2022 ANNUAL REPORT

Semler Scientific

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

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, 2022

or

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

For the transition period from: to

Commission file number: 001-36305

SEMLER SCIENTIFIC, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-1367393**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2340-2348 Walsh Avenue, Suite 2344
Santa Clara, CA 95051
(Address of principal executive offices) (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	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	SMLR	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 $155,160,658 as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of the registrant's common stock outstanding as of March 16, 2023 was 6,844,512.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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In this report, unless otherwise stated or as the context otherwise requires, references to "Semler Scientific," "the Company," "we," "us," "our" and similar references refer to Semler Scientific, Inc. The Semler Scientific logo, QuantaFlo and other trademarks or service marks of Semler Scientific, Inc. appearing in this report are the property of Semler Scientific, Inc. This report also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

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

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

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

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

RISK FACTOR SUMMARY

Our business involves significant risks. Below is a summary of the material risks that our business faces, which makes an investment in our common stock speculative and risky. This summary does not address all these risks. These risks are more fully described below under the heading "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K. Before making investment decisions regarding our common stock, you should carefully consider these risks. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such event, the market price of our common stock could decline, and you could lose all or part of your investment. In addition, there are also additional risks not described below that are either not presently known to us or that we currently deem immaterial, and these additional risks could also materially impair our business, operations or market price of our common stock.

- If we do not successfully implement our business strategy, our business and results of operations will be adversely affected.
- We predominantly market only one U.S. Food and Drug Administration, or FDA, cleared product, QuantaFlo, a cardiac and vascular testing product, and it may not achieve broad market acceptance or be commercially successful. We may also fail to generate meaningful revenues from our Insulin Insights distribution arrangement, which includes prepaid licenses, or benefit from our recent investments in other companies developing other complementary products.
- Changes in the regulatory reimbursement landscape, such as the recent "Advance Notice" issued by Centers for Medicare and Medicaid Services, or CMS, could impact the perceived profitability of using our products to aid diagnosis of cardiovascular diseases.
- Physicians and other customers 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 devices, including ankle brachial index, or 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 cardiac and vascular testing product is generally but not specifically approved for reimbursement under any third-party payor codes; if third-party payors refuse to reimburse our customers for their use of our product, it could have a material adverse effect on our business.
- Our business has been and could continue to be adversely affected by the ongoing COVID-19 pandemic.
- We rely heavily upon the talents of a small number of key personnel, the loss of whom could severely damage our business.
- We rely on a small number of employees in our direct sales force and face challenges and risk in managing and maintaining our distribution network and the parties who make up that network.
- To adequately commercialize our products and any new products we add, 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 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.
- We are exposed to risk as a significant portion of our revenues and accounts receivables are with a limited number of customers.
- We rely on a small number of independent suppliers and facilities for the manufacturing of our cardiac and vascular testing product. 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 or services that we may provide.
- 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.
- If we fail to properly manage our anticipated growth, our business could suffer.
- An information security incident, including a cybersecurity breach, could have a negative impact on our business or reputation.
- Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.
- We will need to generate significant revenues to remain profitable.
- Our future financial performance will depend in part on the successful improvements and software updates to our vascular testing product on a cost-effective basis.
- 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.
- 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.
- We have used our cash resources to invest in other companies, and there is no guarantee that we will be repaid on maturity nor realize any other expected benefits from such investments, which could harm our business.
- 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.
- 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 payment provisions enacted under government healthcare reform, we also face significant uncertainty in the industry regarding the implementation, transformation or repeal and replacement of the Health Care Reform Law.
- 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.
- Our ability to use net operating loss, or NOL, carryforwards to offset future taxable income may be subject to limitations.
- We have had material weaknesses in our internal control over financial reporting. Although we have remedied our prior material weaknesses, if we identify additional material weaknesses in the future, or if our former material weaknesses recur, 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.
- 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.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- Our business could be impacted by macroeconomic factors, such as the effects of the Russian invasion of Ukraine on the global economy and supply chain and inflation.
- Our executive officers, directors and significant stockholders, if they choose to act together, have the ability to significantly influence 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.

PART I

ITEM 1. BUSINESS

General

We are a company providing technology solutions to improve the clinical effectiveness and efficiency of healthcare providers. Our mission is to develop, manufacture and market innovative products and services that assist our customers in evaluating and treating chronic diseases. Our patented and U.S. Food and Drug Administration, or FDA, cleared product, QuantaFlo, measures arterial blood flow in the extremities to aid in the diagnosis of peripheral arterial disease, or PAD, and serves as an aid to measure hemodynamics related to heart dysfunction.

We have an agreement with Mellitus Health, Inc, or Mellitus, a private company to exclusively market and distribute Insulin Insights, an FDA-cleared software product that recommends optimal insulin dosing for diabetic outpatients in the United States, including Puerto Rico, except for selected accounts.

We have also made cash investments in Mellitus, in Monarch Medical Technology, LLC, or Monarch, a privately-held digital health company whose proprietary product, EndoTool Glucose Management System, or EndoTool, offers a technology-enabled approach to inpatient glycemic management, and in NeuroDiagnostics Inc., a privately-held company that is doing business as SYNAPS Dx, or SYNAPS, whose product, Discern, is a test for early Alzheimer's disease. We continue to develop additional complementary proprietary products in-house (such as our recently released QuantaFlo extension as an aid to measure hemodynamics related to heart dysfunction), and seek out other arrangements for additional products and services that we believe will bring value to our customers and to our company. We believe our current products and services, and any future products or services that we may offer, position us to provide valuable information to our customer base, which in turn permits them to better guide patient care.

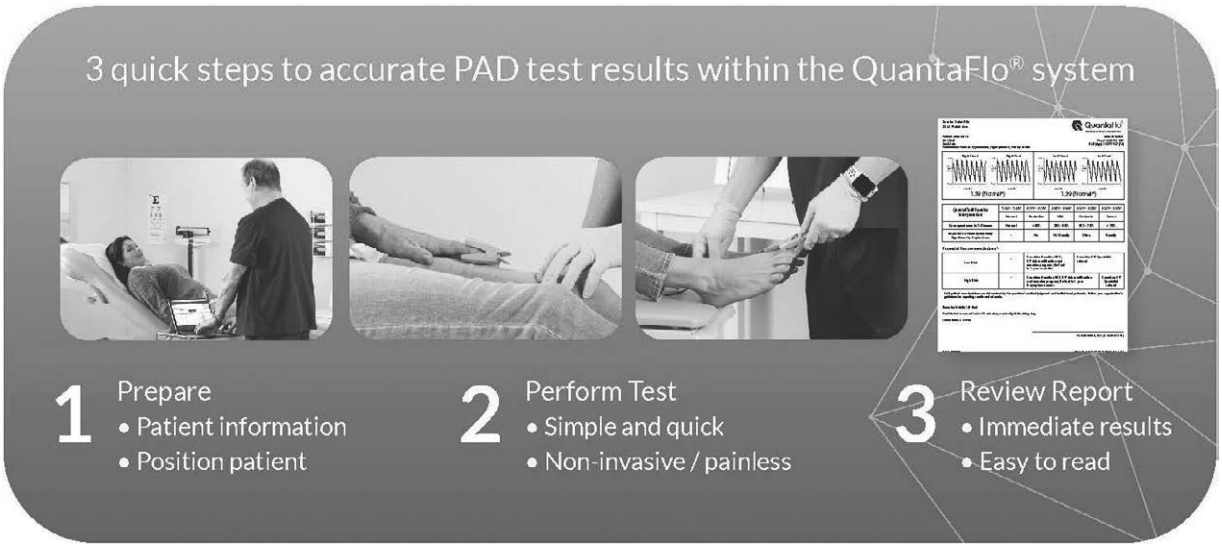
In the year ended December 31, 2022, we had total revenues of $56.7 million and net income of $14.3 million compared to total revenues of $53.0 million and net income of $17.2 million in 2021.

Our Products and Services

We currently market a patented and FDA-cleared, cardiac and vascular testing product, QuantaFlo, to our customers, who include insurance plans, physician groups, risk assessment groups, hospitals and retailers. We also have an exclusive distribution arrangement for the United States, including Puerto Rico, to distribute Insulin Insights, an FDA-cleared, software solution designed to provide insulin dosing recommendations to clinicians for the adjustment and maintenance of blood glucose levels in insulin-dependent patients with Type 2 diabetes. We believe this product will be attractive to our existing customers as well as help expand our customer base.

QuantaFlo

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



QuantaFlo features a sensor clamp that is placed on the toe or finger. Infrared light emitted from the clamp on the dorsal surface of the digit is scattered and reflected by the red blood cells coursing through the area of illumination. Returning light is 'sensed' by the sensor. A blood flow waveform is instantaneously constructed by our proprietary software algorithm. Both index fingers and both large toes are interrogated, which takes about 30 seconds for each. The product may be used with provocative maneuvers.

We have primarily developed a license model rather than an outright sales model for QuantaFlo. This license model eliminates the need to make a capital equipment sale. Consequently, we generally require no down payment or long-term commitment from our customers. QuantaFlo has an expected average lifetime of at least three years. To date, we roughly estimate that routine office usage of the QuantaFlo has ranged from a few tests per week up to 10 tests per day. We also offer contracts in which we invoice on a per test basis for use of QuantaFlo. Approximately 62% of our customers are on the fixed-fee software licensing model, whereas 38% are on the variable fee model based on usage.

We have placed our QuantaFlo product with healthcare insurance plans, integrated delivery networks, independent physician groups, hospitals and companies contracting with the healthcare industry such as risk assessment groups and retailers in addition to doctors' offices. Our two largest customers are U.S. diversified healthcare companies and affiliated plans, and in the year ended December 31, 2022, they accounted for 40.4% and 29.0% of our revenues, respectively, compared to 40.8% and 28.6%, respectively, in the prior year.

Other Blood Flow Testing Methods

Blood flow is the amount of blood delivered to a given region per unit time, whereas blood pressure is the force exerted by circulating blood on the walls of arteries. Given a fixed resistance, blood flow and blood pressure are proportional. The ABI with Doppler test uses a blood pressure cuff to measure the systolic blood pressure in the lower legs and in the arms. A blood pressure cuff is inflated proximal to the artery in question. Using a Doppler device, the inflation continues until the pulse in the artery ceases. The blood pressure cuff is then slowly deflated. When the artery's pulse is re-detected through the Doppler probe the pressure in the cuff at that moment indicates the systolic pressure of that artery. The test is repeated on all four extremities. Well-established criteria for the ratio of the blood pressure in a leg compared to the blood pressure in the arms are used to assess the presence or absence of flow obstruction. Generally, these tests take 15 minutes to perform and require a vascular technician to be done properly. Like QuantaFlo, the

traditional analog ABI test with Doppler is a non-invasive physiologic measurement that may be abnormal in the presence of PAD. Alternatively, primary care physicians may palpate the pedal pulses to assess blood flow in the lower extremities. However, pulse palpation is generally not sensitive for the detection of vascular disease. Other options to detect arterial obstructions or hemodynamic problems are imaging systems that use ultrasound, x-ray technology or magnetic resonance to obtain anatomic information about blood vessels in the legs. However, as compared to QuantaFlo, imaging tests are much more expensive, time consuming and are performed by specialists in special laboratories or offices.

Insulin Insights

Insulin Insights is a software program that is used by a healthcare provider to optimize outpatient insulin dosing. In April 2021, we entered into an agreement with Mellitus to exclusively market and distribute this software program in the United States, including Puerto Rico, except for selected accounts. Under this agreement and its December 2022 amendment, we have pre-paid for an aggregate of $2.5 million of licenses ($2.0 million in April 2021 and $0.5 million in December 2022).

We currently are distributing Insulin Insights using a software as a service, or SaaS, license model on a per patient per month fee rather than an outright sales model. We generally require no down payment or long-term commitment from our customers. We intend to reevaluate the price periodically. As we have only recently deployed Insulin Insights with customers, we do not have enough experience with the product to be able estimate routine usage of Insulin Insights in terms of patients per location.

We seek to distribute Insulin Insights to healthcare insurance plans, integrated delivery networks, independent physician groups, and companies that contract with the healthcare industry, such as risk assessment groups, long-term care, or remote patient monitoring organizations, in addition to doctors' offices. We believe that this software product will be of interest to our existing customer base, as well as help us to expand interest in QuantaFlo to additional customers.

Market Opportunity

QuantaFlo

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.

The current coding system used by CMS for the Medicare Advantage program is a hierarchical condition category, or HCC, diagnostic classification system that began by classifying over 14,000 diagnosis codes into approximately 1,500 diagnostic groups, or DXGs. Each code maps to exactly one DXG, which represents a well-specified medical condition, such as DXG 96.01 pre-cerebral or cerebral arterial occlusion with infarction. DXGs are further aggregated into 204 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 CC100 Ischemic or Unspecified Stroke, which includes DXG 95.02 iatrogenic cerebrovascular infarction or hemorrhage (e.g., postoperative stroke), DXG 96.01 precerebral or cerebral arterial occlusion with infarction, DXG 96.02 acute but ill-defined cerebrovascular disease (ICD-9), and DXG 170.59 neonatal cerebral infarction.

