Semler Scientific, Inc.
Form 424B4
February 21, 2014
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Filed pursuant to Rule 424(b)(4)
Reg. No. 333-192362

PROSPECTUS

1,430,000 Shares

Common Stock

This is a firm commitment initial public offering of 1,430,000 shares of common stock by Semler Scientific, Inc. No public market currently exists for our common stock.

Our common stock has been approved for listing on The NASDAQ Capital Market under the symbol “SMLR.”

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 and have elected to comply with certain reduced public company disclosure standards.

Investing in our common stock involves risks that are described in the “Risk Factors” section beginning on page 11 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$ 7.00	$ 10,010,000
Underwriting discounts and commissions (1)	$ 0.49	$ 700,700
Proceeds, before expenses, to us	$ 6.51	$ 9,309,300

(1)

- The underwriters will receive compensation in addition to the underwriting discount. See “Underwriting” beginning on page 74 of this prospectus for a description of compensation payable to the underwriters.

We have granted the underwriters a 45-day option to purchase up to 214,500 additional shares of common stock solely to cover over-allotments, if any.

Certain of our directors, officers and more than 5% stockholders and their affiliates have agreed to purchase an aggregate of 285,713 of our common stock in this offering at the initial public offering price. See “Underwriting” for a full description of compensation payable to the underwriters.

The underwriters expect to deliver the shares against payment therefor on or about February 26, 2014.

Aegis Capital Corp

February 20, 2014

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You should rely only on the information contained in this prospectus or in any free writing prospectus that we may specifically authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with any information other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus may only be used where it is legal to offer and sell our securities. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are not, making an offer of these securities in any jurisdiction where the offer is not permitted.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

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Prospectus Summary

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our securities, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in each case included elsewhere in this prospectus. Unless otherwise stated or the context requires otherwise, references in this prospectus to “Semler Scientific,” “we,” “us,” or “our” refer to Semler Scientific, Inc.

Semler Scientific, Inc.

Business Overview

We are an emerging medical risk-assessment company. Our mission is to develop, manufacture and market patented products that identify the risk profile of medical patients to allow healthcare providers to capture full reimbursement potential for their services. 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, 2013 we had total revenue of $2,274,000 and a net loss of $2,233,000 compared to total revenue of $1,199,000 and a net loss of $2,741,000 in 2012. Our net loss attributable to common stockholders was $2,233,000 for the year ended December 31, 2013 compared to $2,826,000 for 2012.

Our Product

We currently have only one patented and FDA cleared product, FloChec™, that we market and lease 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, Borderline Flow Obstruction and No Flow Obstruction.

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Other Methods

Blood flow is the amount of blood delivered to a given region per unit time, whereas a 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 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 peripheral artery disease, or 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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, 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. 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 health care utilization of that patient, with greater payment for patients with significant medical history. For Medicare Advantage patients, Centers for Medicare & Medicaid Services, or CMS, pays the fee per patient. 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 adjustments per patient will provide payment that is higher for sicker patients who have conditions that are codified. 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 14 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. 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. Published studies have shown that persons with PAD are four times more likely to die of heart attack, and two to three times more likely to die of stroke. According to a study by P.G. Steg published in the Journal of the American Medical Association, or JAMA, patients with

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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.

We believe medical personnel who care for those older than 50 years are the target market for FloChec™. 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 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 thousands of 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 in 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. 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.

Our Business Strategy

Our mission is to develop, manufacture and market patented products that identify the risk profile of medical patients to allow healthcare providers to capture full reimbursement potential for their services, while growing revenues and becoming and maintaining profitability. We intend to do this by:

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- Capitalizing on opportunities provided by the Health Care Reform Law. Under the Health Care Reform Law, for 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 would be a perverse incentive for the provider to only want to care for healthy 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.

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- 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 our FloChec™ system, on a lease-based service model, to 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 the patients of whom 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.

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- 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 products that allow healthcare providers to capture the full reimbursement potential for their services. We are currently developing several new products in conjunction with our consultant engineering groups that are intended to provide cost-effective wellness solutions for our growing, established customer base. The new products under development or to 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.

Risks

Since inception, we have incurred substantial losses. Our business and our ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should carefully consider the following risks, which are discussed more fully in “Risk Factors” beginning on page 11 of this prospectus.

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

- Our independent registered public accounting firm’s report for the year ended December 31, 2013 includes a “going concern” explanatory paragraph.

