Semler Scientific, Inc.
Form ARS
September 28, 2015
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ANNUAL REPORT

Providing Diagnostic and Testing Services to America’s Top Health Plans

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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, 2014
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.)

2330 NW Everett St.
Portland, Oregon 97210
(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:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	The NASDAQ Capital Market

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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, or a smaller reporting company.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company

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 $10,971,919 as of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter.
The number of shares of the registrant's common stock outstanding as of February 12, 2015 was 4,716,017.
DOCUMENTS INCORPORATED BY REFERENCE
Part III incorporates information by reference from the Proxy Statement relating to the 2015 Annual Meeting of Stockholders.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This annual report 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.

You should read this annual report 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 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, and particularly our forward-looking statements, by these cautionary statements.

This annual report 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 medical risk-assessment company. Our mission is to develop, manufacture and market patented products that assist healthcare providers in monitoring patients and evaluating chronic diseases. Our first patented and U.S. Food and Drug Administration, or FDA cleared product, is FloChec®. FloChec® is used in the office setting to allow providers to measure arterial blood flow in the extremities and is a useful tool for internists and primary care physicians for whom it was previously impractical to conduct blood flow measurements. FloChec® received FDA 510(k) clearance in February 2010, we began Beta testing in the third quarter of 2010, and we began commercially leasing FloChec® in January 2011. In the year ended December 31, 2014 we had total revenue of $3,635,000 and a net loss of $4,515,000 compared to total revenue of $2,274,000 and a net loss of $2,233,000, in 2013.

Our Product

We currently have only one patented and FDA-cleared product, FloChec®, that we market and license to our customers. FloChec® 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 FloChec®:

FloChec® 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 and displayed on the video monitor. 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 developed a license model rather than an outright sales model for FloChec®. Our license model pricing is based on data collected on use rates of FloChec® and third-party payment rates to physicians and facilities using our product. The pricing model eliminates the need to make a capital equipment sale. Consequently, we currently require no down payment, long-term commitment or maintenance contract or fees from our customers. We replace damaged products free of charge in the license model. FloChec® has an expected average lifetime of at least three years. We intend to reevaluate the monthly price periodically in consideration of the revenue generation associated with FloChec®. To date, we roughly estimate that routine office usage of FloChec® has ranged from a few tests per week up to 10 tests per day. We are currently pilot testing a model in which we invoice on a per test basis for use of FloChec®, and where we or our sub-contractor may perform other non-proprietary tests alongside FloChec®.

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Our Chairman and co-founder, Dr. Herbert Semler, is an inventor of the technology behind FloChec®. Dr. Semler formed Semler Scientific, Inc. in 2007 to further develop, patent and commercialize his idea. We applied for our patent protecting our proprietary technology in 2007 and U.S. Patent No. 7,628,760 was granted in 2009. FloChec® received FDA 510(k) clearance in February 2010, we began Beta testing in the third quarter of 2010, and we began commercially leasing FloChec® in January 2011. We have placed our FloChec® product with cardiologists, internists, nephrologists, endocrinologists, podiatrists and family practitioners and three insurance plans among the top 15 plans with the most Medicare Advantage members. Many of the 50 years or older patients under the care of these physicians have cardiovascular risk factors such as diabetes, cigarette smoking, high cholesterol or hypertension that lead to the development of peripheral arterial disease, or PAD.

Other 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 FloChec®, 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 FloChec®, imaging tests are much more expensive tests that are performed by specialists in special laboratories or offices.

Market Opportunity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, was signed in March 2010. This sweeping law is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. This legislation includes reforms and reductions that have affected Medicare reimbursements and health insurance coverage for certain services and treatments. The Health Care Reform Law has brought a new way of doing business for providers and health insurance plans. We believe that fee-for-service programs will be reduced in favor of capitated programs that pay a monthly fee per patient.

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, 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.

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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 precerebral 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 will induce higher payments per patient. These changes are already in place for the approximately 16 million participants in the Medicare Advantage program and are expected to expand to more types of insured patients as healthcare reform is deployed.

Undiagnosed vascular disease of the legs has been called a major under-diagnosed health problem in the United States by the National Institute of Health and the Wall Street Journal. We believe vascular disease in leg arteries is undiagnosed in 75% of cases, which is about 12 million Americans. Known as peripheral artery disease, or 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-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 18 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 SAGE Group, there are approximately 160,000 amputations due to PAD per year and, according to the National Limb Loss Information Center, an estimated 2 million Americans are amputees.