Undiagnosed cardiac and vascular diseases are major under-diagnosed health problems in the United States. These conditions are common and deadly cardiovascular disease is often undiagnosed. As with clogged arteries in the heart, clogged arteries in the legs place patients at an increased risk of heart attack and stroke. Published studies have shown that persons with PAD are four times more likely to die of heart

attack, and two to three times more likely to die of stroke. According to a study by P.G. Steg published in the JAMA, patients with PAD have a 21% event rate of cardiovascular death, heart attack, stroke or cardiovascular hospitalization within 12 months. The SAGE Group has estimated that as many as 20 million people are affected with PAD in the United States alone and A.T. Hirsch et al. in a JAMA published article further estimate that only 11% have claudication (pain on exertion), a classic symptom of PAD.

The spectrum of heart dysfunction includes heart failure. Published studies have shown that there are over one million hospitalizations per year in the United States from heart failure and the annual cost of care exceeds $30 billion. According to a study published in AHA Journals by S.L. Jackson, et al, heart failure affects ~approximately 6.5 million adults in the United States and the lifetime risk of heart failure is estimated to be one in five at 40 years of age. The study also notes persons with heart failure have mortality rates 20% to 25% higher after hospitalization within one year after diagnosis.

Many people affected with cardiac and vascular diseases do not have noticeable symptoms. When symptoms are present, they often include fatigue, heaviness, cramping or pain during activity, leg or foot pain, sores, wounds or ulcers on the toes, feet, or legs, which are slow to heal, shortness of breath, peripheral edema, or enlarged liver. Persons with cardiac and vascular diseases may become disabled and not be able to work.

Risk factors for developing cardiac and vascular diseases 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 and insurance plans who care for those older than 50 years are the target market for QuantaFlo. Based on U.S. Census data, we believe there are more than 80 million older Americans who could be evaluated for the presence of cardiac and vascular diseases.

There are over 400,000 medical professionals practicing primary care in the United States. In addition, based on American Heart Association data, there are over 20,000 cardiologists and 7,500 vascular and cardiovascular surgeons. Also, there are millions of diabetic patients seen routinely by endocrinologists. Many podiatrists who see patients with these problems and orthopedic surgeons may see value in screening patients for circulation issues prior to leg procedures. Neurologists may need a tool to differentiate leg pain from vascular versus neurologic etiology. Nephrologists see patients with kidney disease, who have a higher frequency of cardiac and vascular diseases. 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 cardiac and vascular diseases and to look for signs on physical exam, we believe that it is often the case in busy practices that the questions go unasked.

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

Insulin Insights

Of the growing diabetic population in the United States, over a quarter use insulin according to the Center for Disease Control and Prevention. Insulin is a necessary medication as nearly all Type 1 diabetics (approximately 1.6 million people in the United States, and roughly 21% of Type 2 diabetics (of the over 30 million people in the United States with Type 2 diabetics) must also use insulin to bring their blood glucose levels down to a healthy range. Without insulin, patients are likely to suffer from blurred vision,

weight loss, and intolerable thirst. Eventually, uncontrolled diabetes can lead to blindness, kidney failure, gangrene, loss of limbs, and ultimately death. Tighter control of glucose is proven to improve the outcomes in diabetes care.

In the United States, about 90% of diabetic patients treating with insulin are managed by primary care practitioners. Insulin Insights is designed to be used by such practitioners to recommend optimal insulin dosing for each individual patient.

CMS has established a star rating system to measure and report on the quality of health services received by consumers in Medicare Advantage plans. Based on the star ratings, high performing health plans are also eligible to be paid bonuses by CMS. Among measures factored into plans' star ratings are measures assessing diabetes care, including a measure adapted from the Healthcare Effectiveness Data and Information Set (HEDIS) that assesses the percentage of diabetic plan enrollees aged 18-75 who demonstrate good blood sugar control (HbA1c <9.0%). We believe this provides a financial incentive to potential customers for an Insulin Insights software license, as it will assist them in working with their diabetic patients to optimize insulin dosing and achieve better control of their blood glucose levels.

Other Products and Services

In addition to our internal research and development efforts, in October 2020, we invested in SYNAPS, whose product, Discern, is a test for early Alzheimer's disease. In December 2022, we purchased a senior secured convertible promissory note of Monarch, maker of EndoTool, a technology-enabled approach to inpatient glycemic management. We do not have a distribution agreement for Discern or EndoTool.

Strategy

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

- ***Targeting customers with patients at risk of developing cardiac and vascular diseases.*** Healthcare providers use blood flow measurements as part of their assessment of a patient's cardiac and vascular condition. Our strategy is to keep marketing QuantaFlo on a recurrent revenue model to insurance plans and medical personnel who care for those older than 50 years, including cardiologists, internists, nephrologists, endocrinologist, podiatrists, and family practitioners. Specifically, we believe there are more than 400,000 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 cardiac and vascular diseases. Based on U.S. Census data, the evaluable patient population for QuantaFlo is estimated to be more than 80 million patients in the United States annually.
- ***Expanding the tools available to internists and non-peripheral vascular experts.*** Our intention is to provide a tool to internists and non-cardiovascular experts, for whom it was previously impractical to conduct a blood flow measurement unless in a specialized vascular laboratory. For cardiovascular specialists, QuantaFlo does not require the use of blood pressure cuffs (which should not be used on some breast cancer patients), and measures without blood pressure in obese patients and patients with non-compressible, hard, calcified arteries. Currently, these patients often are unable to be measured satisfactorily with traditional devices.
- ***Developing additional product and service offerings that allow healthcare providers to deliver cost-effective wellness and receive increased compensation for their services.*** In March 2015, we received FDA 510(k) clearance of our product, QuantaFlo, reflecting several updates and modifications to the original model that were developed in conjunction with our consultant engineering groups. We recently began marketing QuantaFlo as an aid to measure hemodynamics related to heart dysfunction and continue to explore potential new product and service offerings through our research and development programs. Our goal is to provide cost-effective wellness solutions for our growing, established customer base, achieve a reputation for outstanding service, all while leveraging our gains in the marketplace for such product and service offerings.
- ***Exploring additional product and service offerings through arrangements or potential acquisitions.*** In addition to our in-house research and development efforts, we are also seeking out opportunities

to expand our product and service offerings through marketing, distribution and licensing arrangements, such as our agreement to exclusively market and distribute Insulin Insights line in the United States, including Puerto Rico. Such arrangements will allow us to sell products related to chronic disease management through our network of physicians and other customers. We may also consider opportunistically acquiring additional products if we believe they fit within our strategy.

Sales and Marketing

We provide our QuantaFlo product to our customers through our salespersons, who have experience selling products and services to our anticipated market.

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

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

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

We have an agreement with Mellitus to exclusively market and distribute Insulin Insights, a new software product, in the United States, including Puerto Rico, except for selected accounts. Under this April 2021 agreement as amended in December 2022, we pre-paid for an aggregate $2.5 million of licenses ($2.0 million in April 2021 and $0.5 million in December 2022. We signed several customers to a license for this product in late 2022. As of December 31, 2022, we had not generated any material revenues from this product.

Manufacturing

We manufacture our product, QuantaFlo, in the United States through independent contractors whom we pay for finished goods. Our contracts provide for subassemblies, product final assembly, test, serialization, finished goods, inventory and shipping operations. Our current contracts will remain in force until terminated by us upon three months written notice, or until terminated by either party for cause. Although we believe we have a good working relationship with our current contract manufacturers, there are many such qualified contract manufacturers available around the country should we need to replace them or if they are not able to meet demand as we grow our business as anticipated. While our current independent contract manufacturers source some supplies from China, we believe QuantaFlo is relatively easy to manufacture, and should we encounter issues due to supply chain disruptions as a result of the ongoing COVID-19 pandemic or other global supply chain constraints, we believe alternative sources should be available. We employ a consultant vendor qualification expert to monitor and test the quality controls and quality assurance procedures of our contract manufacturer.

Competition

The principal competitor for QuantaFlo is the standard blood pressure cuff ABI device. QuantaFlo does not include a blood pressure cuff. There are several companies that manufacture the traditional ABI device, which range in price from $2,500 to $20,000. Some of these companies are much larger than us and have more financial resources and their own distributor network. The traditional ABI devices are differentiated by the degree of automation designed into each product. ABI devices that rely more heavily on operator assessment (*i.e.*, listening to the return of pulse while decreasing cuff pressure), are thought to have less objectivity in their measurement. Because standard ABI devices require a better trained operator, the products

are usually sold to specialized vascular labs that are supervised by a vascular surgeon, with the tests performed by a licensed vascular technician. It is not uncommon for such ABI devices to be marketed to the offices of internists, podiatrists, endocrinologists or most cardiologists.

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

Competitors are beginning to market competing digital devices seeking to provide fast results that may be used outside of a specialized vascular laboratory. Given the potential size of the market, we expect competitors to continue to enter the space.

Research and Development Program

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

Clinical Experience

Several studies of our blood flow measurement products have been conducted by our customers or authors facilitated by access to our database. Other studies were conducted by our customers using their own independently generated datasets.

One of these studies, the results of which were compiled in 2012 and published in a peer reviewed journal in 2013, sought to determine the frequency of finding undiscovered vascular disease in primary care practices using our vascular testing product. In the study of 632 patients at 19 office practices, the frequency of flow obstruction was 12% and of these patients, 75% did not have classic symptoms of PAD. Among other limitations of the study, the publication mentioned 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 was designed to assess the side-by-side performance of our vascular testing product compared with traditional analog ABI with Doppler measurements in medical practices. In the study of 181 limbs from 121 patients at 5 medical practices during 2012 and 2013, three techniques were used on all limbs: our test, traditional analog ABI with Doppler, and Duplex ultrasound imaging as a gold standard. Traditional analog ABI with Doppler was unable to perform a conclusive study in 8.7% of limbs. In the remaining limbs, our vascular testing product and the ABI with Doppler measurements were in agreement, or in other words concordant, in 78% of limbs. Among the discordant limbs, Duplex imaging judged that the true positive rate of our vascular testing product was significantly higher than that of ABI with Doppler by a 2 to 1 margin. The results of the study are available as a white paper that may be shown to potential customers or other interested parties. Among other limitations of the study, the study had a small sample size, was conducted at specialty practices not primary care practices, had a retrospective design with incomplete collection of demographic information and clinical characteristics of the population, was not peer reviewed and was not peer reviewed.

Another study also was designed to assess the side-by-side performance of our vascular testing product compared with traditional analog ABI with Doppler measurements in medical practices. In this prospective study at five medical practices during 2013 through 2015, 360 limbs from 180 patients were examined with

three techniques: Our vascular testing product, traditional analog ABI with Doppler, and Duplex ultrasound imaging as a gold standard. Results demonstrated that our test demonstrated greater sensitivity, greater accuracy and equivalent specificity compared to ABI with Doppler measurements. The results of the study are available as a white paper. Among limitations of the study are that it had a small sample size, was conducted at a mix of primary care and specialty practices, had no formal tracking of consecutive patients, and was not peer reviewed.

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

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

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

Women may lack early detection programs and have inadequate preventive disease management. A study was compiled and published in a peer reviewed journal in 2019 that presented a retrospective analysis of 68,402 female patients tested with our product at primary care medical practices in the United States. The author concluded that our product was an efficient means to aid in the diagnosis of PAD in vulnerable women who are currently underserved by their health care providers. Limitations of the study include that it was a retrospective analysis with self-reporting of clinical characteristics.

A February 2022 published peer-reviewed study analyzed screening tests using QuantaFlo for undetected and asymptomatic heart failure in a Medicare Advantage population between January 2016 and December 2016. In this study, 13,971 patients were tested and 31.6% had a positive result for PAD. Almost 60% had lower socio-economic income level with 15.1% living under the poverty level. The risk associated with detecting PAD was substantial with a 60-70% increased risk of all-cause mortality or morbidity at one year and a 40-50% increased risk of all-cause mortality or morbidity at three years. The risk was not modified by a history of coronary or cerebrovascular artery disease. The authors concluded that these findings highlight an enormous potential to realize cost-savings by reducing cardiovascular event rates and deploying population-based PAD risk mitigation strategies. Among other limitations of the study, the publication mentioned that they were not able to study the potential impact of PAD risk management strategies used after a positive PAD screen was communicated with the primary care provider and patient. This may have led to an underestimation of the true risk as targeted PAD risk management and behavior modification strategies may have been initiated at the discretion of the provider and patient.