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

- We currently only have one product, FloChec™; FloChec™ may not achieve broad market acceptance or be commercially successful.

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

- 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.

- 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.

- We have limited experience marketing FloChec™, are dependent on our distribution partner and we may not be able to generate anticipated sales.

- We face challenges and risk in managing and maintaining our distribution network and the parties who make up that network.

- To adequately commercialize FloChec™, we may need to increase our sales and marketing network, which will require us to hire, train, retain and supervise employees.

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

- We rely heavily upon the talents of our Chief Executive Officer and Chief Operating Officer, the loss of either could severely damage our business.

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- 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.

- 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.

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

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

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

- We will need to generate significant revenues to become and remain profitable.

- Our future financial performance will depend in part on the successful improvements and software updates to FloChec™ on a cost-effective basis.

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

- One of our business strategies is developing additional products that allow healthcare providers to capture the full reimbursement potential for their services. The development of new products involves time and expense and we may never realize the benefits of this investment.

- 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.

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

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

- 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.

- Our business may be adversely impacted by the recent sequestration signed into law in the United States.

- 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.

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

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

- We currently have material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses in our internal control over financial reporting, it could have an adverse effect on our company.

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

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- 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.

- 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.

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

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

- After this offering, our executive officers, Directors and principal stockholders, if they choose to act together, will continue to have the ability to control all matters submitted to stockholders for approval.

- 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.

- If you purchase shares of common stock in this offering, you will suffer immediate dilution of your investment.

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

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

- We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

- A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

- 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.

Corporate Information

We were founded in Portland, Oregon as an Oregon corporation in August 2007. In March 2012, we converted from an S-Corporation to a C-Corporation and in September 2013, we reincorporated as a Delaware corporation. Our executive offices are located at 2330 NW Everett St., Portland, OR 97210 and our telephone number is (877) 774-4211. Our website address is semlerscientific.com. Information contained in our website does not form part of the prospectus and is intended for informational purposes only.

Implications of Being an Emerging Growth Company

As a company with less than $1.0 billion in revenue during our last fiscal year, we qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from specified 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;

- reduced disclosure obligations regarding executive compensation; and

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

We may take advantage of these provisions, including the extended adoption period for new or revised accounting pronouncements described below, for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenues, have more than $700.0 million in market value of our capital stock held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. Even if we cease to be an emerging growth company, we may still enjoy reduced reporting obligations insofar as we remain a smaller reporting company. As an emerging growth company, we may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

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 provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards 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. However, if we later decide to opt out of the extended period for adopting new accounting standards, we would need to disclose such decision and it would be irrevocable.

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THE OFFERING

Common Stock offered by us

1,430,000 shares.

Common stock to be outstanding immediately after this offering

4,708,017 shares. If the underwriter's over-allotment option is exercised in full, the total number of shares of common stock outstanding immediately after this offering would be 4,922,517.

Over-allotment option

The underwriters have an option for a period of 45 days to purchase up to 214,500 additional shares of our common stock to cover over-allotments, if any.

Use of proceeds

We intend to use the net proceeds received from this offering for working capital and general corporate purposes. See "Use of Proceeds" on page 28.

Risk factors

See "Risk Factors" beginning on page 11 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

NASDAQ Capital Market Symbol

"SMLR"

Unless we indicate otherwise, all information in this prospectus:

- is based on 786,750 shares of common stock issued and outstanding as of January 31, 2014;
- assumes the automatic conversion into 2,012,152 shares of common stock of all of our outstanding shares of convertible preferred stock effective upon the closing of this offering;
- assumes the cashless exercise of outstanding warrants for 228,656 shares of our Series A-1 Preferred Stock and 1,067,210 shares of our Series A Preferred Stock in accordance with their terms, all of which shares of convertible preferred stock will be automatically converted into shares of our common stock, resulting in the issuance of an aggregate of 479,115 shares of common stock effective upon the closing of this offering based on an initial public offering price of $7.00 per share;
- excludes 288,214 shares of common stock issuable upon exercise of outstanding warrants to acquire 25,000 shares of our Series A-2 Preferred Stock at a purchase price of $2.00 per share, 16,875 shares of our Series A-1 Preferred Stock at a purchase price of $4.00 per share, and 246,339 shares of our Series A Preferred Stock at a purchase price of $4.50 per share, which will become exercisable for common stock rather than convertible preferred stock upon closing of this offering in accordance with their terms;
- assumes no exercise by the underwriters of their option to purchase up to an additional 214,500 shares of common stock to cover over-allotments, if any; and
-

- excludes 71,500 shares of common stock underlying the warrants to be issued to the underwriters in connection with this offering.