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 FloChec®, 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 Agency for Healthcare Research and Quality, there are over 200,000 internists, family practitioners and gerontologists 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

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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. In addition, the physical exam of the extremities is generally cursory in the absence of a patient complaint. Given the ease of use and speed of FloChec®, we believe that many doctors will incorporate its use in their practice as a routine annual test to measure blood flow in an extremity. It is our intent that FloChec® be incorporated as a tool in the routine physical exam of adult patients by primary care providers in a similar fashion to the use of a thermometer or stethoscope. Providers do not request payment for using a stethoscope during the physical examination. Similarly, we do not expect (or intend) for providers that use our FloChec® to seek such a reimbursement approval. FloChec® is not specifically approved under a third-party payor code and we do not track customer requests for reimbursements. Accordingly, our customers may or may not be successful in receiving reimbursement if sought.

Strategy

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

- Capitalizing on opportunities provided by capitated payment programs. For many capitated programs, payment is higher for sicker patients who have conditions that are codified. We believe a provider would prefer to have more remuneration for taking care of a patient. A provider expects to spend less time caring for a healthy patient than for a sicker patient. If payment per month was the same for both types of patients, there could be a disincentive for the provider to care for more unhealthy persons. Accordingly, CMS anticipated this situation and pays more per month for “sicker” patients who have chronic conditions that are identified on the medical record through use of an established coding system. This creates a business opportunity in finding low-cost, effective means to identify the conditions, which have been established in coding systems for risk adjustment of payments (higher payments paid to providers and healthcare plans to compensate them for caring for sicker or more risky patients). The more common and more dangerous a condition is, the greater the opportunity for profit. The goal is to provide cost-effective wellness.

- 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 FloChec® on a license-based model to insurance plans and medical personnel who care for those older than 50, including cardiologists, internists, nephrologists, endocrinologist, podiatrists, and family practitioners. Specifically, we believe there are more than 250,000 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 FloChec® 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, FloChec® 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. We are currently developing several updates and modifications to FloChec® 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

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development or that may be developed may incorporate some of our current technology or new technology. The goal is to achieve a reputation for outstanding service and sell new cost-effective wellness solutions to leverage our gains in the marketplace for such product offerings.

Sales and Marketing

We provide our FloChec® product and services to our customers through our salespersons and through our co-exclusive distributor, Bard Peripheral Vascular, Inc., or Bard, a large medical device company with a worldwide presence in both interventional cardiology and dialysis. 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 20% of our revenues in each of 2013 and 2014. With certain exceptions, we appointed Bard on a co-exclusive basis to license FloChec® 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 to our anticipated market.

We generally make available to our sales team (including our distributor) an inventory of FloChec® products consistent with their needs. Our product is then directly delivered to our customer and in-service training to the customer is provided either on-line or in person. Because FloChec® is relatively easy to use training can generally be accomplished in less than one day.

Customers who have licensed our FloChec® product may pay by credit card or check 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 FloChec® operating systems as appropriate by direct shipments. In the future, we plan to ship directly to customers and handle the installation and training remotely if appropriate.

In addition to the license model, which we have done historically, we have recently begun exploring other options to generate revenue from our FloChec® product. We are currently pilot testing a fee-per-test model, in which we invoice on a per test basis for use of FloChec®. We or our sub-contractors may also perform other non-proprietary tests alongside FloChec® testing and invoice on a per test basis.

Manufacturing

We manufacture our product, FloChec® through an independent contractor. We entered into our service and supply agreement with the contract manufacturer in April 2011 and pay our manufacturer for finished goods. The contract provides for subassemblies, product final assembly, test, serialization, finished goods, inventory and shipping operations. Our current contract 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 manufacturer, 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 FloChec® 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 FloChec® is the standard blood pressure cuff ankle-brachial index, or ABI, device. FloChec® 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 FloChec®. Because standard ABI devices require a better trained operator, the products are

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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, FloChec® 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, as FloChec® is PC-based. We are currently developing several updates and modifications to FloChec® 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 patent portfolio and protecting proprietary positions.