A September 2022 a peer-reviewed study under real-world conditions, illustrating the benefits of PAD in-home screening was published. The study analyzed screening tests using QuantaFlo for Medicare Advantage beneficiaries aged ≥65 years participating in the Optum HouseCalls program in the U.S. between April 1, 2017 and February 1, 2019. Of the 192,500 patients tested in their homes, 27.7% had a positive result for PAD. One-year all-cause mortality, 1- and 2-year major adverse cardiovascular events (MACE), and major adverse limb events (MALE) in the PAD positive patients were all significantly increased versus those patients who screened negative for PAD ($p < .001$). Moreover, the severity of the test results was associated with worse outcomes. The authors stated, "Detecting previously undiagnosed peripheral artery disease is a way to risk stratify a population that would benefit from further cardiovascular risk management." Among other limitations of the study, the publication mentioned that the findings are only generalizable to individuals aged ≥65 years and the study could not assess the proportion of deaths due to cardiovascular causes.

A February 2023 a peer-reviewed study was published assessing the accuracy our vascular testing product using cardiac echocardiography (Echo) as a gold standard of heart failure. Results were that our test showed a significant correlation with Echo ($p<.01$). Among other limitations of the study, the publication mentioned that data on severity were not including and outcomes following preventative measures were not studied.

Patents and Licenses

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

Government Regulation

U.S. Food and Drug Administration Regulation

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

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

FDA's Pre-market Clearance and Approval Requirements

To commercially distribute QuantaFlo or any future medical device we develop requires or will require either prior 510(k) clearance or prior approval of a pre-market approval, or PMA, application or de novo classification from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either class I or II, which requires the manufacturer to submit to the FDA a

pre-market notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to FDA's "general controls", which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions through the submission of Medical Device Reports, or MDRs, and appropriate, truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to FDA's general controls and any other "special controls" deemed necessary by FDA to ensure the safety and effectiveness of the device, such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. 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. To market low to moderate risk devices that are automatically placed into class III, a manufacturer may request a de novo classification from FDA. Both pre-market clearance, PMA applications and de novo classification requests 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 authorization, 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 a PMA application or a device that has been reclassified from class III to class II or class I. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics, or (ii) different technological characteristics, but the information provided in the 510(k) submission demonstrates that the device does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the notification is submitted, 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 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.

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 studies 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 FDA determines that a PMA application is sufficiently complete to permit a substantive review, 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 the QSR, which impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended

to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

De Novo Classification Pathway

Device types that the FDA has not previously classified as class I, II or III are automatically classified into class III regardless of the level of risk they pose. To market low to moderate risk devices that are automatically placed into class III due to the absence of a predicate device, a manufacturer may request a de novo classification. This procedure allows a manufacturer whose novel device is automatically classified into class III to request classification of its device into class I or II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. A device may be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent or a manufacturer may request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 days following receipt of the de novo classification request, although in practice, the FDA's review may take significantly longer. If the manufacturer seeks reclassification into class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the device. The FDA may reject the de novo classification request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. In the event FDA determines the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, FDA will grant the de novo request for classification. When FDA grants a de novo request for classification, the device is granted marketing authorization and further can serve as a predicate for future devices of that type through a 510(k) premarket notification.

Clinical Trials

Clinical trials are typically required to support a PMA and often for a de novo classification request, and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational devices, and specify an array of recordkeeping, reporting and monitoring responsibility of study sponsors and study investigators. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to submit an IDE application to the FDA, which must be approved prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, purported or represented to be used in supporting or sustaining human life, is for a use that is substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. A clinical trial may begin 30 days after receipt of the IDE application by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. Acceptance of an IDE application for review does not guarantee that the FDA will approve the IDE and, if it is approved, the FDA may or may not determine that the date derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before

a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

In addition, the study must be approved by, and conducted under the oversight of, an institutional review board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin a specific number of investigational sites with a specific number of patients, as approved by the FDA.

If the device is considered a "non-significant risk," an IDE application to the FDA is not required. Instead, only approval from the IRB overseeing the investigation at each clinical trial site is required. Abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements also apply to non-significant risk device studies.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all applicable reporting and record keeping requirements.

Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a clinical trial is completed, there can be no assurance that the data generated during a clinical study will meet the safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval. Information about certain device clinical trials must be posted on clinicaltrials.gov.

Pervasive and Continuing FDA Regulation

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

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

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

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- recall or seizure of our products;

- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or pre-market approval or de novo classification of new products;
- withdrawing pre-market approvals that are already granted or reclassifying the devices; and
- criminal prosecution.

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

Third-Party Coverage and Reimbursement

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

Physician coding for procedures is established by the American Medical Association. CMS, the agency responsible for administering Medicare and Medicaid, and the National Center for Health Statistics, are jointly responsible for overseeing changes and modifications to billing codes used by hospitals for reporting inpatient procedures, and many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. All physician and hospital coding is subject to change, which could impact coverage and reimbursement and physician practice behavior. We do not track denial of requests for reimbursement made by the users of QuantaFlo. It is our belief that such denials have occurred and might occur in the future with more or less frequency. We are not in the business of performing QuantaFlo measurements that require us to seek reimbursement from third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, commercial health insurers, including those that offer Medicare Advantage plans, and managed care programs. Many of our customers are third-party payors who pay us directly for use of our product and services.

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

Particularly in the United States, third-party payors carefully review, have undertaken cost-containment initiatives, and increasingly challenge, the prices charged for procedures and medical products as well as any technology that they, in their own judgment, consider experimental or investigational. In addition, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval or pre-authorization of the services that a

member will receive. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined amount per member per month. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

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

Healthcare Fraud and Abuse

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

The federal Anti-Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The federal Anti-Kickback Law is subject to evolving interpretations. For example, the government has enforced the federal Anti-Kickback Law to reach large settlements with healthcare companies based on, among other things, inappropriate consultant arrangements with physicians or questionable joint venture arrangements. The majority of states also have anti-kickback laws, which establish similar prohibitions that may apply to items or services reimbursed by any third-party payor, including commercial insurers. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Health Care Reform Law, among other things, amended the intent requirement of the federal Anti-Kickback Law and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Health Care Reform Law provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act and certain criminal healthcare fraud statutes.

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

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

The Health Care Reform Law also included the federal Physician Payments Sunshine Act, which requires device manufacturers for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program to disclose annually to CMS any "transfer of value" made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other licensed

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

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

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

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

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

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

Healthcare Reform

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. For example, the Health Care Reform Law significantly changed the health care industry and brought a new way of doing business for providers and health insurance plans.

There have been executive, judicial and Congressional challenges to certain aspects of the Health Care Reform Law. For example, several executive orders were issued along with other directives designed to delay the implementation of certain provisions of the Health Care Reform Law or otherwise circumvent some of the requirements for health insurance mandated by the Health Care Reform Law. Concurrently, Congress

considered legislation that would repeal or repeal and replace all or part of the Health Care Reform Law. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Health Care Reform Law such as removing penalties, effective January 1, 2019, for not complying with the Health Care Reform Law's "individual mandate" to carry health insurance, delaying the implementation of certain Health Care Reform Law-mandated fees, and repealing the medical device excise tax. In June 2021, in an appeal from a lower court decision holding that the individual mandate under the Health Care Reform Law is unconstitutional, the United States Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the Health Care Reform Law. In January 2021, an executive order was issued to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Health Care Reform Law marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Health Care Reform Law. It is unclear how additional litigation or executive orders will impact the Health Care Reform Law and our business.

Other legislative changes have been proposed and adopted in the United States since Health Care Reform Law. For example, through the process created by the Budget Control Act of 2011 and subsequent legislation, there are automatic reductions of Medicare payments to providers of generally 2% per fiscal year; these reductions went into effect in April 2013 and except for a period of temporary relief that was afforded in response to the COVID-19 public health emergency will remain in effect through fiscal year 2031 unless additional Congressional action is taken.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to cost-containment initiatives within the health care industry. We cannot predict what healthcare reform initiatives may be adopted in the future, particularly in light of the new presidential administration. Further, it is possible that additional governmental action is taken in response to the ongoing COVID-19 pandemic or other global pandemics.

Human Capital Management

As of December 31, 2022, we had 127 employees, all of which were full-time. None of our employees are represented by a labor union, and we consider our relationship with our employees to be positive. We also regularly engage consultants and subcontractors on an as-needed basis. We increased our head count in the fiscal year 2022 from 124 to 127, which represents a 2% increase from the prior year. As we grow our business, we expect to continue to experience growth in the number of our employees, particularly in the areas of sales, marketing, and distribution.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. We use different incentive plans such as annual cash bonuses, no-cost healthcare for employees and their families, paid vacation and generous referral bonuses to attract, retain and motivate our employees.

Governance and Culture — Our board of directors, including committees thereof, and executive management team are actively involved in overseeing our employee-related strategies and practices as well as our company culture. Our director of human resources and her team are also actively involved in implementing these decisions. We believe our company culture has been a critical component of our success in attracting and retaining personnel.

Diversity and Inclusion — We aim to create an inclusive working environment where all employees are respected and treated equally. We value diversity of backgrounds and perspectives and our policy is that we do not discriminate based on race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, military and veteran status, sexual orientation or any other protected characteristics established by federal, state or local laws. This message is emphasized from the top of our organization down to all of our employees.

Health, Safety and Well-Being — The safety and well-being of our employees is critical to our successful operation. Our health and safety activities are overseen by our board of directors, executive management team and director of human resources. Most of our employees work remotely, with the exception of a few employees who work in the office. These employees are generally in fulfillment and sales support roles. Our human resources department coordinates on-line training programs with the help of outside consultants. We believe that this model of training better fits our business operations and needs.

Response to COVID-19

As a virtual company, we believe we were better prepared than many at home offices to deal with the effects of the global spread of the still ongoing COVID-19 pandemic. As a result of governmental restrictions mandating "shelter-in-place" or similar limitations, which at the time resulted in our sales personnel eliminating travel, we increased the use of our on-line platforms and created new means to replace training methods and hands-on interactions with the customers that we relied on pre-pandemic. To date, we have not terminated any of our employees due to the pandemic. We continue to closely monitor the COVID-19 situation and, if needed, will evolve our plans and policies to keep our employees and customers safe.

ITEM 1A. RISK FACTORS

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

Risks Related to Our Business

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

Our business strategy was formed based on assumptions about the cardiac and vascular diseases market and healthcare reform that might prove wrong. We believe that various demographics and industry-specific trends, including the aging of the general population, growth of capitated payment programs, numbers of undiagnosed patients with cardiac and vascular or other diseases and the importance of codifying vascular disease and potentially other diseases will help drive growth in the cardiac and vascular diseases market and our risk assessment business. However, these demographics and trends, and our assumptions about them, are uncertain. Actual demand for our products and service offerings could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternatives to our products or other risk assessment service providers gain widespread acceptance. Moreover, if our customers do not believe they can benefit from increased capitated payments by identifying sicker patients in their patient pools, they may not see the benefit in screening patients for PAD or heart dysfunction using our products, which would have material and adverse effect on our business, financial condition and results of operations. Recently CMS issued an Advance Notice, which proposes to revise the HCC codes for vascular disease, created uncertainty in the future whether identifying patients with PAD or heart dysfunction will qualify for an increased capitated payment. Although the Advance Notice is not final and is open to public comment, there may be uncertainty regarding proper HCC codes and reimbursement, which could negatively impact our business.

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. Although we recently began distributing licenses to Insulin Insights, there is no guarantee that we will be successful or that our customers will be interested in this software, which we view as complementary to QuantaFlo. We also mutually terminated a distribution agreement for a different product line in November 2021, and in the fourth quarter of 2021 wrote down $1.2 million of inventory that we had acquired, as our expectations regarding the marketing and distribution of this product line did not prove to be accurate. We may also need to develop or acquire rights to other products and services that would be of interest to our customers given the patient populations they serve. In addition, we are seeking to increase our sales and, in order to do so, might need to continue 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 or changes in the regulatory landscape that may undermine the economic rationale for QuantaFlo. Our attempts to alter aspects of our business strategy, such as our recent entry into an exclusive marketing and distribution agreement and our investments in private companies, may not yield positive effects on our business, results of operations and financial condition. Any delay or failure to implement our business strategy may adversely affect our business, results of operations and financial condition.

Our business has been and could continue to be adversely affected by the ongoing COVID-19 pandemic.

Our business has been and could continue to be adversely affected by the global ongoing COVID-19 pandemic. In the first half of 2020, we experienced decreased test volumes due to "social distancing" and other executive orders mandating "shelter-in-place" or similar restrictions, which limited patient visits by our customers, and restricted participation in trade shows and in-person training, among other items. The testing volume decrease primarily affected revenues from our variable-fee licenses, which are based on usage of our QuantaFlo product, often during home visits by our customers. The extent to which COVID-19 may continue to impact us will depend on a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope and severity of the pandemic, business closures or other business disruptions, including supply chain disruptions and labor shortages, and the effectiveness of actions taken in the United States and other countries to contain and treat COVID-19, including global vaccination efforts. Any recurrence or subsequent "wave" of COVID-19 cases, including those caused by new variants, could cause other widespread or more severe impacts depending on where infection rates are highest.

