and per share data)

	Common Stock		Treasury Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholder's Equity/(Deficit)
	Shares Issued	Common Stock Amount	Shares	Amount			
Balance at December 31, 2017	5,902,244	$ 6	(25,000)	$ —	$ 23,843	$(26,432)	$ (2,583)
Issuance of shares to settle related party loan	12,943	—	—	—	294	—	294
Warrant exercises	212,517	—	—	—	414	—	414
Stock option exercises	222,281	—	—	—	456	—	456
Stock-based compensation	—	—	—	—	601	—	601
Net income	—	—	—	—	—	5,014	5,014
Balance at December 31, 2018	6,349,985	$ 6	(25,000)	$ —	$ 25,608	$(21,418)	$ 4,196
Warrant repurchases	—	—	—	—	(6,633)	—	(6,633)
Warrant exercises	36,197	—	—	—	—	—	—
Stock option exercises	170,039	1	—	—	60	—	61
Stock-based compensation	—	—	—	—	365	—	365
Net income	—	—	—	—	—	15,084	15,084
Balance at December 31, 2019	6,556,221	$ 7	(25,000)	$ —	$ 19,400	$ (6,334)	$13,073

(See accompanying notes to financial statements)

Semler Scientific, Inc.

Statements of Cash Flows
(In thousands of U.S. Dollars)

	For the years ended December 31	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$15,084	$ 5,014
Reconciliation of Net Income to Net Cash Provided by Operating Activities:		
Amortization of debt discount	—	22
Accretion of non-cash interest	—	231
Depreciation	632	503
Deferred tax benefit	(4,501)	—
Loss on disposal of assets for lease	206	200
Allowance for doubtful accounts	48	46
Stock-based compensation expense	365	601
Changes in Operating Assets and Liabilities:		
Trade accounts receivable	(734)	(1,503)
Prepaid expenses and other current assets	(63)	(42)
Accounts payable	58	(208)
Accrued expenses	1,113	(71)
Deferred revenue	520	(96)
Net Cash Provided by Operating Activities	12,728	4,697
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(174)	(138)
Proceeds from sale of property and equipment	—	1
Purchase of assets for lease	(1,524)	(706)
Net Cash Used in Investing Activities	(1,698)	(843)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Repurchase of warrants	(6,633)	—
Proceeds from exercise of warrants	—	414
Proceeds from exercise of stock options	60	456
Payments of loans payable	—	(2,897)
Net Cash Used in Financing Activities	(6,573)	(2,027)
INCREASE IN CASH	4,457	1,827
CASH, BEGINNING OF PERIOD	3,284	1,457
CASH, END OF PERIOD	$ 7,741	$ 3,284
Cash paid for interest	$ —	$ 575
Cash paid for taxes	$ 123	$ 18
Supplemental disclosure of noncash financing activity:		
Issuance of shares to settle related party loan	$ —	$ 294

(See accompanying notes to financial statements)

Semler Scientific, Inc.

Notes to Financial Statements
(In thousands of U.S. Dollars, except share and per share data)

1. The Company

Semler Scientific, Inc. (the "Company") was incorporated in the State of Oregon on August 9, 2007, established C-corporation status in 2012, and reincorporated as a Delaware corporation during 2013. The Company is a company providing technology solutions to improve the clinical effectiveness and efficiency of healthcare providers. In 2011, the Company began commercializing its first patented and U.S. Food and Drug Administration ("FDA") cleared product, which measured arterial blood flow in the extremities to aid in the diagnosis of peripheral arterial disease ("PAD"). In March 2015, the Company received FDA 510(k) clearance for the next generation version of its product, QuantaFlo®, which the Company commercially launched in August 2015. The Company has one operating segment and generates revenues domestically primarily through direct licensing to direct customers. The Company is based in San Jose, California.

2. Summary of Significant Accounting Policies and Estimates

Basis for Presentation

The Company's financial statements and accompanying notes are prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of the accompanying financial statements in conformity with U.S. GAAP requires management to make certain estimates and assumptions that affect the amounts of assets and liabilities reported, disclosures about contingent assets and liabilities at the date of the financial statements, and reported amounts of revenues and expenses, and related disclosures during the reporting period. Significant items subject to such estimates include revenue recognition, allowance for doubtful accounts, valuation of equipment on lease, deferred tax asset valuation allowance, stock-based compensation and valuation of warrants. These estimates and assumptions are based on management's best estimates and judgment. Management regularly evaluates its estimates and assumptions using historical experience and other factors; however, actual results could differ significantly from these estimates.

Revenue Recognition

The Company generates revenues primarily from the rental or license of its vascular testing product, or providing diagnostic testing service to its customers. The Company recognizes revenues from the licensing of its vascular testing product pursuant to agreements that automatically renew each month with revenue recognized on a daily convention basis. The Company's arrangements with customers for its vascular testing product are normally on a month-to-month basis with fees billed at the rates established in the customer agreement. The Company recognizes revenues for providing diagnostic testing services on a per test basis to customers, as earned. The Company also recognizes revenue for hardware and supplies sales as of the date of shipment.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are recorded at the invoiced amount, net of allowances for doubtful accounts. The allowance for doubtful accounts is based on management's assessment of the collectability of accounts. The Company regularly reviews the adequacy of this allowance for doubtful accounts by considering historical experience, the age of the accounts receivable balances, the credit quality of the customers, current economic conditions, and other factors that may affect customers' ability to pay to determine whether a specific allowance is appropriate. Accounts receivable deemed uncollectable are charged against the allowance for doubtful accounts when identified.