We have sponsored three studies of FloChec®. 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 FloChec®. 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 FloChec® compared with traditional analog ABI with Doppler measurements in medical practices. In the study of 181 limbs from 121 patients at 5 medical practices during 2012 and 2013, three techniques were used on all limbs: FloChec®, traditional analog ABI with Doppler, and Duplex ultrasound imaging. Traditional analog ABI with Doppler was unable to perform a conclusive study in 8.7% of limbs. In the remaining limbs, the FloChec® measurement 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 FloChec® was significantly higher than that of ABI with Doppler by a 2 to 1 margin. The results of the study have not been submitted for publication in a peer reviewed journal and 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.

The third study also was designed to assess the side by side performance of FloChec® compared with traditional analog ABI with Doppler measurements in medical practices. In this prospective study at 5 medical practices during 2013, 215 limbs from 108 patients were examined with three techniques: FloChec®, traditional analog ABI with Doppler, and Duplex ultrasound imaging as a gold standard. Results demonstrated that FloChec® demonstrated greater sensitivity, similar accuracy and less specificity than ABI with Doppler measurements. The results of the study have been submitted for publication in a peer reviewed journal. Among limitations of the study are that it had a small sample size, was conducted at specialty practices not primary care practices, and was sponsored by us.

Patents and Licenses

We have been issued one patent for our apparatus, U.S. Patent No. 7,628,760, which expires December 11, 2027. Three other U.S. patent applications are pending. Other patents are in process.

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Governmental Regulation

FloChec® received FDA 510(k) clearance in February 2010 as a Class II Medical Device. Advanced Vascular Technologies, an entity formerly affiliated with our founder and Chairman, Dr. Semler, applied for and obtained the 510(k) clearance. However, any interests it may have had in such 510(k) clearance were subsequently assigned to us and it did not manufacture any products for our company. The Class II Medical Device designation means that FloChec® is a commercial device and is currently being sold in the United States. Class II devices are 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. Pre-market notification submissions are subject to user fees, unless a specific exemption applies.

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.

Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations 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

FloChec® 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 in the United States, FloChec® or any future medical device we develop requires or will require either prior 510(k) clearance or prior approval of a premarket 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

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pre-market notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in class III, requiring approval of a PMA application. Both pre-market clearance and PMA applications are subject to the payment of user fees, paid at the time of submission for FDA review. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

510(k) Clearance Pathway

To obtain 510(k) clearance, a medical device manufacturer must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMA applications. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is completed, but it can take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new pre-market submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to FloChec® 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. In addition, the FDA is currently evaluating the 510(k) clearance process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearance and additional requirements that may significantly impact the process.

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

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

Pervasive and Continuing FDA Regulation

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

- establishing registration and device listings with the FDA;

- quality system regulation, which requires 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

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federal false claims laws. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons 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 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 and criminal 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 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 civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for “knowing failures”), 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

Although it is our intent that FloChec® be incorporated as a tool in the routine physical exam of adult patients by primary care providers in a similar fashion to the use of a thermometer or stethoscope (such that reimbursement is not sought), we cannot control whether or not providers who use FloChec® will seek third-party coverage for such procedures or reimbursement. If providers intend to seek third-party coverage or reimbursement for use of FloChec®, 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

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practice behavior. We do not track denial of requests for reimbursement made by the users of FloChec®. 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 FloChec® measurements or seeking reimbursement from third-party payors as our customers, should they choose to do so, are responsible for performing tests and seeking reimbursements.

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 FloChec® 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 Anti-Kickback Law is subject to evolving interpretations. For example, the government has enforced the 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 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 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 statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

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If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid. Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the 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.

Employees

As of December 31, 2014, we had 24 employees, all of whom were full time employees. None of our employees is represented by a labor union, and we consider our relationship with our employees to be good. These employees include three executive officers and 16 employees dedicated to sales and marketing of our product. 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 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 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.

Risks Related to our Business

We have incurred significant losses since inception. There is no assurance that we will ever achieve or maintain profitability.

Since inception, we have incurred significant operating losses. Our net loss was $4,515,000 for the year ended December 31, 2014 compared to $2,233,000 for the year ended December 31, 2013. As of December 31, 2014, we had an accumulated deficit of $13,867,000. To date, we have financed our operations primarily through the sale of our equity securities and, to a limited extent, bank financing. In the current economic environment, financing for technology and medical device companies has become increasingly difficult to obtain. Additional financing may not be available in the amount that we need or on terms favorable to us, if at all. If we raise additional funds through the issuance of equity or convertible debt securities, the percentage ownership of us by our stockholders would be diluted. In addition, in order to raise additional funds we may have to issue equity or debt securities that have rights, preferences and privileges senior to our existing securities. We have devoted substantially all of our financial resources and efforts to research and development and marketing of our FloChec® system. There can be no assurance that we will be able to achieve or maintain profitability.