Dr. Murphy-Chutorian, our Chief Executive Officer and Director, and William H.C. Chang, our Director, have agreed to purchase 53,571 shares and 89,285 shares, respectively, and Eric Semler, one of our existing principal stockholders, or entities affiliated with Mr. Semler, have agreed to purchase 142,857 shares of our common stock in this offering at the initial public offering price. See “Underwriting” for a full description of compensation payable to the underwriters.
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SUMMARY FINANCIAL DATA

The following table sets forth our summary statement of operations data for the fiscal years ended December 31, 2013 and 2012 derived from our audited financial statements and related notes included elsewhere in this prospectus. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. The results indicated below are not necessarily indicative of our future performance. You should read this information together with the sections entitled "Capitalization," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2013	**2012**
Revenue	$ 2,274,000	$ 1,199,000
Operating expenses:		
Cost of revenue	469,000	364,000
Engineering and product development	356,000	277,000
Sales and marketing	2,256,000	1,718,000
General and administrative	1,317,000	1,255,000
Total	4,398,000	3,614,000
Loss from operations	(2,124,000)	(2,415,000)
Other Income (expenses)		
Interest expense	(108,000)	(120,000)
Other expense	(1,000)	(203,000)
Loss before income tax expense	(2,233,000)	(2,738,000)
Income tax expense	—	3,000
Net loss	$ (2,233,000)	$ (2,741,000)
Deemed dividend	$ —	$ (85,000)
Net loss attributable to common stockholders	$ (2,233,000)	$ (2,826,000)
Net loss per share, basic and diluted	$ (2.84)	$ (2.54)
Weighted average share outstanding	786,750	1,113,622
Weighted average number of shares excluded in basic and diluted net loss per share:		
Convertible preferred stock	1,614,531	542,678
Preferred stock warrants	1,361,218	471,161
Common stock warrants	—	170,152
Options	337,500	267,758
Total	3,313,249	1,451,749

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	As of December 31, 2013		
	Actual	**Pro Forma (1) (3)**	**Pro Forma, As Adjusted (2) (3)**
Balance Sheet Data:			
Cash and cash equivalents	$ 734,000	$ 734,000	$ 9,033,822
Total assets	1,724,000	1,724,000	10,023,822
Total liabilities	2,019,000	2,019,000	2,019,000
Total stockholders' equity (deficit)	(295,000)	(295,000)	8,004,822

(1)

- Pro forma amounts give effect to the issuance of 2,491,267 shares of common stock upon the closing of this offering reflecting (i) the automatic conversion into 2,012,152 shares of common stock of all our outstanding shares of convertible preferred stock and (ii) the issuance of 479,115 shares of common stock upon the cashless exercise at the initial public offering price of $7.00 per share of outstanding warrants for convertible preferred stock and subsequent automatic conversion of that convertible preferred stock into common stock.

(2)

- The pro forma as adjusted balance sheet data reflects the items described in footnote (1) above and gives effect to our receipt of estimated net proceeds from the sale of 1,430,000 shares of common stock at an initial public offering price of $7.00 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3)

- The pro forma and pro forma as adjusted data are illustrative only.

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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 prospectus 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 prospectus 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 prospectus.

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 $2,233,000 for the year ended December 31, 2013 compared to $2,741,000 for the year ended December 31, 2012. Our net loss attributable to common stockholders was $2,233,000 for the year ended December 31, 2013 compared to $2,826,000 for the year ended December 31, 2012. As of December 31, 2013, we had an accumulated deficit of $9,352,000. Losses are continuing through the date of this prospectus. To date, we have financed our operations primarily through private placements 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, 2013 includes a “going concern” explanatory paragraph.

As noted above, our limited capital resources and operations to date have been funded primarily through private placements of our equity securities and, to a limited extent, bank financing. As of December 31, 2013, we had an accumulated deficit of approximately $9.4 million. 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, 2013 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 product could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternatives to FloChec™ gain widespread acceptance.

In addition, we may not be able to successfully implement our business strategy. To implement our business strategy we need to, among other things, find new applications for and improve FloChec™ and educate healthcare providers about the clinical and cost benefits of our product, all of which we believe

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could increase acceptance of our product 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 product 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 product, FloChec™; FloChec™ may not achieve broad market acceptance or be commercially successful.