(In thousands of U.S. Dollars, except share and per share data)

Assets for Lease

Assets for lease are recorded at cost. At December 31, 2019 and 2018, assets for lease consisted of vascular testing devices, which are leased to customers. The cost of such assets for lease is depreciated on a straight-line basis over 36 months for the units outstanding and recorded as cost of revenues.

The Company regularly reviews whether facts and circumstances exist which indicate that the carrying amounts of assets, may not be recoverable or that the useful life of assets are shorter or longer than originally estimated. The Company assesses the recoverability of its assets by comparing the projected undiscounted net cash flows associated with the related assets over their estimated remaining lives against their respective carrying amounts. The Company considers factors such as estimated usage and expected lives of its assets for lease in this analysis. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets. At December 31, 2019 and 2018, there were no impairment indicators.

Property and Equipment

Capital assets are recorded at cost. The cost of such capital assets is depreciated on a straight-line basis over a term depending on the assigned category (described below) and recorded as depreciation for capital assets recorded in engineering and product development, sales and marketing and general and administrative expenses.

At December 31, 2019 and 2018, capital assets are classified into one of the following categories:

Category Name	Description
Machinery & Equipment	Manufacturing, R&D, or other non-office equipment
Computer Equipment & Software	Software, computers, monitors, printers and other related equipment.
Furniture & Fixtures	Office equipment and furniture owned by the company

At December 31, 2019 and 2018, capital assets are depreciated based on the following estimated useful life for each category:

Account Name	Useful Life
Machinery & Equipment	Five years
Computer Equipment & Software	Three years
Furniture & Fixtures	Five years

The Company regularly reviews whether facts and circumstances exist which indicate that the carrying amounts of capital assets, may not be recoverable or that the useful life of assets are shorter or longer than originally estimated. The Company assesses the recoverability of its assets by comparing the projected fair value of the related asset over the estimated remaining life against the respective carrying amounts. The Company considers factors such as estimated usage and expected lives of its capital assets in this analysis. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets. The Company did not have any impairments to record during either the years ended December 31, 2019 or 2018.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three

levels of the fair value hierarchy under Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 820, Fair Value Measurement, are described as follows:

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

Level 2 — Inputs other than quoted prices included in Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data; and

Level 3 — Unobservable inputs that are supported by little or no market activity, which requires the Company to develop its own models.

The financial instruments of the Company consist primarily of cash, accounts receivable, and accounts payable. These items are considered Level 1 due to their short term nature and their market interest rates and are therefore considered a reasonable estimate of fair value at December 31, 2019 and 2018.

Deferred Revenue

Deferred revenue represents amounts billed to or collected from customers for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The full amount is expected to be recognized as revenues within one year from the balance sheet date and, therefore, such deferred amounts have been classified as current liabilities in the balance sheets presented. The Company generally invoices its clients in advance of a rental period with payment due upon receipt of the invoice.

Research and Development

The Company expenses costs related to the research and development associated with the design, development, testing and enhancement of its products and services. Such expenses include salaries and related employee benefits, and fees paid to external service providers.

Stock-Based Compensation

Stock-based compensation expense is measured based on the grant-date fair value of the stock-based awards. The Company recognizes stock-based compensation expense for the portion of each option grant or stock award that is expected to vest over the estimated period of service and vesting. The Company uses the Black-Scholes option pricing model as the method for determining the estimated grant-date fair value of stock options. The Black-Scholes option pricing model requires the use of subjective assumptions which determine the fair value of stock-based awards, including the option's expected volatility. Stock-based compensation expense is recognized on a straight-line basis over the requisite service period of the grant.

Employee Benefit Plan

The Company has a savings plan that qualifies under Section 401(k) of the Internal Revenue Code of 1986, as amended (the "Code"). There were no matching or discretionary employer contributions made to this plan during the years ended December 31, 2019 and 2018.

Income Taxes

The Company uses the asset and liability method to account for income taxes. Deferred tax assets and liabilities are recognized for the expected tax consequences attributable to the differences between financial reporting and the tax bases of existing assets and liabilities and net operating loss ("NOL") carry forwards, and they are measured using enacted tax rates expected to be in effect when differences are expected to reverse. The U.S. Tax Cuts & Jobs Act of 2017 reduced the U.S. corporate income tax rate to 21%, effective January 1, 2018. In addition, NOLs generated after December 31, 2017 are carried forward indefinitely

with yearly NOL utilization limited to 80% of taxable income. A valuation allowance is recorded for loss carry-forwards and other deferred tax assets where it is more likely than not that such loss carry-forward and deferred tax assets will not be realized. The estimate for the valuation allowance for deferred tax assets requires management to make significant estimates and judgments about projected future operating results. If actual results differ from these projections or if management's expectations of future results change, it may be necessary to adjust the valuation allowance