Our independent registered public accounting firm's report for the year ended December 31, 2014 includes a "going concern" explanatory paragraph.

As noted above, we have incurred recurring losses since inception and expect to continue to incur losses as a result of costs and expenses related to our marketing and other promotional activities, research and continued development of our FloChec® product. Our limited capital resources and operations to date have been funded primarily through sales of our equity securities and, to a limited extent, bank financing and revenue from leasing our FloChec® product. As of December 31, 2014, we had working capital of $2,682,000, cash and restricted cash of $6,256,000 (which includes $2,100,000 of restricted cash), stockholders' equity of $3,436,000 and an accumulated deficit of approximately $13,867,000. As our revenue grows, our operating expenses will continue to grow and, as a result, we will need to generate significant additional revenues to achieve profitability. Based on our currently available cash, we do not have adequate cash on hand to cover our anticipated expenses for the next 12 months. Accordingly, as a result of our available cash, our auditor's report for year ended December 31, 2014 includes an explanatory paragraph that expresses substantial doubt about our ability to continue as a "going concern." In the event that we are unable to generate sufficient cash from our operating activities or raise additional funds, we may be required to delay, reduce or severely curtail our operations or otherwise impede our on-going business efforts, which could have a material adverse effect on our business, operating results, financial condition and long-term prospects.

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 peripheral arterial disease, or PAD, market 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 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 gain widespread acceptance.

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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, will 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 only have one FDA cleared product, FloChec®; FloChec® may not achieve broad market acceptance or be commercially successful.

We currently only have one marketed product. Accordingly, we expect that revenues from FloChec® will account for the vast majority of our revenues for at least the next several years. FloChec® may not gain broad market acceptance unless we continue to convince physicians and plans of its benefits. Moreover, even if physicians understand the benefits of FloChec®, they still may elect not to use FloChec® 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 FloChec® 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 FloChec® 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 FloChec® 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 per-reviewed journal articles and recommendations and support by influential physicians regarding FloChec® 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 adequate coverage and reimbursement from third-party payors, including government programs such as

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Medicare and Medicaid, private insurance plans and managed care programs. Healthcare providers that use medical devices such as FloChec® 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 adequate coverage and reimbursement for the procedures or patient care performed with FloChec® by government and private insurance plans is central to the acceptance of FloChec® 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 the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and/or hospitals. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures or patient care performed with FloChec®. 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 FloChec® 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 product, FloChec®, is 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 product, FloChec®, 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 FloChec® is used. Reimbursement is a significant factor considered by healthcare providers in determining whether to license medical devices or systems such as FloChec®. Although it is our intent that FloChec® be incorporated as a tool in the routine physical exam of adult patients by primary care providers in a similar fashion to the use of a thermometer or stethoscope (such that reimbursement is not sought), we cannot control whether or not providers who use FloChec® will seek reimbursement. Therefore, our ability to successfully commercialize FloChec® could depend on the adequacy of coverage and reimbursement from these third-party payors.

Currently, FloChec® is 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 FloChec®. Obtaining approval for a particular reimbursement code is time consuming and can be costly. Accordingly, at this time, and given the way we intend FloChec® to be used, we do not intend to pursue formal approval for FloChec® 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.

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We have limited experience marketing FloChec® and may not be able to generate anticipated sales.

Because we launched FloChec® in the first quarter of 2011, we have limited experience marketing our product. As of December 31, 2014, we had 16 employees dedicated to sales and marketing of our product. In August 2012, we began a co-exclusive supply and distribution arrangement with Bard Peripheral Vascular, Inc., a large medical device company, to distribute FloChec®. Our operating results are directly dependent upon our sales and marketing efforts and to a lesser extent, the efforts of our co-exclusive contract distributor. While we expect our sales and marketing force and our co-exclusive contract distributor to develop long-lasting relationships with the physicians and healthcare providers they serve and provide services in accordance with our standards. However, we do not control our co-exclusive contract distributor, and it operates and oversees its own daily operations. There is a risk that our co-exclusive contract distributor will not always act consistent with our best interests. If our co-exclusive contract distributor fails to adequately promote and market FloChec®, our revenues could decrease and we might not be able to achieve or maintain profitability and it could have a material adverse effect on our business and financial condition.