We currently only have one 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 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 FloChec™ unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of FloChec™ provides a safe and effective alternative to other existing ABI devices.

We believe that physicians will not widely adopt FloChec™ unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of FloChec™ 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 FloChec™ is 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 FloChec™ will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician’s actual experience with FloChec™ will vary. We also believe that published per-reviewed journal articles and recommendations and support by influential physicians regarding FloChec™ 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 FloChec™ 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 FloChec™ depends on the availability of adequate coverage and reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Healthcare providers that use medical

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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 purchased by healthcare providers, who 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 acquire 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 timely 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 January 31, 2014, our U.S. sales force consisted of 5 exclusive sales representatives. In August 2012, we signed a co-exclusive supply and distribution agreement 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 representatives 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 direct sales representatives were to leave us, or if our 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, 2013 and 2012. 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 2014, 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 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 representatives 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 FloChec™, we may need to increase our sales and marketing network, which will require us to hire, train, retain and supervise employees.

If we increase our marketing efforts with respect to FloChec™, or launch new products we will need to expand the reach of our marketing and sales 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. New hires 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 in the future, we cannot be certain that new hires will become as productive as may be necessary to 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™ which would adversely affect our business, results of operations and financial condition.

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

Our business is based on a service model rather than an outright sale of our FloChec™ product. Our service model pricing is based on data collected on use rates of FloChec™ and third-party payment rates to physicians and facilities using 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.

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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.

The development, manufacture and sale of products used in a medical setting entails significant risks of product liability claims. Although we maintain product liability insurance to cover us in the event of liability claims, and as of the date of this prospectus, no such claims have been asserted or threatened against us, our insurance may not be sufficient to cover all possible future product liabilities. 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 of our product. A successful product liability 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 insurance is expensive and may not always be available to us on acceptable terms, if at all.

We may implement a product recall or voluntary market withdrawal 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 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.

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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 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™. 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 lease term, and we may be required to devote significant resources to address any quality issues associated with FloChec™. Failure to successfully introduce improve or update FloChec™ on a cost-effective basis, or delays in customer decisions related to the evaluation of FloChec™ 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 could become obsolete or uncompetitive.

The market for medical systems, equipment and other devices 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,

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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 that we may develop, if and when they are approved for sale or lease. 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 that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing 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 that allow healthcare providers to capture the full reimbursement potential for their services. The development of new products 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 that allow healthcare providers to capture the full reimbursement potential for their services. Such product 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 if developed that such products will obtain the necessary regulatory approvals for commercialization. Even if approved, there is no guarantee that such products 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.

FloChec™ and any future are medical devices that we may develop 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 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 use 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 devices are cleared or approved, the products may not be cleared or approved 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.

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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;
- 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

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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 14 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.

Our business may be adversely impacted by the recent sequestration signed into law in the United States.

On March 1, 2013, most agencies of the federal government automatically reduced their budgets according to an agreement made by Congress in 2012 known as “sequestration.” Originally devised as an incentive to force Congressional agreement on budget issues, the sequestration order was approved on March 1, 2013 by the President of the United States. For claims submitted with dates of service or dates of discharge after April 1, 2013, these cuts will result in Medicare payments to health care providers, health care plans and drug plans being reduced by 2%.

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

We are subject to healthcare fraud and abuse laws and regulations including, but not limited to, the Federal Anti-Kickback Statute, state anti-kickback statutes, the Federal False Claims Act, and state false claims acts. Additionally, to the extent we maintain financial relationships with physicians and other healthcare providers, we may be subject to Federal and state physician payment sunshine laws and regulations, which require us to track and disclose these financial relationships. These and other laws regulate interactions amongst health care entities and with sources of referrals of business, among other things. The Federal Anti-Kickback Statute is a criminal statute that imposes substantial penalties on persons or entities that offer, solicit, pay or receive payments in return for referrals, recommendations, purchases or orders of items or services that are reimbursable by Federal healthcare programs. The 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

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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, including 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;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. 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,

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

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act 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. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our Board of Directors.

We are evaluating 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, 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.

We currently have material weaknesses in our internal control over financial reporting. If we are unable to successfully remediate these material weaknesses in our internal control over financial reporting, it could have an adverse effect on our company.

In connection with the audits of our financial statements for the years ended December 31, 2013 and 2012, our management and independent registered public accounting firm identified certain material weaknesses in our internal control over financi