Recently Issued Accounting Pronouncements

Accounting Pronouncements Recently Adopted

In May 2014, the FASB issued Accounting Standard Update ("ASU") No. 2014-09, Revenue from Contracts with Customers ("ASU No. 2014-09"). The amendment in this ASU provides guidance on the revenue recognition to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The core principle of this update provides guidance to identify the performance obligations under the contract(s) with a customer and how to allocate the transaction price to the performance obligations in the contract. It further provides guidance to recognize revenue when (or as) the entity satisfies a performance obligation. This standard replaced most existing revenue recognition guidance. On August 8, 2015, the FASB issued ASU 2015-14, which deferred the effective date of ASU No. 2014-09 by one year, and permits early adoption as long as the adoption date is not before the original public entity effective date. Since the issuance of ASU 2014-09, the FASB has issued several amendments that clarify certain points, including ASU 2016-08, Principal versus Agent Considerations (Reporting Revenue Gross versus Net), ASU 2016-10, Revenue from Contracts with Customers (Topic 606), Identifying Performance Obligations and Licensing ("Topic 606"), ASU 2016-11, Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 Emerging Issues Task Force Meeting, and ASU 2016-12, Narrow-Scope Improvements and Practical Expedients, and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606. The updated revenue standard allows two methods of adoption: (1) retrospectively to each prior period presented ("full retrospective method"), or (2) retrospectively with the cumulative effect recognized in retained earnings as of the date of adoption ("modified retrospective method"). The new standard further requires new disclosures about contracts with customers, including the significant judgments the company has made when applying the guidance. The Company adopted the new standard effective January 1, 2019, using the modified retrospective method. The Company determined that the adoption of this new standard did not have a material impact on its financial statements.

Topic 606 affects revenue recognition for the Company's variably-priced (i.e., fee per test) license fee contracts and sales of hardware equipment and accessories. Total variably-priced license fees represent approximately $8,927 and $4,759 of revenues for the years ended December 31, 2019 and 2018, respectively. Total sales of hardware and equipment accessories represents approximately $927 and $386 of revenues for the years ended December 31, 2019 and 2018, respectively. Essentially all of the variably-priced license fee contracts are with large healthcare organizations. The initial contract is for a specified time period with automatic renewal each period thereafter until canceled. In case there is a violation of any term of the contract, the Company may deactivate the service remotely, so that the customer cannot continue to use the product. The reusable hardware equipment or accessories may be provided to a customer for a set price and then use of the associated software is billed to the customer monthly based on volume of use. Under this scenario, revenue is recognized when and only when the customer uses the product. The sale of the equipment or accessories is recognized as hardware sales upon shipment to the customer. It was determined that the impact of the new standard has no effect on the way revenue is currently being recognized. The remainder of the revenue is earned from leasing the Company's testing product for a fixed monthly fee, which is not subject to Topic 606.

In February 2016, the FASB issued ASU No. 2016-02, Leases. This standard, along with other guidance subsequently issued by the FASB (collectively, "ASC 842"), requires lessees to recognize lease assets and liabilities for all leases with lease terms of more than 12 months. The standard makes similar changes to lessor accounting and aligns key aspects of the lessor accounting model with the revenue recognition standard. Presentation of leases within the statements of operations and statements of cash flows will primarily depend on its classification as a finance or operating lease. ASC 842 is effective for the Company in the first quarter of fiscal 2020 with early adoption permitted. The Company adopted ASC 842 on January 1, 2019 using the modified retrospective transition method. Therefore, upon adoption, the Company recognized and measured leases without revising comparative period information or disclosures. The adoption of this standard did not have an impact on the Company's revenue recognition. In addition, the Company has elected to apply the package of practical expedients permitted under the transition guidance within ASC 842 which does not require reassessment of initial direct costs, classification of a lease and definition of a lease which resulted in the Company foregoing a reassessment of (1) whether any expired or existing contracts are or contain leases; (2) the lease classification for any expired or existing leases; and (3) the initial direct costs for an existing lease. See Note 7 for additional information and details of the effects of adopting the new standard.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("Topic 326"). This ASU requires timelier recording of credit losses on loans and other financial instruments held. Instead of reserves based on a current probability analysis, Topic 326 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. All organizations will now use forward-looking information to better inform their credit loss estimates. Topic 326 requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization's portfolio. These disclosures include qualitative and quantitative requirements that provide information about the amounts recorded in the financial statements. In addition, Topic 326 amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. In April 2019, the FASB issued ASU2019-04 Codification Improvements to Topic 326, Financial Instruments — Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments to introduce amendments which will affect the recognition and measurement of financial instruments, including derivatives and hedging. In May 2019, the FASB issued ASU 2019-05, Financial Instruments — Credit Losses (Topic 326); Targeted Transition Relief. The amendments in this ASU provide entities that have certain instruments within the scope of Subtopic 326-20 with an option to irrevocably elect the fair value option in Subtopic 825-10, applied on an instrument-by-instrument basis for eligible instruments upon adoption of Topic 326. This standard and related amendments are effective for the Company's fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of fiscal year 2023. The Company does not anticipate this new standard will have a material impact on its financial statements.