We 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. If any of our sales or marketing force were to resign us, 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 20% of our revenue for each of the years ended December 31, 2014 and 2013. If our co-exclusive distributor were to cease to distribute our product, it would slow down our efforts to gain widespread market acceptance of FloChec®. 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 2015 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 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 revenue 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 FloChec® 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

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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 rely heavily upon the talents of our Chief Executive Officer and Chief Operating Officer, the loss of either 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, and our Chief Operating Officer, Robert G. McRae. Dr. Murphy-Chutorian and Mr. McRae each provide highly valuable contributions in instituting a strong focus of specification methods, test method development and improved product quality. In particular, Mr. McRae has defined our product development pipeline and budget, provided design controls and enhanced the customer support functions. We do not have key man insurance for either Mr. McRae, or Dr. Murphy-Chutorian. The loss of either Dr. Murphy-Chutorian or Mr. McRae's services could still severely damage our business prospects, which could have a material adverse effect on our financial condition and results of operations.

We rely on a sole independent supplier and single facility for the manufacturing of FloChec®. Any delay or disruption in the supply of the product or facility, may negatively impact our operations.

We manufacture our product, FloChec®, through a sole independent contractor. 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 vendor to comply with our contract terms, we do not have control over our vendor. 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 FloChec® through this sole contract manufacturer in one single facility. If an event occurred that resulted in material damage to this manufacturing facility or our manufacturing contractor lacked sufficient labor to fully operate the facility, we may be unable to transfer the manufacture of FloChec® 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 annual report, 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 claim 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.

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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 FloChec® 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 FloChec® or one of our future products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall or as a result of the damage to our reputation for quality and safety. Further any product recall, voluntary market withdrawal or shipment stoppage of our product could significantly increase our costs and have a material adverse effect on our business.

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

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

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 become and remain profitable.

We intend to increase our operating expenses substantially as we add sales representatives to increase our geographic sales 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 achieve and maintain profitability and we might not be able to do so. Even if we do generate significant sales, we might not be able to become profitable or 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 FloChec® 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 FloChec® will achieve significant commercial success as in the past 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 FloChec® or our other products in development. Further, we may not be able to develop improvements and software updates to FloChec® 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 FloChec®.

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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 FloChec® 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 FloChec® 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 revenue 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.

FloChec® 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 premarket 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 premarket 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 FloChec® 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.

FloChec® was cleared through the 510(k) clearance process in February 2010. However, any 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 revenue, 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 FloChec® device, 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 also may change its policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay premarket approval or 510(k) clearance of a device, or could impact our ability to market our currently cleared device. We anticipate significant changes in the near future that will affect the way the 510(k) clearance program will operate. On August 3, 2010, the FDA released for public comment two internal working group reports with numerous recommendations to improve the 510(k) clearance process and utilize science in regulatory decision making to encourage innovation yet maintain predictability of the clearance process. In July, 2011, the Institute of Medicine, which was asked by the FDA to evaluate and make recommendations on the 510(k) clearance program released its report entitled "Medical Devices and the Public's Health, The FDA 510(k) Clearance Process." The report contained numerous and broad recommendations that, if followed, will have a significant impact on the medical device industry. Also in July, 2011, the FDA issued a draft guidance titled "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device." This draft guidance document was withdrawn on July 17, 2012 in accordance with Section 510(n)(2)(B) of the Federal Food, Drug, and Cosmetic Act as amended by the Food and Drug Administration Safety and Innovation Act. An existing 1997 guidance on the same topic therefore remains in effect, but any 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 FloChec® 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;

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- 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 premarket approval of new products or new intended uses;
- withdraw 510(k) clearances that are already granted;
- impose operating restrictions, including requiring a partial or total shutdown of production;
- enjoin or restrain conduct resulting in violations of applicable law pertaining to medical devices; and/or
- assess criminal or civil penalties against our officers, employees or us.