We predominantly market only one FDA-cleared cardiac and vascular testing product; it may not achieve broad market acceptance or be commercially successful. We may also fail to generate meaningful revenues from our Insulin Insights distribution arrangement, which includes prepaid licenses, or benefit from our recent investments in other companies developing complementary products.

We currently actively market only one cardiac and vascular testing product, QuantaFlo, and have an agreement to exclusively market and distribute Insulin Insights, a new software product line in the United States, including Puerto Rico, for which we have prepaid an aggregate of $2.5 million of software licenses ($2.0 million in April 2021 and $0.5 million in December 2022). We also have a minority investment in, NeuroDiagnostics Inc., doing business as SYNAPS Dx, which is developing an additional potentially complementary product offering, Discern, although such product is in early stages and may not ultimately fit with our strategy and customer base. In December 2022, we committed to loan up to $5.0 million through the purchase of a senior convertible promissory note to Monarch, a digital health company whose proprietary product, EndoTool, offers a technology-enabled approach to inpatient glycemic management. We do not have any distribution agreement for Discern or EndoTool and we may never generate meaningful revenues from distribution of our prepaid licenses for Insulin Insights. Moreover, there is a risk that we may never receive repayment of our loans to Mellitus or Monarch, nor receive any benefit from our equity investment in SYNAPS Dx. Accordingly, we expect that revenues from our cardiac and vascular testing product will account for the vast majority of our revenues for at least the next several years.

Our cardiac and vascular testing product, including our recent extension of QuantaFlo to aid in diagnosis of heart dysfunction, and any other products we may be offering in the future, may not gain broad market acceptance unless we continue to educate physicians and plans of their benefits. Moreover, even if insurance plans, home health care providers and physicians understand the benefits of cardiovascular and other risk assessment testing, they still may elect not to use our products for a variety of reasons, such as familiarity with other devices and approaches, or the impact of the recent CMS Advance Notice, which may change the regulatory landscape for HCC codes and could impact the perceived profitability of using QuantaFlo to aid diagnosis of cardiovascular diseases. 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. Providers may also object to renting an examining tool with ongoing 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. Providers may also not synch their devices as required per their service contracts in the fee-per-test (variable license fees) model, and thus we may not capture all revenue to which we are entitled.

If our cardiac and vascular testing product, QuantaFlo, our diabetes software, Insulin Insights, or other products we may offer are not viewed 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 any products we offer are not commercially successful or are 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 and other customers 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 and other customers will not widely adopt our vascular testing product or our other products in development or products we distribute unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of such product provides a safe and effective alternative to other existing ABI devices.

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

Moreover, we acquired exclusive distribution rights to a new product area and may in the future acquire rights to other complementary products. If we are not able to convince potential customers of their benefits, these rights and potential future rights may not generate any meaningful revenues for our company.

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

Maintaining and growing revenues from our products and service offerings depends on the availability of coverage and adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Healthcare providers that use medical devices such as our cardiac and vascular testing product to test their patients generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices, or to compensate them for their patient care services. The existence of coverage and adequate reimbursement for the procedures or patient care performed with our cardiac and vascular testing product by third-party payors is central to the acceptance of our cardiac and vascular testing product and any future products. During the past several years, third-party payors have undertaken cost-containment initiatives including different payment methods, monitoring healthcare expenditures, and anti-fraud initiatives. We may not be able to achieve or maintain profitability if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Further, many private payors use coverage decisions and payment amounts determined by CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and/or hospitals or may undermine the economic rationale for using QuantaFlo if there is no increased capitated payment for the vascular diseases it helps diagnose. The recent CMS Advance Notice has created uncertainty about whether identifying patients with PAD or heart dysfunction will qualify for an increased capitated payment. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures or patient care performed with our vascular testing product. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures or patient care performed with our cardiac and vascular testing product if any payment is made at all. As the portion of

the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures or patient care performed with our product will be reimbursed at a cost-effective level.

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

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

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

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

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

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

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

We face significant challenges and risks in managing our distribution network and retaining the parties who make up that network. We had 81 sales and marketing employees as of December 31, 2022. If any of our sales or marketing force were to resign, our sales could be adversely affected. 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 a 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 and any new products we add, we may need to increase our sales and marketing network, which will require us to hire, train, retain and supervise employees and other independent contractors.

We are currently exploring other sales models to generate revenues from our products in addition to the leasing model, such as our fee per test model. We also have exclusive distribution rights to a new product area and may in the future acquire rights to other complementary products. As we increase our marketing efforts to pursue these new strategies and expand our efforts to target insurance plans that serve Medicare Advantage members, we may need to increase our sales and marketing network. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives, independent sales representatives or distributors with significant technical knowledge about our product, in addition to coordinating networks of contract medical assistants and other personnel to staff health and wellness fairs and physicians' offices in fee-for-service models. New hires and independent contractors require training, supervision and take time to achieve full productivity. If we fail to train and supervise new hires adequately, or if we experience high turnover in our sales force or trained professionals in the future, we cannot be certain that we will maintain or increase our sales. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our cardiac and vascular testing product or our other products and service offerings in development, which would adversely affect our business, results of operations and financial condition.

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

Our business is primarily based on a leasing model rather than an outright sale of our products although we also generate variable fee revenues, which are based on usage (fee-per-test). Our pricing is based on data collected on use rates and third-party payment rates to physicians and facilities for the use of our product. We require no down payment, long-term commitment or maintenance contract or fees from our customers and replace damaged products free of charge in the service model. If we lose current customers on short notice, we may not be able to find new customers to replace them with in a timely manner and that could adversely affect our business, results of operations and financial condition. In addition, our business model of replacing damaged products free of charge may prove to be costly and affect the profitability of our service model. In our fee-per-test model, we rely on our customers to comply with the terms of service that require them to synchronize devices on a regular and routine basis such that we are able to invoice them for the tests done using our device. There is a risk that customers use our device without synching as agreed, which could lead to inadequate billing and failing to capture revenue based on actual usage. Although we have procedures in place to limit usage of our device if it has not synchronized for a period of time, there is no guarantee that our customers will act in compliance with their terms of service and we may not appropriately capture all per-test fees to which we are entitled.

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

A limited number of customers account for a significant portion of our revenues and accounts receivable. For the year ended December 31, 2022, two customers accounted for 40.4%, and 29.0% of our revenues, and as of December 31, 2022, three customers accounted for 26.8%, 25.9% and 16.8% of our accounts receivable. If our largest customers were to cease using or stop payment for our vascular testing devices, it would have a material adverse effect on our revenues and/or our accounts receivable. Our efforts to diversify and potentially expand our product offering such as by distributing licenses to Insulin Insights, are preliminary in nature. This concentration of revenues and accounts receivable among a limited number of customers represents a significant risk.

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

We manufacture our cardiac and vascular testing product through a small number of independent contractors based in the United States. We also purchase inventory under our exclusive marketing and

distribution agreement with Mellitus. The loss or disruption of our relationships with outside vendors and suppliers could subject us to substantial delays in the delivery to customers. Our current contractor manufacturers source some supplies from China and should these outside vendors encounter issues due to supply chain disruptions as a result of the ongoing COVID-19 pandemic or otherwise, we believe alternative suppliers should be available. However, significant delays in the delivery of our product or inventory to us could result in possible cancellation of orders and the loss of customers. Although we expect our vendors and suppliers to comply with our contract terms, we do not have control over such parties. Our inability to provide a product that meets delivery schedules could have a material adverse effect on our reputation in the industry, which could have a material adverse effect on our financial condition and results of operations.

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

We will need to generate significant revenues to remain profitable.

We will need to generate significant sales to maintain profitability and we might not be able to do so. Even if we do generate significant sales, we might not be able to sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we anticipate or if our operating expenses exceed our expectations, our financial performance will likely be adversely affected.

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

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

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

One of our business strategies is developing additional products and service offerings that allow healthcare providers to deliver cost-effective wellness programs 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 programs and receive increased compensation for their services. Such product and service offering development may require substantial investments and we may commit significant resources and time before knowing whether our efforts will translate into profits for our company. We may continue to choose to invest some of our cash resources in other entities that may

have complementary technologies or product offerings and may not realize the benefit of such investments. For example, in November 2021 we mutually terminated a distribution agreement for a product line and wrote down $1.2 million of inventory. It is possible that our development efforts will not be successful and that we will not be able to develop new products or service offerings, either alone or in partnership with others, or if developed that we will obtain the necessary regulatory approvals for commercialization. Even if we receive necessary regulatory approvals, there is no guarantee that such approved products or any new service offerings will achieve market acceptance and we may never realize the benefits of any investment in this strategy.

We have used our cash resources to invest in other companies, and there is no guarantee that we will be repaid on maturity nor realize any other expected benefits from such investments, which could harm our business.

From time to time, we have invested, and may in the future invest, in other companies with potentially complementary products or technologies. For example, in September and October 2020, we made investments in Mellitus and SYNAPS Dx, two private companies working in other product areas, Discern and Insulin Insights (for which we have an exclusive distribution agreement) and in December 2022, we extended a loan to Monarch, maker of EndoTool. There can be no assurance that the businesses we invest in will become profitable or remain so or that we will realize any financial benefit from our investments, including whether or not we will distribute Discern and EndoTool or realize any benefits from our efforts to distribute Insulin Insights, or that we will be repaid upon maturity of our loans. Additionally, investments in privately held companies are inherently risky, in some instances because the markets for the technologies or products these companies have under development may never materialize or achieve expectations. If these companies do not succeed, we may be forced to record impairment charges and could lose some or all of our investment in these companies. Further, we may need to divest our investments or increase our investment to become a controlling interest sooner than we may like in order to comply with regulations regarding the amount of our assets represented by minority investments. These regulatory requirements may not always coincide with our business objectives and could adversely affect our investments and strategy.

Risks Related to Our Legal and Regulatory Environment

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

Our cardiac and vascular testing product and any future medical devices that we may develop or services that we may offer are subject to extensive regulation in the United States by the federal government, including by the FDA. For example, our operations are subject to regulations governing packaging and labeling requirements, adverse event reporting, quality system and manufacturing requirements, clinical testing and recalls. For a discussion of the relevant regulatory regime, see "Business — Government Regulation." We cannot assure that any new medical devices or new uses or modifications for our cardiac and vascular testing product that we develop will be cleared or approved in a timely or cost-effective manner, if cleared or approved at all. Even if such clearances or approvals are received, they may not be for all indications. Because medical devices may only be marketed for cleared or approved indications, this could significantly limit the market for that product and may adversely affect our results of operations.

Furthermore, although QuantaFlo has received FDA clearance, we must make our own determination regarding whether a modification to the device requires 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. We also may need to undertake a recall of any modified product that has been distributed.

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

The FDA may change its policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay pre-market approval or 510(k) clearance of a device, or could impact our

ability to market our currently cleared device. Future reforms could require us to file new 510(k) clearances and could increase the total number of 510(k) clearances 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, untitled letters or other forms of more significant enforcement action. More specifically, if FDA concludes that we are not in compliance with applicable laws or regulations, or that our vascular testing product or any future medical device we develop is ineffective or poses an unreasonable health risk, the FDA could:

- require us to notify health professionals and others that our devices present unreasonable risk of substantial harm to public health;
- order us to recall, repair, replace or refund the cost of any medical device that we manufactured or distributed;
- detain, seize or ban adulterated or misbranded medical devices;
- refuse to provide us with documents necessary to export our product;
- refuse requests for 510(k) clearance or pre-market approval of new products or new intended uses;
- withdraw 510(k) clearances that are already granted or reclassify our device;
- 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.

We may rely on third parties to support certain aspects of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory clearance or approval or commercialize our products, and our business could be substantially harmed.

We have retained the services of knowledgeable external service providers, including consultants and clinical research organizations, to develop and supervise our clinical trials and regulatory processes. We will remain dependent upon these third-party contract research organizations and consultants to carry out portions of our clinical and preclinical research studies and regulatory filing assistance for the foreseeable future. As a result, we have had and will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events, and the management of data developed through the trials than would be the case if we were relying entirely on our own staff. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. Failure by these third parties to comply with regulatory requirements or to meet timing expectations may require us to repeat clinical trials or preclinical studies, which would delay the regulatory clearance or approval process, or require substantial unexpected expenditures.

If we are found to have improperly promoted our products for off-label uses, we may become subject to significant fines and other liability.

FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. For example, devices cleared under section 510(k) cannot be marketed for any intended use that is outside of FDA's substantial equivalence determination for such devices. Physicians nevertheless may use our products on their patients in a manner that is inconsistent with the intended use cleared by FDA.