In June 2018, the FASB issued ASU No. 2018-07, Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). This ASU expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of costs. The ASU specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. This standard is effective for the Company's annual periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of fiscal year 2020. The Company does not anticipate this new standard will have a material impact on its financial statements.

(In thousands of U.S. Dollars, except share and per share data)

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement. The amendments in this ASU modify the disclosure requirements on fair value measurements removing the requirements to disclosure amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. In addition, it modified certain disclosures related to Level 3 fair value measurements and added additional disclosures regarding the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period. This update is effective for the Company's annual periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of fiscal year 2020. The Company does not anticipate this new standard to have a material impact on its financial statements.

In November 2019, the FASB issued ASU 2019-08 — Compensation — Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606). The amendments on this update require that an entity measure and classify share-based payment awards granted to a customer by applying the guidance in Topic 718. The amount recorded as a reduction in the transaction price should be based on the grant-date fair value of the share-based payment award. This standard is effective for the Company's annual periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of fiscal year 2020. The Company does not anticipate this new standard will have a material impact on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles for income taxes. This update is effective for the Company's annual periods beginning after December 15, 2020, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of fiscal year 2021. The Company does not anticipate this update to have a material impact on its financial statements.

3. Assets for Lease, net

The Company provides financing of certain equipment through operating leases (see Note 7). Assets for lease consist of the following:

	As of December 31,	
	2019	2018
Assets for lease	$ 3,374	$2,218
Less: accumulated depreciation	(1,295)	(975)
Assets for lease, net	$ 2,079	$1,243

Depreciation expense amounted to $483 and $395 for the years ended December 31, 2019 and 2018, respectively. Reduction to accumulated depreciation for returned items was $163 and $120 for the years ended December 31, 2019 and December 31, 2018, respectively. The Company recognized a loss on disposal of assets for lease in the amount of $206 and $200 for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019 and 2018, total assets for lease, net, in use at customer locations were $849 and $640, respectively.

(In thousands of U.S. Dollars, except share and per share data)

4. Property and Equipment, net

Capital assets consist of the following:

	As of December 31,	
	2019	2018
Capital assets	$ 636	$ 457
Less: accumulated depreciation	(387)	(234)
Capital assets, net	$ 249	$ 223

Depreciation expense amounted to $149 and $108 for the years ended December 31, 2019 and 2018, respectively.

5. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2019	2018
Compensation	$2,803	$2,442
Accrued Taxes	66	81
Miscellaneous Accruals	1,045	354
Total Accrued Expenses	$3,914	$2,797

6. Concentration of Credit Risk

Credit risk is the risk of loss from amounts owed by the financial counterparties. Credit risk can occur at multiple levels; as a result of broad economic conditions, challenges within specific sectors of the economy, or from issues affecting individual companies. Financial instruments that potentially subject the Company to credit risk consist of cash and accounts receivable.

The Company maintains cash with major financial institutions. The Company's cash consists of bank deposits held with banks that, at times, exceed federally insured limits. The Company limits its credit risk by dealing with counterparties that are considered to be of high credit quality and by performing periodic evaluations of the relative credit standing of these financial institutions.

Management periodically monitors the creditworthiness of its customers and believes that it has adequately provided for any exposure to potential credit loss. For the year ended December 31, 2018, two customers accounted for 52.0% and 19.5% of the Company's revenue. For the year ended December 31, 2019, three customers accounted for 49.4%, 13.2% and 12.5% of the Company's revenue. As of December 31, 2018, two customers accounted for 43.5% and 40.4% of the Company's accounts receivable, respectively. As of December 31, 2019, three customers accounted for 55.9%, 17.6% and 12.0% of the Company's accounts receivable, respectively.

As of December 31, 2019 and 2018 the allowance for doubtful accounts was $36 and $52, respectively.

As of December 31, 2018, two vendors accounted for 11.0% and 10.8% of the Company's accounts payable, respectively. As of December 31, 2019, two vendors accounted for 15.9% and 14.1% of the Company's accounts payable, respectively.

7. Leases

Lessee Arrangements

The Company leases facilities under a long term lease arrangement that has been determined to be an operating lease under new lease accounting standard that would require the Company to reflect a right of

use ("ROU") lease asset and lease liabilities associated with this lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of the lease payments over the lease term. As of December 31, 2019, the remaining lease term is one year and two months with no options to renew. Upon adoption of ASC 2016-02, in accordance with the elected practical expedient transition rules, the ROU asset and liability related to this lease was immaterial. The Company recognized facilities lease expenses of $68 and $69 for the years ended December 31, 2019 and 2018, respectively. Future minimum rent expense for 2020 and 2021 is $64 and $11, respectively.

