Semler Scientific, Inc.
Form 10-K
March 07, 2019
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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, 2018
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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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 $73,633,896.60 as of June 30, 2018, 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 March 5, 2019 was 6,324,985.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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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.

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PART I

ITEM 1. BUSINESS

General

We are an emerging growth 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, 2018, we had total revenues of $21,491,000 and net income of $5,014,000 compared to total revenues of $12,452,000 and a net loss of $1,510,000, in 2017.

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

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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, 2018, it accounted for 52.5% 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, Centers for Medicare and 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.

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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
- 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.

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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 8% of our revenues in each of 2017 and 2018. 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.

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Manufacturing

We manufacture our product, QuantaFlo™ 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. We believe QuantaFlo™ is relatively easy to manufacture. 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. We are not aware of another product that performs “digital ABI” without the use of 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. We know of no direct ‘digital ABI’ competitor to QuantaFlo™. 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.

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

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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.

Patents and Licenses

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

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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

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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.

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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.

Sales and Marketing Commercial Compliance

Federal anti-kickback laws and regulations prohibit, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for, or to induce either the referral of an individual, or the purchase, order or recommendation of, any good or service paid for under federal healthcare programs such as the Medicare and Medicaid programs. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions.

In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Off-label promotion has been pursued as a violation of the federal false claims laws. 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. Additionally, the majority of states in which we market our products have

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similar 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.

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.

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 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, also imposed new reporting and disclosure requirements on device manufacturers for any “transfer of value” made or distributed to prescribers and other healthcare providers, effective March 30, 2013. 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. 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.

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 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 for Medicare 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.

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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 reverse any non-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

Healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded healthcare programs. 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 sham 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 recently enacted Health Care Reform Law, among other things, amends 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 provides 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 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

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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. 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.

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.

Employees

As of December 31, 2018, we had 46 employees, all of which were full-time employees. These employees included three executive officers and 29 employees dedicated to sales and marketing of our product and services, three of which do direct sales and the remainder support sales functions. 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.

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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

We have incurred significant losses since inception and only recently became profitable. There is no assurance that additional financing will be available to us should we need it for any reason such as failing to generate sufficient cash from operations to support our business.

We only recently became profitable. Since inception, we have incurred significant operating losses in aggregate. Our net income was $5,014,000 for the year ended December 31, 2018 compared to a net loss of $1,510,000 for the year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of $21,418,000. To date, we have financed our operations primarily through the sale of our equity securities and, to a limited extent, bank financing and issuance of promissory notes. If we are not able to generate sufficient cash from operations, we may need to raise additional capital through other means. Such additional financing may not be available in the amount that we need or on terms favorable to us, if at all. There can be no assurance that we will be able to maintain profitability on an annual basis.

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, which we also incorporate into our wellness testing service; 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

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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

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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 at December 31, 2018. 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 8% of our revenues for each of the years ended December 31, 2018 and 2017. 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. Although we have a good relationship with our co-exclusive distributor and have no reason to believe that our current contract will not be renewed when it expires at the end of December 2019 or that our co-exclusive distributor will terminate our arrangement prior to expiration (which it is permitted to do upon 90 days' notice under our contract), we may need to seek out

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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 our accounts receivables are with a limited number of customers.

Two customers account for a significant portion of our revenues and our accounts receivable. For the year ended December 31, 2018, two customers accounted for 52.5% and 19.5% of our revenues, and as of December 31, 2018, two customers accounted for 43.5% and 40.4% of our accounts receivable, respectively. 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 our Chief Executive Officer, 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. In particular, we believe our success is highly dependent upon the services and reputation of our Chief Executive Officer, Dr. Douglas Murphy-Chutorian. We do not have key man insurance for Dr. Murphy-Chutorian. The loss of Dr. Murphy-Chutorian's services could still severely damage our business prospects, which could have a material adverse effect on our financial condition and results of operations.

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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. The loss or disruption of our relationships with outside vendors could subject us to substantial delays in the delivery of our product to customers. 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, we manufacture our vascular testing product 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

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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.

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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. 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, 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

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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;

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- 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.

Some of the provisions of the Health Care Reform Law have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law, as well as recent 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. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, 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 imposes 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. Generally, the lease of a taxable medical device by the manufacturer will be treated as a sale for purposes of the medical device excise tax, and the medical device excise tax will be imposed on the portion of the lease payment that relates to the use of the taxable medical device (subject to limitation in certain circumstances). This new and significant tax burden could have a negative impact on our results of our operations. Although this tax was suspended as of January 1, 2016 for a two-year period ending December 31, 2017, and further suspended through December 31, 2019, in accordance with a continuing resolution on appropriations for fiscal year 2018, signed by President Trump, the potential tax burden could still be significant for 2020 and beyond, if not repealed altogether. Further,

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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.

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 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, over the past ten years, partially as the result of the passage of the Health Insurance Portability and Accountability Act of 1996 and of the Health Care Reform Law, the government has pursued 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.

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The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation, known as the Tax Cuts and Jobs Act of 2017, that significantly revises the Internal Revenue Code of 1986, as amended, or the Code. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses, or NOLs, to 80% of current year taxable income and elimination of NOL carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Our ability to use NOLs to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had federal NOL carryforwards of $15.4 million. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, 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 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 an “emerging growth company” and may remain one through 2019 and are also a “smaller reporting company,” and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company through 2019 (for up to five years from our first sale of securities pursuant to an effective registration statement). We are also a “smaller reporting company.” For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;

-

reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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Many of the foregoing scaled disclosure requirements also apply to smaller reporting companies. 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. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to other companies that comply with public company effective dates.

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 an emerging growth company, and in particular if 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. Although we are currently both an emerging growth company and non-accelerated filer, and thus not yet required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm, our management and other personnel will nevertheless need to continue 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 a material weakness in our internal control over financial reporting. If we are not able to remedy this material weakness 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, 2018, our management identified a new material weakness in our internal control over financial reporting pertaining to employee stock options and payroll withholding taxes. Specifically, we determined that we did not have adequate procedures and controls to appropriately comply with, and account for, certain payroll tax withholdings and related expenses. These payroll tax withholdings and expenses resulted in an underpayment of federal and state tax withholdings in connection with the exercise of vested employee stock options. 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. As an emerging growth company and as a non-accelerated filer, our independent registered public accounting firm is not required to attest to our management’s evaluation of our internal control over financial reporting. Had our independent registered public accounting firm performed such an attestation of on our management’s evaluation of our internal control over financial reporting, additional control deficiencies may have been identified by management or our independent registered public accounting firm, and those control deficiencies could have also represented one or more material weaknesses.

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Although we implemented measures in 2017 and 2018 to remedy former material weaknesses, we are now in the process of implementing measures to address this recently identified material weakness. 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, 2018, 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.

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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.

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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 53.8% of our common stock as of December 31, 2018. 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.

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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;

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- 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.
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