If we are found to have promoted such "off-label" uses, we may become subject to significant government fines and other related liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

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

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

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

Further, the Health Care Reform Law encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, as well as other bundled payment initiatives, which may ultimately result in the reduction of medical device acquisitions and the consolidation of medical device suppliers used by hospitals. Changes to or repeal of the Health Care Reform Law could adversely affect our financial results and business.

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

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

Additionally, the government has continued to pursue an increasing number of enforcement actions. This increased enforcement environment may increase scrutiny of us, directly or indirectly, and could increase the likelihood of an enforcement action targeting us. 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.

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

As of December 31, 2022, we had no federal NOL carryforwards. Federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. In

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

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

In prior years, we have identified certain material weaknesses in connection with management's evaluation of our internal control over financial reporting that we have remedied. These weaknesses have included issues arising from our size and inability to segregate duties; ineffective design of certain of our information technology and change management controls; insufficient controls to validate the completeness and accuracy of underlying data; insufficient protocols and procedures to retain adequate documentary evidence related to the timely review and approval of manual journal entries and those supporting the design and operating effectiveness of certain important management review controls; a lack of controls to identify and analyze related party transactions; a lack of technical accounting competence; and inadequate procedures and controls to appropriately comply with, and account for, certain payroll tax withholdings and related expenses.

Although we have remedied our prior material weaknesses, we cannot assure you that we have identified all material weaknesses or that we will not in the future have additional, or recurrence of our prior, material weaknesses in our internal control over financial reporting. If we have 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.

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, 2022, we have been issued, or have rights to, one U.S. patent. The patent we hold may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on this patent. These risks are also present for the process we use for manufacturing our product. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our product, either in the United States or in international markets. The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. We may institute, become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product and technology, including interference or derivation proceedings before the U.S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to

infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. The defense and prosecution of intellectual property suits, USPTO proceedings and related legal and administrative proceedings are both costly and time consuming. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings.

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

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

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

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

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

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

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

In addition to seeking patents for some of our technology and product, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and

consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party infringed a patent or illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Common Stock

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

Our executive officers, directors and significant stockholders beneficially own in the aggregate shares representing approximately 47.0% of our common stock as of March 16, 2023. If these stockholders choose to act together, they are able to substantially influence the outcome of 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 impact the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may:

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

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

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

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

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

Our amended and restated bylaws designate exclusive forums for the adjudication of certain disputes, which could limit our stockholders' ability to bring claims in a judicial forum it finds favorable for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that a state or federal court located within the State of Delaware is the sole and exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee or stockholder of our company to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our charter or our bylaws, as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim governed by the internal affairs doctrine.

Our amended and restated bylaws further provide that a federal district court of the United State is the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These provisions further provide that any person or entity that acquires any interest in shares of our capital stock will be deemed to have notice of and consented to these provisions.

These provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find any of these provisions to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

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

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

General Risk Factors

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

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

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

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

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

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

To meet business objectives, we rely on both internal information technology systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research and patient data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these information technology systems and networks, and the confidentiality, integrity, and availability of our sensitive data. We continually assess these threats and make investments to increase internal protection, detection, and response capabilities, as well as ensure our third-party providers have required capabilities and

controls, to address this risk. To date, we have not experienced any material impact to our business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for us to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. At December 31, 2022, we held approximately $30.1 million of U.S. Treasury bills, and the remainder of our cash was held in non-interest bearing bank accounts, primarily at First Republic Bank and Edward Jones, and we are taking steps to diversify further. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any financial instruments (such as letters of credit) were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected.

Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of government securities with interest rates below current market interest rates, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect our company, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general.

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

The market for medical systems, equipment and other devices and services is highly competitive. We compete with many medical service companies in the United States and internationally in connection with

our vascular testing product and products under development. We face competition from numerous companies in the diagnostic area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our cardiac and vascular testing product or any other future products, if and when they are approved for sale or license, or service offerings that we may develop. Our future success will depend largely upon our ability to anticipate and keep pace with developments and advances. Current or future competitors could develop alternative technologies or products or service offerings that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products or service offerings become obsolete or uncompetitive, our related revenues would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

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 or in claiming tax credits or taking other tax positions. During the ordinary course of business, there are many transactions for which the ultimate tax determination is uncertain or if we were to be audited, the Internal Revenue Service may not agree with our tax positions. 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 and practices are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. The results of an audit or litigation, or the effects of a change in tax policy in the United States, could have a material effect on our operating results in the period or periods for which that determination is made. In addition, new income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our earnings. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

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

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Our common stock has been trading on the Nasdaq Stock Market LLC under the symbol "SMLR" since September 27, 2021.

Holders

On March 16, 2023, the closing sale price of a share of our common stock was $19.73 per share and there were 6,844,512 shares of our common stock outstanding. On that date, our shares of common stock were held by approximately 33 stockholders of record. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of our common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

Dividends

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

Securities Authorized for Issuance Under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

Not applicable.

Issuer Purchases of Equity Securities

Not applicable.

ITEM 6. Reserved

Not applicable.

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

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

Overview

We are a company providing technology solutions to improve the clinical effectiveness and efficiency of healthcare providers. Our mission is to develop, manufacture and market innovative proprietary products and services that assist our customers in evaluating and treating chronic diseases. Our patented and FDA cleared product, QuantaFlo, which measures arterial blood flow in the extremities to aid in the diagnosis of PAD, and as an aid to measure hemodynamics related to heart dysfunction.

We have an agreement with Mellitus, a private company to exclusively market and distribute Insulin Insights, an FDA-cleared software product that recommends optimal insulin dosing for diabetic outpatients in the United States, including Puerto Rico, except for select accounts. We have also made cash investments in Mellitus, in Monarch, a privately-held a digital health company whose proprietary product, EndoTool, offers a technology-enabled approach to inpatient glycemic management, and in NeuroDiagnostics Inc., a privately-held company that is doing business as SYNAPS Dx, whose product, Discern is a test for early Alzheimer's disease. We continue to develop additional complementary proprietary products in-house (such as our recently released QuantaFlo extension as an aid to measure hemodynamics related to heart dysfunction), and seek out other arrangements for additional products and services that we believe will bring value to our customers and to our company. We believe our current products and services, and any future products or services that we may offer, position us to provide valuable information to our customer base, which in turn permits them to better guide patient care.

In the year ended December 31, 2022, we had total revenues of $56.7 million and net income of $14.3 million compared to total revenues of $53.0 million and net income of $17.2 million in 2021. We had an income tax expense of $3.4 million in 2022, compared to $2.2 million in 2021. Our pre-tax net income was $17.7 million in 2022 compared to $19.5 million in 2021.

Recent Developments

On March 14, 2022, our Board of Directors authorized a share repurchase program under which we may repurchase up to $20.0 million of our outstanding common stock. Under this program, we may purchase shares on a discretionary basis from time to time through open market purchases, privately negotiated transactions or other means, including through Rule 10b5-1 trading plans or through the use of other techniques such as accelerated share repurchases. The timing and amount of any transactions will be subject to our discretion and based upon market conditions and other opportunities that we may have for the use or investment of our cash balances. The repurchase program has no expiration date, does not require the purchase of any minimum number of shares and may be suspended, modified or discontinued at any time without prior notice. We purchased 148,500 shares of our common stock for approximately $5.0 million during the twelve months ended December 31, 2022.

In May 2022, we acquired $179 thousand aggregate principal amount of outstanding convertible notes of Mellitus, which bear interest at a rate of 10% per annum, and as amended, mature July 2025, if not automatically converted into preferred stock prior thereto. We acquired these notes to facilitate their subordination in connection with our June 2022 purchase of an aggregate $1.0 million of senior secured notes, that bear interest at a rate of 5% per annum and mature in three years, unless accelerated due to an event of default as provided in the notes. Repayment of these notes is secured by a first priority interest in all of Mellitus' assets. In December 2022, we amended our April 2021 distribution agreement with Mellitus to

prepay for an additional $0.5 million of licenses (for an aggregate $2.5 million when including the $2.0 million of licenses prepaid in April 2021).

In December 2022, we announced a commitment to loan up to $5.0 million to Monarch, a Nevada limited liability company, through the purchase of a senior secured convertible promissory note that bears interest at a rate of 10% per annum. The note also contemplates payment of up to $100 thousand of transaction expenses. Repayment of the note is secured by a first priority interest in all of Monarch's assets. Monarch is a digital health company whose proprietary EndoTool offers a technology-enabled approach to inpatient glycemic management. The software-as-a-service solution is FDA 510(k) cleared, patent protected and installed at more than 100 health systems across the United States. We believe the investment in Monarch complements our offering of Insulin Insight, a glycemic management software application that healthcare providers can use to optimize outpatient insulin dosing for persons with diabetes. As of December 31, 2022, Monarch had borrowed $3.5 million, out of the $5.0 million committed. In January 2023, Monarch borrowed an additional $0.5 million from the balance of the note.

In February 2023, CMS issued an Advance Notice, which proposes to revise the HCC codes for vascular disease, created uncertainty in the future whether identifying patients with PAD or heart dysfunction will qualify for an increased capitated payment. Although the Advance Notice is not final and is open to public comment, there may be uncertainty regarding proper HCC codes and reimbursement, which could negatively impact our business.

Sources of Revenues and Expenses

Revenues

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

Cost of revenues

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

Engineering and product development expense

Our engineering and product development expense consists of costs associated with the design, development, testing and enhancement of our cardiac and vascular testing product and other products in

development. We also include salaries and related employee benefits, research-related overhead expenses and fees paid to external service providers in our engineering and product development expense.

Sales and marketing expense

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

General and administrative expense

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

Total other income and expense

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

Critical Accounting Policies and Estimates

Our accounting policies are more fully described in Note 2 of the Financial Statements. As disclosed in Note 2, the preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following discussion addresses the Company's most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments.

Accounting for income taxes

Significant management judgment is required in determining our provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets in accordance with GAAP. These estimates and judgments occur in the calculation of tax credits, benefits, and deductions and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes, as well as the interest and penalties related to uncertain tax positions. Significant changes to these estimates may result in an increase or decrease in our tax provision in the current period or subsequent periods.

Factors Affecting Future Results

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

Results of Operations

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Revenues

We had revenues of $56.7 million for the year ended December 31, 2022, compared to $53.0 million in 2021. Our revenues are primarily from fees charged to customers for use of our products and from sale of accessories used with these products. We recognized revenues of $55.3 million from fees for our products in 2022, consisting of $34.0 million from fixed-fee licenses and $21.3 million from variable-fee licenses, compared to $52.0 million in 2021, consisting of $30.5 million from fixed-fee licenses and $21.5 million from variable-fee licenses. The remainder was from other equipment/supply sales of accessories, which were $1.4 million in 2022 as compared to $1.0 million in 2021.

Revenues from fees for products are recognized monthly, usually billed as a fixed monthly fee or as a variable monthly fee dependent on usage. The primary reason for the increase in revenues was growth in the

number of installed units from both new customers and established customers, which we believe is the result of our sales and marketing efforts.

Operating Expenses

We had total operating expenses of $39.5 million for the year ended December 31, 2022, compared to $33.6 million in 2021. The primary reason for this change was overall growth in our business, increased compensation of the sales team and increased headcount of field sales and technical support personnel to service the expanding number of customers. As a percentage of revenues, operating expenses increased to 70% in 2022, as compared to 63% in 2021. The changes in the various components of our operating expenses are described below.

Cost of Revenues

We had cost of revenues of $4.3 million for the year ended December 31, 2022, compared to $6.1 million for 2021. The primary reasons for this change were that 2021 includes a $1.2 million inventory write-down due to cancellation of the distribution agreement, as well as lower consulting expenses in 2022, which were partially offset by increased personnel costs due to increased headcount and annual salary increases. As a percentage of revenues, cost of revenues decreased to 8% in 2022, as compared to 12% in 2021.

Engineering and Product Development Expense

We had engineering and product development expense of $4.8 million for the year ended December 31, 2022, compared to $3.8 million in 2021. The increase was primarily due to personnel, consulting fees and other costs associated with our product development and customization efforts, which were partially offset by lower clinical studies. As a percentage of revenues, engineering and product development expense was 9% in 2022 compared to 7% in 2021.

Sales and Marketing Expense

We had sales and marketing expense of $17.7 million for the year ended December 31, 2022, compared to $14.4 million in 2021. The increase was primarily due to higher sales compensation and personnel expense, trade shows expenses, travel expenses and subscriptions expenses. In the prior year we could not travel, attend trade shows or contact the customers personally due to COVID. As a percentage of revenues, sales and marketing expense increased to 31% in 2022 compared to 27% in 2021.

General and Administrative Expense

We had general and administrative expense of $12.7 million for the year ended December 31, 2022, compared to $9.2 million in 2021. The increase was primarily due to employee compensation related expenses, higher insurance, patent and legal expenses and dues and subscriptions, partially offset by lower stock-based compensation and other miscellaneous expenses. As a percentage of revenues, general and administrative expense was 23% in 2022, compared to 17% in 2021.