Lessor Arrangements

The Company enters into contracts with customers for the Company's QuantaFlo® product. The Company has determined these contracts meet the definition of a lease under Topic 842. The lease portfolio primarily consists of operating leases that are short-term in nature (monthly, quarterly or one year, all of which have renewal options). The Company allocates the consideration in a bundled contract with its customers based on relative standalone selling prices of the lease and non-lease components. The Company made an accounting policy election to apply the practical expedient to not separate lease and eligible non-lease components. The lease component is the predominant component and consists of fees charged for use of the equipment over the period of the arrangement. The nature of the eligible non-lease component is primarily software support. The assets associated with these leasing arrangements are separately identified in the Balance Sheet as Assets for Lease and separately disclosed in Note 3. During the year ended December 31, 2019, the Company recognized approximately $22,858 in lease revenue related to these arrangements, which is included in revenue on the Statements of Income.

8. Commitments and Contingencies

Indemnification Obligations

The Company enters into agreements with customers, partners, lenders, consultants, lessors, contractors, sales representatives and parties to certain transactions in the ordinary course of the Company's business. These agreements may require the Company to indemnify the other party against third party claims alleging that its product infringes a patent or copyright. Certain of these agreements require the Company to indemnify the other party against losses arising from: a breach of representations or covenants, claims relating to property damage, personal injury or acts or omissions of the Company, its employees, agents or representatives. The Company has also agreed to indemnify the directors and certain of the officers and employees in accordance with the by-laws of the Company. These indemnification provisions will vary based upon the nature and terms of the agreements. In many cases, these indemnification provisions do not contain limits on the Company's liability, and the occurrence of contingent events that will trigger payment under these indemnities is difficult to predict. As a result, the Company cannot estimate its potential liability under these indemnities. The Company believes that the likelihood of conditions arising that would trigger these indemnities is remote and, historically, the Company had not made any significant payment under such indemnification provisions. Accordingly, the Company has not recorded any liabilities relating to these agreements. In certain cases, the Company has recourse against third parties with respect to the aforesaid indemnities, and the Company believes it maintains adequate levels of insurance coverage to protect the Company with respect to potential claims arising from such agreements.

9. Stockholders' Equity

The Company has 50,000,000 authorized shares of capital stock, all of which are designated as common stock with par value of $0.001 per share.

Each holder of shares of common stock is entitled to one vote for each share held.

(In thousands of U.S. Dollars, except share and per share data)

For the years ended December 31, 2019 and 2018, a total of 1,658,457 and 2,037,661 shares of common stock, respectively, were reserved for issuance upon (i) exercise of common stock warrants, and (ii) the exercise of outstanding stock options, as follows:

	Year ended December 31,	
	2019	2018
Common stock warrants	76,875	276,214
Stock options	1,581,582	1,761,447
Total	1,658,457	2,037,661

10. Warrant Repurchases — Related Party

On May 3, 2019, the Company entered into a warrant purchase agreement (the "May Repurchase Agreement"), with the Murphy-Chutorian Family Trust U/D/T dated January 13, 1997 (the "Murphy-Chutorian Family Trust"), of which Dr. Murphy-Chutorian, the Company's director and chief executive officer is co-Trustee with his spouse and of which he is a beneficiary. Pursuant to the May Repurchase Agreement, the Company repurchased a warrant to acquire 65,542 shares of its common stock (the "May Repurchase Warrant"), held by the Murphy-Chutorian Family Trust, which warrant had an exercise price equal to $4.50 per share and an expiration date of July 31, 2023, at an aggregate purchase price of $2,687. The purchase price reflects the difference between the aggregate exercise price of the May Repurchase Warrant and the aggregate fair market value of the shares underlying the May Repurchase Warrant, based on the last trade price of the Company's common stock on May 3, 2019, the date of the May Repurchase Agreement. Following this repurchase, the May Repurchased Warrant was cancelled and is no longer issued and outstanding.

On November 6, 2019, the Company entered into a warrant purchase agreement (the "November Repurchase Agreement"), with the Murphy-Chutorian Family Trust. Pursuant to the November Repurchase Agreement, the Company repurchased warrants to acquire an aggregate of 93,797 shares of its common stock (collectively, the "November Repurchase Warrants"), held by the Murphy-Chutorian Family Trust, which warrants had exercise prices ranging from $2.00 to $4.50 per share and an expiration date of July 31, 2023, at an aggregate purchase price of $3,946. The purchase price reflects the difference between the aggregate exercise price of the November Repurchase Warrants and the aggregate fair market value of the shares underlying the November Repurchase Warrants, based on the last trade price of the Company's common stock on November 6, 2019, the date of the November Repurchase Agreement. Following this repurchase, the November Repurchased Warrants were cancelled and are no longer issued and outstanding.

Following these repurchases, the Murphy-Chutorian Family Trust holds warrants to acquire 16,875 shares of the Company's common stock at an exercise price of $4.00 per share, and 60,000 shares of the Company's common stock at an exercise price of $4.50 per share, all of which are exercisable and expire July 31, 2023.