If the FDA concludes that we failed to comply with any regulatory requirement during an inspection, it could have a material adverse effect on our business and financial condition. We could incur substantial expense and harm to our reputation, and our ability to introduce new or enhanced products in a timely manner could be adversely affected.
Although part of our business strategy is based on certain advantageous new payment provisions enacted under the current government healthcare reform, we also face significant uncertainty in the industry regarding the implementation of the Health Care Reform Law.
Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. In March 2010, President Obama signed into law the Health Care Reform Law. The Health Care Reform Law has brought a new way of doing business for providers and health insurance plans. We believe that fee for service programs will be reduced in favor of capitated programs that pay a monthly fee per patient. Risk factor adjustments per patient will provide payment that is higher for sicker patients who have conditions that are codified. Quality of care measured by completeness and wellness will induce higher payments per patient. These changes are already in place for 16 million participants in the Medicare Advantage program and are expected to expand to more types of insured patients as healthcare reform is deployed. Although we expect these measures to be mainly positive for our business given the ability of FloChec® to measure blood flow in an in-office setting, which can assist doctors and other providers to suspect PAD and other vascular diseases, due to uncertainties regarding the ultimate features of the new federal legislation and its implementation, we cannot predict what impact the Health Care Reform Law may have on us, our customers or our industry. If the Health Care Reform Law is not implemented as we anticipate, or if changes are made in the implementation of the Health Care Reform Law 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). The total cost to the industry is expected to be approximately $30 billion over ten years. This new and significant tax burden could have a negative impact on our results of our operations. Further, the Health Care Reform Act 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. While passage of the Health Care Reform Law may ultimately expand the pool of potential patients for FloChec®, the above-discussed changes 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

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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 False Claims Act imposes liability, including treble damages and per claim penalties, 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. 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 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. 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.

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

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

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

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

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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;

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- reduced disclosure obligations regarding executive compensation; and

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

We have taken advantage of reduced reporting burdens in this annual report. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. 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 newly 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, the listing requirements of The NASDAQ Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Although we are currently both an emerging growth company and smaller reporting company, 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 are continuing to evaluate these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.
Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, even if we are no longer a smaller reporting company, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, 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. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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We have previously identified material weaknesses in our internal control over financial reporting. If we identify additional material weaknesses in our internal control over financial reporting in the future, or if our former material weaknesses recur, it could have an adverse effect on our company.

In connection with the audit of our financial statements for the year ended December 31, 2013, our management and independent registered public accounting firm identified certain material weaknesses in our internal control over financial reporting. These material weaknesses related to our lack of a sufficient complement of personnel with an appropriate level of knowledge and experience in the application of U.S. generally accepted accounting principles, or GAAP, commensurate with our financial reporting requirements and the fact that policies and procedures with respect to the review, supervision, and monitoring of our accounting and reporting functions were either not designed and in place or not operating effectively. As a result, numerous audit adjustments to our financial statements were identified during the course of the audit. Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2014 or 2013 in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, 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. Although we implemented measures to remedy these material weaknesses, we cannot assure you that we have identified all or that we will not in the future have additional material weaknesses. Accordingly, material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting for purposes of our attestation when required by reporting requirements under the Exchange Act or Section 404 of the Sarbanes-Oxley Act. If we have additional 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, 2014, we have been issued, or have rights to, one U.S. patent. In addition, we have filed three U.S. patent applications that are still pending. 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

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

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

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

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

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

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

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

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Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

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

Risks Related to our Common Stock

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

Our executive officers and Directors beneficially own in the aggregate shares representing approximately 22.6% of our common stock as of January 31, 2015. 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;

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- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors;

- require that stockholder actions must be effected at a duly called stockholder meeting; and

- 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.

An active trading market for our common stock may not develop.

Prior to our initial public offering, there was no public market for our common stock. Although our common stock has traded on The NASDAQ Capital Market since February 2014, an active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop, it may be difficult for you to sell our shares without depressing the market price for the shares or at all.

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. 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.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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ITEM 1B.
UNRESOLVED STAFF COMMENTS

None.

ITEM 2.
PROPERTIES

Because we outsource our manufacturing to a “turn-key” manufacturer and have a geographically dispersed sales force and distributor arrangement, we have minimal needs for office space to conduct our day-to-day business operations. We currently use space for our corporate headquarters on a rent-free basis in a building located at 2330 NW Everett St., Portland, OR, that is owned by our Chairman and co-founder, Dr. Herbert Semler. We have also leased other facilities on an as-needed basis for our sales and marketing operations. For example, we lease a sales office in Menlo Park, CA as well as other smaller facilities in the Bay Area. See Note 7 to our