Other Income and Expense

We had other income of $0.5 million for 2022, compared to $10 thousand in 2021. The increase was primarily due to interest income associated with higher rates on short term government debt and money market funds, as well as interest from notes receivable.

Provision for Taxes

In 2022, we recorded an income tax expense of $3.4 million, compared to $2.2 million in 2021. The increase was primarily due to lower windfall gains resulting from the exercise of stock options compared to the prior year.

Net Income

For the foregoing reasons, we had a net income of $14.3 million for the year ended December 31, 2022, compared to a net income of $17.2 million for the year ended December 31, 2021.

Liquidity and Capital Resources

We had cash and cash equivalents and short-term investments of $43.1 million at December 31, 2022, compared to $37.3 million at December 31, 2021, and total current liabilities of $6.9 million at December 31, 2022, compared to $4.9 million at December 31, 2021. As of December 31, 2022, we had working capital of approximately $42.1 million. We believe that our current sources of funds will provide us with adequate liquidity during the 12-month period following December 31, 2022, as well as in the long-term.

Our cash is held in a variety of non-interest bearing bank accounts and three-month treasury bills. At December 31, 2022, we held approximately $30.1 million of U.S. Treasury bills, and the remainder of our cash was held in non-interest bearing bank accounts. We have banking relationships with First Republic Bank and Edward Jones, and are taking steps to diversify further. Our investment guidelines allow for holdings in U.S. government and agency securities, corporate securities, taxable municipal bonds, commercial paper, money market accounts and treasury bills. In addition, we have, and may in the future, choose to invest some of our cash resources in other entities that may have complementary technologies or product offerings.

Operating Activities

We generated $17.5 million of net cash from operating activities for the year ended December 31, 2022, compared to $16.1 million for the year ended December 31, 2021. The improvement was primarily due to changes in non-cash adjustments and operating assets and liabilities. Non-cash adjustments to reconcile net income to net cash from operating activities were $1.5 million in the year ended December 31, 2022, compared to $3.4 million in the year ended December 31, 2021, primarily due to stock-based compensation expense, depreciation expense, and loss on disposal of leased assets, partially offset by an increase in deferred tax expense. Prior year adjustments of $3.4 million were due to a $1.2 million inventory write-off, an increase of stock-based compensation and depreciation, partially offset by a decrease in deferred tax expense. Changes in operating assets and liabilities provided $1.7 million of net cash in the year ended December 31, 2022, compared to used $4.6 million of net cash in the year ended December 31, 2021, primarily due an increase of accrued expenses and trade payables due to timing of payments to the vendors, decrease of prepaid and other current assets, partially offset by increase in other non-current assets and trade receivable.

Investing Activities

We used $26.8 million of net cash in investing activities for the year ended December 31, 2022, compared to $0.8 million of net cash in investing activities for the year ended December 31, 2021. The increase was primarily attributable to purchase of short-term treasury bills of $20 million, notes held for investments of $4.7 million, an increase in purchase of assets for lease and an increase of property, plant and equipment.

Financing Activities

We used $4.9 million of net cash in financing activities during the year ended December 31, 2022, compared to generating $13 thousand during the year ended December 31, 2021, primarily due to the treasury stock acquisition of $5.0 million, under our recently announced share purchase program, and taxes paid related to equity awards of $0.1 million, partially offset by the exercise of stock options of $0.2 million.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Under the supervision of and with the participation of our management, including our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance, we evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2022. Based upon that evaluation, our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). We maintain internal control over financial reporting designed to provide reasonable, but not absolute, assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Therefore, internal control over financial reporting determined to be effective provides only reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our Chief Executive Officer, our Senior Vice President, Finance and Accounting and our Vice President, Finance, our management evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022. In making its assessment of internal control over financial reporting, our management used the criteria described in the 2013 Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our evaluation included documenting, evaluating and testing the design and operating effectiveness of our internal control over financial reporting. Based on this evaluation, we concluded that we maintain effective internal control over financial reporting as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors and Executive Officers

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

Name	Age	Position	Director Since	Term Expires
Douglas Murphy-Chutorian, M.D.[(1)]	68	Chief Executive Officer and Director	September 2012	2024
Andrew B. Weinstein	58	Senior Vice President, Finance and Accounting	N/A	N/A
Daniel E. Conger	46	Vice President, Finance	N/A	N/A
Arthur "Abbie" Leibowitz, M.D., F.A.A.P.	76	Director	June 2014	2023
Daniel S. Messina	67	Director	August 2020	2024
Cindy H. Moon	46	Director	November 2020	2023
Wayne T. Pan, M.D., Ph.D.	59	Director	May 2014	2025

(1) On March 19, 2023, Dr. Murphy-Chutorian notified our board of directors of his intent to resign as our chief executive officer. In light thereof, on March 21, 2023, our board of directors appointed Wayne T. Pan as his successor effective as of April 3, 2023.

Board of Directors

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

Arthur "Abbie" Leibowitz, M.D., F.A.A.P., — Dr. Arthur "Abbie" Leibowitz has served as a member of our board of directors since June 2014. Dr. Leibowitz has over 50 years of experience in healthcare, with more than 35 years in leading positions with several healthcare companies. Dr. Leibowitz is the chief medical officer and president emeritus at Health Advocate, Inc., a health advocacy and assistance company he co-founded in 2000 that provides support and helps consumers navigate the healthcare system. In June 2014, Health Advocate, Inc. became a wholly owned subsidiary of the West Corporation. West Corporation was in turn acquired and taken private by Apollo Global Management, LLC in October 2017. In July 2021, Teleperformance (TEP.PA), a global leader in digitally integrated business solutions acquired Health Advocate. Health Advocate Inc.'s clients include more than 12,000 small, medium, and large sized companies, not-for-profit organizations and associations, schools, colleges and universities, unions, health plans, and third-party administrators across the United States. Prior to his role at Health Advocate, Inc., Dr. Leibowitz served as executive vice president of digital health strategies and a member of the board of

directors at Medicologic, Inc., where he was responsible for developing healthcare data, information services and strategies targeted at users of the company's electronic medical record system, as well as data customers including payors, pharmaceutical companies, employers, regulatory and government agencies. Dr. Leibowitz served as vice president, medical delivery systems and chief medical officer at Aetna U.S. Healthcare, from 1996 to 2000, where he directed medical affairs and policies for one of the largest health benefits companies in the nation. In this role he was responsible for clinical policy development, technology assessment, patient management activities, and quality improvement programs. From 1993 to 1996, Dr. Leibowitz was the vice president, health delivery, corporate medical director at U.S. Healthcare, where he coordinated the expansion of medical programs regionally into eight new markets. Dr. Leibowitz had also served as vice president, health delivery, and a network medical director at U.S. Healthcare, from 1987 to 1993. From 1975 to 1987, Dr. Leibowitz was the senior physician at Drexel Hill Pediatric Associates, where he established seven physician pediatric group practice serving a large and diverse urban/suburban patient population. Dr. Leibowitz has authored many articles in the medical literature and has made numerous media appearances. Dr. Leibowitz received both his B.A. and M.D. degrees from Temple University. We believe Dr. Leibowitz's extensive background, experience and knowledge of the healthcare industry qualify him to be a director of our company.

Daniel S. Messina — Daniel S. Messina has served as a member of our board of directors since August 2020. Mr. Messina has nearly 40 years of broad business experience as both a healthcare system professional and a technology solutions entrepreneur. Mr. Messina is the co-founder of HandsFree Health, the creator of WellBe®, the premier voice enabled virtual health assistant platform designed to help individuals access their health and wellness resources from home. Prior to co-founding HandsFree Health in 2016, he was a partner of West Corporation's health advocate division for ten years, and he concluded his time there as co-president. From 2002 to 2006, Mr. Messina was the president of Rendina Healthcare Real Estate. Before that, from 2000 to 2002, Mr. Messina served as chief executive officer and president of Magellan Health and from 1998 to 2000 as the chief financial officer and head of business strategy of Aetna Health. For the decade prior to that, he was vice president of Financial Reporting at Cigna Corporation. Mr. Messina began his career as a certified public accountant at Deloitte. Mr. Messina earned a Bachelor of Science in accounting from the University of Notre Dame. We believe Mr. Messina's extensive experience in virtual health and healthcare systems qualifies him to be a director of our company.

Cindy Moon — Cindy Moon has served as a member of our board of directors since November 2020. Ms. Moon, a D.C.-based, healthcare payment policy expert, is vice president of Health Care Payment and Delivery Reform with Hart Health Strategies Inc., a bipartisan consulting and lobbying firm specializing in legislative and regulatory health care issues. Prior to joining Hart Health Strategies Inc., Ms. Moon worked at the White House Office of Management and Budget (OMB) where she advised on policy solutions affecting the Medicare program. In this role, Ms. Moon collaborated with federal stakeholders across the Executive Office of the President, the Department of Health and Human Services Office of the Secretary, and the Centers for Medicare and Medicaid Services (CMS) to oversee implementation of major payment and programmatic changes to the Medicare program. Prior to joining OMB, Ms. Moon held successively increasing leadership positions within the Health Plan of San Mateo, a quasi-public health plan offering publicly-sponsored health coverage for qualifying residents of San Mateo County, California. Ms. Moon earned her Master of Public Policy and Master of Public Health from the University of California at Berkeley and her Bachelor of Arts from Harvard University. We believe Ms. Moon's extensive experience in shaping federal healthcare policy and promoting high-value care qualifies her to be a director of our company.

Wayne T. Pan, M.D., Ph.D., MBA — Dr. Wayne T. Pan, M.D., Ph.D. has served as a member of our board of directors since May 2014 and was appointed as chief executive officer in March 2023 effective April 3, 2023. Dr. Pan has over 20 years of broad healthcare industry experience from clinical medicine, to managed care, health information technology and biotechnology. Prior to his appointment as chief executive officer, from May 2022 through March 2023, Dr. Pan served as medical director at Banner Health, Insurance Division, responsible for all of Banner's Medicare Programs, including HMO, PPO and D-SNP. Prior to Banner, from June 2021 to May 2022, he was co-founder and chief medical officer of Salusive, Inc., a technology-enabled healthcare services company, based in Emeryville, CA, providing chronic care management and remote patient monitoring services to help physicians manage older adults with chronic conditions, leveraging a proprietary NLP/AI platform that enhances the effectiveness of clinical coaches in real-time as they connect with their patients. From May 2018 to June 2021, he was employed by BioMarin

Pharmaceutical Inc., a biotechnology company based in Novato, CA, initially as a medical director in Global Medical Affairs, functioning as the Global Medical Lead for products in development and marketed products treating the mucopolysaccharidoses (MPS) diseases, Morquio A (MPS IVA), Maroteaux-Lamy (MPS VI) and Sanfilippo B (MPS IIIB) syndromes. In January 2021 he moved to the Product Portfolio Development organization as a director, core team leader supporting the PKU gene therapy program. He is also a part-time medical director at San Francisco Health Plan, since May 2014, responsible for utilization management, appeals and grievances and quality improvement programs. From April 2016 to February 2018, he was a medical director in Quality of Care and Health Economics and Outcomes Research, US Medical Affairs at Genentech, Inc., a biotechnology company based in South San Francisco. Earlier in his career, Dr. Pan was a practicing fellowship-trained orthopedic hand surgeon, a CMO at several regional Medicaid/ Medicare Advantage health plans, and CMO of medical groups in the San Francisco Bay Area. Dr. Pan holds an M.B.A. from The Wharton School, University of Pennsylvania and an M.D. and Ph.D. from the Mt. Sinai School of Medicine, and a B.S. in Biology from Johns Hopkins University.

There are no family relationships among any of our directors or executive officers.

Executive Officers

Andrew B. Weinstein — Mr. Weinstein has served as our Senior Vice President, Finance and Accounting since October 2018. He previously served as the Vice President of Accounting since joining our company in March 2017. From May 2006 until joining our company, Mr. Weinstein served as Vice President, Controller and member of senior management at Health Advocate, Inc., a health advocacy and assistance company that provides support and helps consumers navigate the healthcare system. During his tenure at Health Advocate, Mr. Weinstein was responsible for all accounting, finance, payroll, benefits and financial reporting activities of the company and its four subsidiaries, leading a team of eighteen people. He also served as a director of two of Health Advocate's subsidiaries. Prior to joining Health Advocate, Mr. Weinstein was Chief Financial Officer and General Manager for Service Plus Distributors, Inc. (SPD) and SPD Division, a Barnes Group. Previously, he was a forensic accountant and economic analyst for Barach & Company and Supervising Senior Accountant at KPMG. Mr. Weinstein received a B.S. in Accounting from Pennsylvania State University and is a Certified Public Accountant (Pennsylvania).