11. Stock Option Plan

The Company's stock-based compensation program is designed to attract and retain employees while also aligning employees' interests with the interests of its stockholders. Stock options have been granted to employees under the stockholder-approved 2007 Key Person Stock Option Plan ("2007 Plan") or the stockholder-approved 2014 Stock Incentive Plan ("2014 Plan"). Stockholder approval of the 2014 Plan became effective in September 2014. The 2014 Plan originally provided that the aggregate number of shares of common stock that may be issued pursuant to awards granted under the 2014 Plan may not exceed 450,000 shares (the "Share Reserve"), however in October 2015, the stockholders approved a 1,500,000 increase to the Share Reserve. In addition, the Share Reserve automatically increases on January 1st of each year, for a period of not more than 10 years, beginning on January 1st of the year following the year in

which the 2014 Plan became effective and ending on (and including) January 1, 2024, in an amount equal to 4% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. The Company's board of directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of common stock than would otherwise occur. The Share Reserve is currently 2,783,616 shares for the year ending December 31, 2019.

In light of stockholder approval of the 2014 Plan, the Company no longer grants equity awards under the 2007 Plan. As of December 31, 2019, there were no shares available for future stock-based compensation grants under the 2007 Plan and 997,163 shares of an aggregate total of 2,783,616 shares available for future stock-based compensation grants under the 2014 Plan.

Aggregate intrinsic value represents the difference between the closing market value as of December 31, 2019 of the underlying common stock and the exercise price of outstanding, in-the-money options. A summary of the Company's stock option activity and related information for 2019 and 2018 is as follows:

	Options Outstanding			
	Number of Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (In Thousands)
Balance, December 31, 2017	**1,855,138**	**$2.69**	**7.48**	**$ 9,850**
Options granted	135,000	8.00		
Options exercised	(222,281)	2.05		
Options forfeited/cancelled	(6,410)	3.44		
Balance, December 31, 2018	**1,761,447**	**$3.18**	**6.84**	**$55,000**
Options exercised	(179,865)	2.72		
Balance, December 31, 2019	**1,581,582**	**$3.23**	**5.86**	**$70,827**
Exercisable as of December 31, 2018	**1,481,591**	**$2.83**	**6.57**	**$46,780**
Exercisable as of December 31, 2019	**1,477,020**	**$3.06**	**5.73**	**$66,389**

The total compensation cost related to unvested stock option awards not yet recognized was $435 as of December 31, 2019. The weighted average period over which the total unrecognized compensation cost related to these unvested stock awards will be recognized is 1.03 years. The total number of unvested shares was 104,563 and 279,856 as of December 31, 2019 and 2018, respectively. The total estimated grant date fair value of unvested options was $435 and $1,038 as of December 31, 2019 and 2018, respectively. The total estimated grant date fair value of options vested during the years ended December 31, 2019 and 2018 was $365 and $601, respectively. There were no options granted or forfeited during the year ended December 31, 2019. The weighted average grant date fair value of options granted during the year ended December 31, 2018 is $5.97 per share or an aggregate grant date fair value of $806. The weighted average grant date fair value of options forfeited during the year ended December 31, 2018 was $1.42.

On January 2, 2018 the Compensation Committee of the Company's Board of Directors granted, and the full Board ratified, an option to acquire an aggregate of 125,000 shares under the 2014 Plan to the Company's CEO. This option vests 25% on the one-year anniversary of the grant date and monthly thereafter for 36 months, such that the option is vested in full on the four-year anniversary of the grant date. On January 2, 2018 the Company's Compensation Committee granted, and the full Board ratified, options to each of the then-seated non-employee Directors to acquire 5,000 shares, for an aggregate of 10,000 shares, under the 2014 Plan. These options vest on the one-year anniversary of their grant date. On February 28, 2018 the Compensation Committee of the Company's Board of Directors accelerated the vesting on stock

(In thousands of U.S. Dollars, except share and per share data)

options issued to consultants such that all unvested shares were vested on that date. This resulted in a one-time expense of $49 during year ended December 31, 2018.

Determining the Fair Value of Stock Options

The fair value of the options granted is estimated on the date of grant using the Black-Scholes pricing model and the following assumptions for the periods presented:

	Year ended December 31, 2018
Expected term (in years)	5
Risk-free interest rate	2.2%
Expected volatility	99.0%
Expected dividend rate	0%

The assumptions are based on the following for each of the years presented:

Valuation Method — The Company estimates the fair value of its stock options using the Black-Scholes option pricing model.

Expected Term — The Company estimates the expected term consistent with the simplified method identified by the Securities and Exchange Commission ("SEC"). The Company elected to use the simplified method because of its limited history of stock option exercise activity and its stock options meet the criteria of the "plain-vanilla" options as defined by the SEC. The simplified method calculates the expected term as the average of the vesting and contractual terms of the award.

Volatility — The Company derives this number from the historical stock volatilities of the Company's stock over a period approximately equal to the expected term of the options.

Risk-free Interest Rate — The risk-free interest rate is based on median U.S. Treasury zero coupon issues with remaining terms similar to the expected term on the options.

Expected Dividend — The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.

The Company has recorded an expense of $365 and $601 as it relates to stock-based compensation for the years ended December 31, 2019 and 2018, respectively, which was allocated as follows based on the role and responsibility of the recipient in the Company:

	Year ended December 31,	
	2019	2018
Cost of Revenues	$ 1	$ 2
Engineering and Product Development	16	36
Sales and Marketing	46	92
General and Administrative	302	471
Total	$365	$601

(In thousands of U.S. Dollars, except share and per share data)

12. Income Taxes

The components of the (benefit) provision for income taxes are as follows:

	2019	2018
Current tax provision:		
Federal	$ —	$—
State	118	26
Subtotal current tax expense	118	26
Deferred tax provision:		
Federal	(3,645)	—
State	(856)	—
Subtotal deferred tax (benefit)	(4,501)	—
Total income tax (benefit) expense	$(4,383)	$26

A summary of the differences between the Company's effective income tax rate and the federal statutory income tax rate for the years ended December 31, 2019 and 2018 are as follows:

	2019	2018
Federal statutory rate	21.00%	21.00%
State income tax rate, net of federal benefit	1.83%	0.95%
Change in valuation allowance	(49.89)%	(2.28)%
Stock-based compensation	(13.12)%	(13.61)%
Permanent Items	0.40%	0.42%
Other	(1.18)%	(5.97)%
Effective income tax rate	(40.96)%	0.51%

Deferred tax assets are comprised of the following at December 31:

	2019	2018
Net operating loss carryforwards	2,646	3,864
Deferred revenue	233	106
Depreciation and amortization	14	45
Stock based compensation	751	670
Accrual and reserves	145	119
Research and development credits, net of tax reserve	711	533
Other	1	—
Total gross deferred tax assets	4,501	5,337
Less valuation allowance	—	(5,337)
Net deferred tax assets	**$4,501**	**$ —**

The net change in the valuation allowance for December 31, 2019 was ($5,337). In assessing the realizability of deferred tax assets, management determined there was sufficient positive evidence that it was more likely than not that the federal and state NOL carryforwards and other related deferred tax assets would be realized and therefore, released the valuation allowance against the deferred tax assets.

Federal and California tax laws impost significant restrictions on the utilization of NOL carryforwards in the event of a change in ownership of the Company, as defined by Internal Revenue Code Section 382 ("Section 382"). The Company has completed a formal Section 382 study for the period January 1, 2012

(In thousands of U.S. Dollars, except share and per share data)

through June 30, 2019 and believed a change in ownership has occurred. The Company has NOL carryforwards for federal and California income tax purposes of approximately $10,256 and $5,769, respectively, as of December 31, 2019. The federal NOL carryforwards, if not utilized, will expire beginning in 2033. The state NOL carryforwards, if not utilized, will expire beginning in 2032. Under The U.S. Tax Cuts & Jobs Act, passed into law in December 2017, effective January 1, 2018, NOLs generated after December 31, 2017 will be carried forward indefinitely with the yearly NOL utilization limited to 80% of taxable income. The Company has research and development ("R&D") tax credit carryforwards for federal income tax purposes of approximately $732 as of December 31, 2019. The federal R&D credit carryforward, if not utilized will expire beginning in 2032.

ASC Topic No. 740. requires companies to determine whether it is "more likely than not" that a tax position will be sustained upon examination by the appropriate taxing authorities before any tax benefit can be recorded in the financial statements. The following table summarizes the activity related to the Company's gross unrecognized tax benefits:

	Gross Unrecognized Tax Benefits 2019	Gross Unrecognized Tax Benefits 2018
Unrecognized tax benefits – January 1	$218	$ 29
Gross increases related to prior tax positions	—	126
Gross increases related to current tax positions	77	62
Unrecognized tax benefits – December 31	$295	$218

As of December 31, 2019, and 2018, the Company had $295 and $218, respectively, unrecognized tax benefits and no adjustments to liabilities or operations that were required for uncertain tax positions under ASC 740-10. The Company's practice is to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was zero for the years ended December 31, 2019 and 2018. The Company files income tax returns in the U.S. federal and several state tax jurisdictions.

The Company's tax years beginning in 2015 remain open for examination by the state tax authorities for four years. The Company's tax years beginning in 2016 remain open for examination by the federal tax authorities for three years. Tax years beginning in 2012 will remain open for examination from the date of utilization of any NOL or credits. The Company does not have any tax positions for which it is reasonably possible the total amount of gross unrecognized tax benefits will increase or decrease within 12 months of the year-ended December 31, 2019.

13. Net Income Per Share, Basic and Diluted

Basic earnings per share ("EPS") represent net income attributable to common shareholders divided by the weighted average number of common shares outstanding during the measurement period. Diluted EPS represents net income attributable to common shareholders divided by the weighted average number of common shares outstanding during the measurement period while also giving effect to all potentially dilutive common shares that were outstanding during the period using the treasury stock method. As of December 31, 2019, there are no warrants or options outstanding that are antidilutive.

Semler Scientific, Inc.

Notes to Financial Statements (continued)
(In thousands of U.S. Dollars, except share and per share data)

Basic and diluted net EPS is calculated as follows:

	For the year ended December 31,					
	2019			2018		
	Shares	Net Income	EPS	Shares	Net Income	EPS
Basic EPS	6,440,724	$15,084	$2.34	6,079,326	$5,014	$0.82
Common stock warrants	69,068	—		191,445	—	
Common stock options	1,520,117	—		1,358,752	—	
Diluted EPS	8,029,909	$15,084	$1.88	7,629,523	$5,014	$0.66

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.