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

Director Independence

As required under the Nasdaq listing standards, a majority of the members of our board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our board of directors consults with our outside counsel to ensure that its determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members and our company, our senior management and our independent auditors, our board of directors has affirmatively determined that the following four directors are independent directors within the meaning of the applicable Nasdaq listing standards: Dr. Leibowitz, Mr. Messina, Ms. Moon, and Dr. Pan. In making this determination, the board of directors found that none of these directors had a material or other disqualifying relationship with our company.

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

Changes to Procedures for Recommending Nominees to Board of Directors

None.

Audit Committee

Our board of directors has established a separately designated standing audit committee, which is currently comprised of Dr. Pan, who serves as both member and Chairman, Mr. Messina, and Ms. Moon. Our board of directors has determined that Mr. Messina qualifies as an "audit committee financial expert" within the meaning of the SEC's rules. In connection with Dr. Pan assuming the role of chief executive officer effective April 3, 2023, Dr. Leibowitz will join the audit committee replacing Dr. Pan, and Mr. Messina will assume the role of Chairman.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the year ended December 31, 2022, all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were in compliance, other than one Form 4 filing by Douglas Murphy Chutorian, reporting an option exercise and 10b5-1 plan sales of the shares; one Form 4 by each of Cindy Moon, Wayne T. Pan,and Arthur Leibowitz reporting their annual non-employee director stock awards; and two Form 4s by Daniel Messina, in each case reporting the grant of stock awards.

Code of Ethics

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

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth the information as to compensation paid to or earned by our (i) principal executive officer and (ii) the two most highly compensated executive officers other than our principal executive officer. These individuals are referred to in this annual report on Form 10-K as our named executive officers, and were our only executive officers during the year ended December 31, 2022. As none of our named executive officers received any stock awards, option awards or nonqualified deferred compensation earnings during the years ended December 31, 2022 and 2021, we have omitted those columns from the table.

Name and Principal Position	Fiscal Year	Salary ($)[1]	Bonus ($)	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total ($)
Douglas Murphy-Chutorian, M.D., director and chief executive officer	2022	$450,000	$ 0	$400,000	$20,459	$870,459
	2021	$400,000	$ 0	$400,000	$71,395	$871,395
Andrew B Weinstein, senior vice president, finance and accounting	2022	$353,750	$72,000	$ 0	$29,491	$455,241
	2021	$322,500	$66,000	$ 0	$46,201	$434,701
Daniel E. Conger, vice president, finance	2022	$216,500	$43,300	$ 0	$29,491	$289,291
	2021	$210,000	$44,500	$ 0	$44,328	$298,828

(1) For Mr. Weinstein, reflects a salary increase effective March 15, 2022.

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

(3) Represents payment of health insurance premiums pursuant to the terms of employment agreements.

Named Executive Officer Compensation Arrangements

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

Douglas Murphy-Chutorian, M.D.

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

In 2022, Dr. Murphy-Chutorian's base salary was $450,000, with target incentive equal to 89% of base salary with up to $100,000 achievable per fiscal quarter based on certain predefined performance objectives.

Andrew B. Weinstein

On March 14, 2017, we entered into an at-will employment agreement with Mr. Weinstein, our senior vice president, finance and accounting. Under the terms of the agreement, Mr. Weinstein can be terminated at any time and his job titles, salaries and benefits may be modified from time to time as we deem necessary. Effective March 15, 2022, Mr. Weinstein's base salary was increased to $360,000 (from $330,000), with a discretionary bonus of $72,000 (increased from $66,000).

Daniel E. Conger

On October 18, 2010, we entered into an at-will employment agreement with Mr. Conger, our vice president of finance. Under the terms of the agreement, Mr. Conger can be terminated at any time and his job titles, salaries and benefits may be modified from time to time as we deem necessary. In 2022, Mr. Conger's base salary was $216,500, with a discretionary bonus of $43,300. Effective January 1, 2023, Mr. Conger's base salary is $229,000, with a discretionary bonus of $45,800.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information about the number of outstanding equity awards held by our named executive officers at December 31, 2022. We have omitted certain columns from the table as our named executive officers do not have any outstanding stock awards.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
Douglas Murphy-Chutorian[1]	71,000	0	$2.10	11/08/2024
Douglas Murphy-Chutorian[1]	75,000	0	$1.96	12/31/2024
Douglas Murphy-Chutorian[1]	180,000	0	$3.44	07/20/2025
Douglas Murphy-Chutorian[1]	60,000	0	$2.56	12/31/2025
Douglas Murphy-Chutorian[1]	125,000	0	$2.23	02/17/2026
Douglas Murphy-Chutorian[1]	125,000	0	$1.72	01/19/2027
Douglas Murphy-Chutorian[1]	125,000	0	$8.00	12/31/2027
Andrew B. Weinstein[1]	30,000	0	$3.15	03/14/2027

(1) All the above options are fully vested.

Director Compensation

The following table shows the compensation earned in the year ended December 31, 2022 by our non-employee directors. Our non-employee directors received only cash director fees and stock awards in 2022, so we have omitted certain columns from the table. The compensation information for Dr. Murphy-Chutorian, our chief executive officer and a director, is set forth in " Summary Compensation Table." Dr. Murphy-Chutorian does not receive additional compensation for his services as an employee director.

Name	Fees Earned or Paid in Cash ($)[1]	Stock Awards ($)[2]	Total ($)
Arthur "Abbie" Leibowitz, M.D., F.A.A.P.	$67,500	$100,000	$167,500
Wayne T. Pan, M.D., Ph.D.	$75,000	$100,000	$175,000
Cindy H. Moon	$59,250	$100,000	$159,250
Daniel S. Messina[3]	$59,250	$175,000	$234,250

(1) Consists of the annual retainer fee for service as a non-employee member of the board of directors or any board committee. For further information concerning such fees, see the section below entitled "— Non-Employee Director Compensation Policy."

(2) Represents the grant date fair value of the awards computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, Compensation — Stock Compensation, or ASC 718.

(3) Stock grants to Daniel Messina include $75,000 for additional director services.

Non-Employee Director Compensation Policy

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

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

- $22,500 per year for service as chairman of the audit committee or $11,250 per year for service as a member of the audit committee;
- $15,000 per year for service as chairman of the compensation committee or $7,500 per year for service as a member of the compensation committee;
- $7,500 per year for service as chairman of the nominating committee or $3,000 per year for service as a member of the nominating committee;

Cash payments to non-employee directors are to be paid quarterly and will be pro-rated for directors who join the board or a board committee mid-year.

In January 2022, we provided equity compensation to each of our non-employee directors for service on our board consisting of 1,340 shares of our common stock, which awards were granted under the 2014 Stock Incentive Plan, or the 2014 Plan. The number of shares of common stock awarded was determined based on $100,000 divided by the closing price on the grant date and such stock awards were fully vested on the grant date. In February 2023, we granted common stock to each of our non-employee directors for service on our board consisting of 2,436 shares, which awards were granted under the 2014 Plan. The number of shares of common stock awarded was determined based on $100,000 divided by the closing price on the grant date and such stock awards were fully vested on the grant date.

We also granted Daniel Messina common stock awards in April, July and October of 2022 consisting of an aggregate 2,028 shares for additional director services related to of our investor relations function, which additional director stock awards were granted under the 2014 Plan. The number of shares of common stock awarded was determined based on $25,000 divided by the closing price on each such grant date and such stock awards were fully vested on the grant date.

Compensation-Related Risk

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

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

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 16, 2023 of:

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

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock and is based on 6,844,512 shares of common stock issued and outstanding as of March 16, 2023. Shares of our common stock subject to options or warrants that are currently exercisable or exercisable within 60 days after March 16, 2023 are considered outstanding and beneficially owned by the person holding the options or warrants for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in the following table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Information with respect to beneficial ownership by 5% stockholders has been based on information filed with the SEC pursuant to Section 13(d) or Section 13(g) of the Exchange Act, as well as our records. Except as otherwise set forth in the footnotes to the following table, the address of each beneficial owner is c/o Semler Scientific, Inc., 2340-2348 Walsh Avenue, Suite 2344, Santa Clara, CA 95051.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders:		
William H.C. Chang[(1)]	883,499	12.9%
Eric Semler	568,221	8.3%
AltraVue Capital, LLC[(2)]	437,227	6.4%
Topline Capital[(3)]	399,860	5.8%
Executive Officers and Directors:		
Daniel E. Conger	—	—
Dr. Arthur N. Leibowitz[(4)]	54,865	*
Cindy H. Moon[(5)]	8,211	*
Daniel S. Messina[(6)]	12,501	*
Dr. Douglas Murphy-Chutorian[(7)]	861,446	11.2%
Dr. Wayne T. Pan	47,554	*
Andrew B. Weinstein[(8)]	30,000	*
All directors and officers as a group (7 persons)	1,014,577	13.1%

* Less than 1%

(1) Includes (a) 300,000 shares held in four grantor retained annuity trusts for Mr. and Mrs. Chang , (b) 341,991 shares of our common stock held by the Chang Family Trust U/A DTD 10/23/2006, or the Chang Family Trust, for which Mr. and Mrs. Chang are co-trustees and share voting and investment control and (c) 241,508 shares of our common stock held by Chang 2020 GP LP, for which Mr. and Mrs. Chang are the managing members of its general partner, Chang 2020 GP, LLC, and share voting and investment control. The address for the Chang Family Trust, Chang 2020 GP LP, Mr. Chang and Mrs. Chang is 520 El Camino Real, 9th Floor, San Mateo.

(2) Shares are held by AltraVue Capital, LLC. The address of AltraVue Capital is 11747 N.E. 1st Street, Suite 205, Bellevue, WA 98005-3018.

(3) Shares are held by and for the benefit of Topline Capital Partners, LP ("TCP"). Topline Capital Management, LLC ("TCM") is the investment manager and general partner of TCP, and Collin McBirney, as the member manager of TCM, may be deemed to beneficially own the shares held by TCP. Each of TCM and Mr. McBirney expressly disclaims beneficial ownership of the shares held by TCP except to the extent of its pecuniary interest therein. The address for each of TCP, TCM and Mr. McBirney is 544 Euclid Street, Santa Monica, CA 90402.

(4) Includes 50,000 shares underlying options to purchase shares of our common stock.

(5) Includes 5,000 shares underlying options to purchase shares of our common stock.

(6) Includes 5,000 shares underlying options to purchase shares of our common stock.

(7) Includes (a) 761,000 share underlying options to purchase shares of our common stock and (b) 76,875 shares underlying warrants to purchase shares of our common stock. Options are held by Dr. Murphy-Chutorian. Other securities are held in a family trust over which Dr. Murphy-Chutorian is co-Trustee with his spouse, and with whom he shares voting and investment power over such securities.

(8) Represents 30,000 shares underlying options to purchase shares of our common stock.

Equity Compensation Plan Information

The following table sets forth information about our equity compensation plans as of December 31, 2022. We do not have any equity compensation plans that have not been approved by securityholders.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (#)	Weighted Average Exercise Price of Outstanding Options, Warrants and Rights ($)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (#)
	(a)	(b)	(c)
Equity Compensation Plans Approved by Securityholders:			
2014 Stock Incentive Plan[(1)]	1,354,722	$3.44	1,471,670
2007 Key Person Stock Option Plan	10,000	$3.85	0
Total	1,364,722	$3.44	1,471,670

(1) As of December 31, 2022, 1,471,670 shares of our common stock were available for issuance under the 2014 Plan and none under 2007 Plan. The number of shares reserved for issuance under the 2014 Plan will be increased on each January 1 through January 1, 2024, in an amount equal to 4% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year unless our board of directors acts prior thereto to set a lower number. Accordingly, on January 1, 2022, the share reserve under the 2014 Plan was increased by 270,338 shares.

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

The following includes a summary of transactions since January 1, 2021 to which we have been a party in which the amount involved exceeded or will exceed the lesser of (x) $120,000 or (y) 1% of our average total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Management — Summary Compensation Table — Named Executive Officer Compensation Arrangements." We also describe below certain other transactions with our directors, executive officers and stockholders.

Review, Approval or Ratification of Transactions with Related Persons

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

Employment of Immediate Family Members

We currently employ the brother-in-law and sister-in-law of Daniel E. Conger, our vice president, finance and since January 1, 2021 we have paid such individuals an aggregate of $388,573 in salary and bonus payments.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents fees for professional audit services rendered by BDO USA, LLP, or BDO, for the audit of our consolidated financial statements for the years ended December 31, 2022 and 2021. In addition to retaining BDO to conduct an audit of the financial statements, we engage the firm from time to time to perform other services. The following table sets forth all fees incurred in connection with professional services rendered to us by BDO during each of the last two fiscal years.

	Year Ended December 31,	
Fee Type	**2022**	**2021**
Audit Fees	$463,380	$350,700
Tax Fees	—	—
Total	$463,380	$350,700

Audit Fees. This category consists of the annual audit of our financial statements and the interim reviews of the quarterly financial statements.