Date: March 9, 2020

Semler Scientific, Inc.

By: /s/ Douglas Murphy-Chutorian, M.D.
Douglas Murphy-Chutorian, M.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Douglas Murphy-Chutorian and Andrew B. Weinstein, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Name	Title	Date
/s/ Douglas Murphy-Chutorian, M.D. Douglas Murphy-Chutorian, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2020
/s/ Andrew B. Weinstein Andrew B. Weinstein	Senior Vice President, Finance and Accounting (Principal Financial Officer)	March 9, 2020
/s/ Daniel E. Conger Daniel E. Conger	Vice President, Finance (Principal Accounting Officer)	March 9, 2020
/s/ Arthur N. Leibowitz, M.D., F.A.A.P. Arthur N. Leibowitz, M.D., F.A.A.P.	Director	March 9, 2020
/s/ Wayne T. Pan, M.D., Ph.D. Wayne T. Pan, M.D., Ph.D.	Director	March 9, 2020

Exhibit 4.2

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock is not complete and may not contain all the information you should consider before investing in our capital stock. This description is summarized from, and qualified in its entirety by reference to, our certificate of incorporation and bylaws, both of which have been publicly filed with the Securities and Exchange Commission.

General

Our authorized capital stock consists of 50,000,000 shares of common stock, $0.001 par value.

Holders of our common stock are entitled to one vote per share. Except as otherwise required by law, all stockholder action is taken by the vote of a majority of the outstanding shares of common stock present at a meeting of stockholders at which a quorum consisting of a majority of the outstanding shares of common stock is present in person or by proxy.

Holders of our common stock are entitled to receive ratably dividends when, as, and if declared by our board of directors out of funds legally available for that purpose and, upon our liquidation, dissolution or winding up, are entitled to share ratably in all assets remaining after payment of liabilities. However, the current policy of our board of directors is to retain earnings, if any, for the operation and expansion of our company. The holders of our common stock have no preemptive rights and have no rights to convert their common stock into any other securities. The outstanding common stock is validly authorized and issued, fully-paid and nonassessable. The common stock will not be subject to call or redemption.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our certificate of incorporation and our bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a “business combination” includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition involving the interested stockholder of assets of 10% or more of the aggregate market value of either all of the assets of the corporation or its outstanding stock;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Our Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or making a tender offer or delaying or preventing a change in control, including changes a stockholder might consider favorable. In particular, our certificate of incorporation and bylaws, as applicable, among other things:

- provide our board of directors with the ability to alter its bylaws without stockholder approval;
- provide that vacancies on our board of directors may be filled by a majority of directors in office, although less than a quorum;
- provide that a special meeting of the stockholders may be called only by our board of directors, the chairman of the board of directors or our chief executive officer; and
- establish advance notice procedures with respect to stockholder proposals and nomination of candidates for election to our board of directors.

Such provisions may have the effect of discouraging a third-party from acquiring our company, even if doing so would be beneficial to our stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by them, and to discourage some types of transactions that may involve an actual or threatened change in control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage some tactics that may be used in proxy fights. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company outweigh the disadvantages of discouraging such proposals because, among other things, negotiation of such proposals could result in an improvement of their terms.

Amendment of Charter Provisions

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Semler Scientific, Inc.
San Jose, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (No. 333-198275, No. 333-198891 and No. 333-207779) of Semler Scientific, Inc. of our report dated March 9, 2020, relating to the financial statements of Semler Scientific, Inc. (which report on the financial statements expresses an unqualified opinion), which appears in this Form 10-K. Our report on the effectiveness of internal control over financial reporting expresses an adverse opinion on the effectiveness of the Company's internal control over financial reporting as of December 31, 2019.

/s/ BDO USA, LLP

New York, New York
March 9, 2020

EXHIBIT 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Douglas Murphy-Chutorian, certify that:

1. I have reviewed this annual report on Form 10-K of Semler Scientific, Inc. (the "registrant");

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

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2020

/s/ Douglas Murphy-Chutorian, M.D.

Douglas Murphy-Chutorian, M.D.
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
UNDER
SECTION 302 OF THE SARBANES-OXLEY ACT

I, Andrew B. Weinstein, certify that:

1. I have reviewed this annual report on Form 10-K of Semler Scientific, Inc. (the "registrant");

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

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2020

/s/ Andrew B. Weinstein

Andrew B. Weinstein,
Senior Vice President, Finance and Accounting
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the annual report of Semler Scientific, Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Executive Officer of the Registrant, certifies, in accordance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Douglas Murphy-Chutorian, M.D.

Douglas Murphy-Chutorian, M.D.
Chief Executive Officer

Date: March 9, 2020

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-K or as a separate disclosure document for purposes of Section 18 of the Exchange Act, or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.1 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

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

In connection with the annual report of Semler Scientific, Inc. (the "Registrant") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Senior Vice President, Finance and Accounting of the Registrant, certifies, in accordance with 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

/s/ Andrew B. Weinstein

Andrew B. Weinstein
Senior Vice President, Finance and Accounting

Date: March 9, 2020

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-K or as a separate disclosure document for purposes of Section 18 of the Exchange Act, or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.2 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.