Audit Committee Pre-Approval Policies and Procedures

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statements and Financial Statement Schedules

(1) Financial Statements:

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

(2) Financial Statement Schedules:

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

(3) Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on November 2, 2015).
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 of our Form 8-K filed with the Securities and Exchange Commission on October 26, 2021).
4.1	Specimen Common Stock certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 1 of our Form S-1 Registration Statement filed with the Securities and Exchange Commission on December 6, 2013).
4.2	Description of Capital Stock (incorporated by reference to Exhibit 4.2 of our Form 10-K filed with the Securities and Exchange Commission on March 4, 2022).
10.1	Form of Series A, Series A-1 and Series A-2 Preferred Stock Warrant (incorporated by reference to Exhibit 10.1 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.2†	Warrant Amendment (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 21, 2015).
10.3†	2007 Key Person Stock Option Plan (incorporated by reference to Exhibit 10.3 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.4†	Form of 2007 Key Person Stock Option Plan Option Grant Notice and Option Agreement (incorporated by reference to Exhibit 10.2 of our Form 10-Q filed with the Securities and Exchange Commission on November 3, 2015).
10.5†	2014 Stock Incentive Plan, dated August 26, 2014 (incorporated by reference to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on September 2, 2014).
10.6†	Form of 2014 Stock Incentive Plan Stock Option Grant Notice and Option Agreement (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed with the Securities and Exchange Commission on November 3, 2015).
10.7†	At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between Semler Scientific, Inc. and Douglas Murphy-Chutorian, M.D., dated November 11, 2013 (incorporated by reference to Exhibit 10.6 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).
10.8†	At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between Semler Scientific, Inc. and Daniel E. Conger, dated October 18, 2010 (incorporated by reference to Exhibit 10.5 of our Form S-1 Registration Statement, as amended (File No. 333-192362), filed with the Securities and Exchange Commission on November 15, 2013).

Exhibit No.	Description
10.9†	At-Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement between Semler Scientific, Inc. and Andrew B. Weinstein, dated March 14, 2017 (incorporated by reference to Exhibit 10.1 of our Form 8-K, filed with the Securities and Exchange Commission on October 5, 2018).
10.10	Form of Indemnification Agreement, approved and entered into between the Company and each of the Company's directors and executive officers as of July 24, 2014 (incorporated by referenced to Exhibit 10.1 of our Form 8-K filed with the Securities and Exchange Commission on July 29, 2014).
10.11	Service & Supply Agreement between Semler Scientific, Inc. and Phoenix DeVentures, Inc. dated as of April 28, 2011(incorporated by reference to Exhibit 10.8 to Amendment No. 1 of our Form S-1 Registration Statement filed with the Securities and Exchange Commission on December 6, 2013).
23.1*	Consent of BDO USA, LLP.
24.1*	Power of Attorney (included on the signature page attached hereto).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*(+)	Certification of Principal Executive Officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*(+)	Certification of Principal Financial Officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104.1*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101).

* Filed herewith

† Indicates a management contract or compensatory plan or arrangement

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

ITEM 16. FORM 10-K SUMMARY

Not Applicable.

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INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Semler Scientific, Inc.
Santa Clara, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Semler Scientific, Inc. (the "Company") as of December 31, 2022 and 2021, the related statements of income, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matter

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

Notes Held for Investment — Secured Convertible Promissory Note

As described in Notes 7, 8 and 13 to the financial statements, in December 2022, the Company entered in a senior convertible promissory note arrangement with Monarch, providing Monarch with up to $5 million in available funding, of which $3.5 million, in principle was drawn on December 6, 2022 (the "Note"). The Note accrues interest at 10% per annum, payable monthly commencing January 5, 2023, and the principal balance is due December 6, 2024. The Note can be converted into Monarch's shares at the Company's option under certain conditions.

We identified the evaluation of the accounting for the Note as a critical audit matter. The principal considerations for our determination were the evaluation as to whether the Note meets the definition of a

debt security under ASC 320, *Investments — Debt Securities* and is eligible for the election of fair value option under ASC 825, *Financial Instruments*. Auditing these elements involved especially challenging auditor judgment due to the nature and extent of audit effort required to address this matter, including the extent of specialized skills or knowledge needed.

The primary procedures we performed to address this critical audit matter included:

- Reviewing and analyzing (i) the terms of the agreement associated with the Note, (ii) the completeness and accuracy of the Company's technical accounting analysis, and (iii) the application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in the relevant technical accounting guidance to assist in: (i) evaluating relevant contract terms of the Note in relation to the appropriate accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2013
New York, NY
March 23, 2023

Semler Scientific, Inc.

Balance Sheets

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

	2022	2021
Assets		
Current Assets:		
Cash and cash equivalents	$23,014	$37,323
Short-term investments	20,073	—
Trade accounts receivable, net of allowance for doubtful accounts of $109 and $61, respectively	3,884	3,619
Inventory, net	469	550
Prepaid expenses and other current assets	1,468	4,044
Total current assets	48,908	45,536
Assets for lease, net	2,478	1,643
Property and equipment, net	667	394
Long-term investments	821	821
Notes held for investment	4,679	—
Other non-current assets	2,842	332
Long-term deferred tax assets	2,298	1,946
Total assets	$62,693	$50,672
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 835	$ 443
Accrued expenses	4,748	3,436
Deferred revenue	1,160	921
Other short-term liabilities	114	80
Total current liabilities	6,857	4,880
Long-term liabilities:		
Other long-term liabilities	160	245
Total long-term liabilities	160	245
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Common stock, $0.001 par value; 50,000,000 shares authorized; 6,906,544, and 6,824,380 shares issued, and 6,692,122, and 6,758,458 shares outstanding (treasury shares of 214,422 and 65,922), respectively	7	7
Additional paid-in capital	16,449	20,645
Retained earnings	39,220	24,895
Total stockholders' equity	55,676	45,547
Total liabilities and stockholders' equity	$62,693	$50,672

(See accompanying notes to financial statements)

Semler Scientific, Inc.

Statements of Income

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

	For the year ended December 31,	
	2022	**2021**
Revenues	$ 56,686	$ 53,027
Operating expenses:		
Cost of revenues	4,252	6,122
Engineering and product development	4,809	3,780
Sales and marketing	17,685	14,445
General and administrative	12,737	9,235
Total operating expenses	39,483	33,582
Income from operations	17,203	19,445
Interest income	494	10
Other expenses	5	—
Other income	489	10
Pre-tax net income	17,692	19,455
Income tax provision	3,367	2,233
Net income	$ 14,325	$ 17,222
Net income per share, basic	$ 2.13	$ 2.56
Weighted average number of shares used in computing basic income per share	6,726,687	6,731,693
Net income per share, diluted	$ 1.79	$ 2.12
Weighted average number of shares used in computing diluted income per share	7,999,750	8,138,608

(See accompanying notes to financial statements)

Semler Scientific, Inc.

Statements of Stockholders' Equity
(In thousands of U.S. Dollars, except share and per share data)

	Common Stock		Treasury Stock				
	Shares Issued	Common Stock Amount	Shares	Amount	Additional Paid-In Capital	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
Balance at December 31, 2020	6,725,422	$ 7	(25,000)	$ —	$22,113	$ 7,673	$29,793
Exercise of put option in SYNAPS Dx	—	—	(40,922)	—	(2,230)	—	(2,230)
Employee stock grant	5,516	—	—	—	512	—	512
Stock option exercises	93,442	—	—	—	58	—	58
Stock-based compensation	—	—	—	—	192	—	192
Net income	—	—	—	—	—	17,222	17,222
Balance at December 31, 2021	6,824,380	$ 7	(65,922)	$ —	$20,645	$24,895	$45,547
Treasury stock acquired	—	—	(148,500)	—	(4,991)	—	(4,991)
Employee stock grant	11,131	—	—	—	723	—	723
Taxes paid related to settlement of equity awards	(1,710)	—	—	—	(114)	—	(114)
Stock option exercises	72,743	—	—	—	168	—	168
Stock-based compensation	—	—	—	—	18	—	18
Net income	—	—	—	—	—	14,325	14,325
Balance at December 31, 2022	6,906,544	$ 7	(214,422)	$ —	$16,449	$39,220	$55,676

(See accompanying notes to financial statements)

Semler Scientific, Inc.

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

	For the years ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 14,325	$17,222
Reconciliation of Net Income to Net Cash Provided by Operating Activities:		
Depreciation	589	628
Deferred tax (income) expense	(351)	408
Loss on disposal of assets for lease	463	362
Gain on short-term investments	(77)	—
Loss on disposal of inventory	—	1,202
Allowance for doubtful accounts	103	63
Stock-based compensation	741	749
Changes in Operating Assets and Liabilities:		
Trade accounts receivable	(367)	(874)
Inventory	81	(1,412)
Prepaid expenses and other current assets	2,576	(2,657)
Other non-current assets	(2,510)	86
Accounts payable	392	(234)
Accrued expenses	1,310	638
Other current and non-current liabilities	188	(125)
Net Cash Provided by Operating Activities	17,463	16,056
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property and equipment	(476)	(318)
Purchase of short-term investments	(19,996)	—
Purchase of notes held for investment	(4,679)	—
Purchase of assets for lease	(1,684)	(507)
Net Cash Used in Investing Activities	(26,835)	(825)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Taxes paid related to net settlement of equity awards	(114)	(45)
Treasury stock acquired	(4,991)	—
Proceeds from exercise of stock options	168	58
Net Cash (Used in) Provided by Financing Activities	(4,937)	13
(DECREASE) INCREASE IN CASH	(14,309)	15,244
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	37,323	22,079
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 23,014	$37,323
Supplemental Disclosure of Cash Flow Information:		
Cash paid for taxes	$ 2,400	$ 2,647
Exercised put option of 211,928 common stock in SYNAPS Dx for 40,922 common stock of the company	$ —	$ 2,230

(See accompanying notes to financial statements)

1. The Company

We are a company providing technology solutions to improve the clinical effectiveness and efficiency of healthcare providers. The Company's mission is to develop, manufacture and market innovative products and services that assist our customers in evaluating and treating chronic diseases. The Company's patented and U.S. Food and Drug Administration, or FDA, cleared product, QuantaFlo, measures arterial blood flow in the extremities to aid in the diagnosis of peripheral arterial disease, or PAD, and serves as an aid to measure hemodynamics related to heart dysfunction.

In April 2021, the Company entered into an agreement, as amended in December 2022, with Mellitus Health, Inc, or Mellitus, a private company to exclusively market and distribute Insulin Insights, an FDA-cleared software product that recommends optimal insulin dosing for diabetic out-patients in the United States, including Puerto Rico, except for selected accounts. In December 2022 certain clauses of this agreement were amended, including an additional prepayment of $500 for licenses, making a total prepayment of $2,500 for licenses.

2. Summary of Significant Accounting Policies and Estimates

Basis for Presentation

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

Use of Estimates

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents, accounts receivable and trade payables. The Company maintains its cash with major financial institutions. The Company's cash consists of bank deposits held with banks that, at times, exceed federally insured limits. The cash and cash equivalents also include short term treasury bills with original maturities of three months or less. The Company manages its accounts receivable credit risk through ongoing credit evaluation of its customers' financial conditions. The Company generally does not require collateral from its customers. For information regarding the Company's significant customers and vendors, see Note 11 to financial statements.

Revenue Recognition

The Company generates revenues primarily from the rental or license of its vascular testing product. The Company recognizes revenues from the licensing of its product primarily pursuant to agreements that automatically renew each month with revenue recognized on a daily convention basis. The Company's arrangements with customers for its vascular testing product are normally on a month-to-month basis with

fees billed at the rates established in the customer agreement, either on a fixed or variable (e.g. fee per test) basis, as earned. The Company also recognizes revenue for hardware and supplies sales as of the date of shipment.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of highly liquid investments purchased with an initial maturity date of three months or less. Funds held as investments in money market funds are included within cash and cash equivalents.

Short-Term Investments

Short-term investments are those that can be readily converted into cash and also any investment instruments that will mature within one year or which are expected to be liquidated within one year. As of December 31, 2022, short-term investments represented a T-Bill that matured on March 2, 2023 and subsequently reinvested in similar instruments.

Accounts Receivable and Allowance for Doubtful Accounts

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

As of December 31, 2021, the allowance for doubtful accounts was $61. Net change due to credit losses during the year was $48. Allowance balance as of December 31, 2022 was $109.

Inventory

Inventory, which is made up of finished goods, is recorded at the lower of cost or net realizable value. Cost is determined on the first-in, first-out method. The Company periodically analyzes its inventory levels to identify inventory that has a cost basis in excess of its estimated realizable value, and writes down such inventory as appropriate.

Assets for Lease

Assets for lease are recorded at cost. At December 31, 2022 and 2021, assets for lease consisted of vascular testing devices, which are leased to customers. The cost of such assets for lease is depreciated on a straight-line basis over 36 months for the units outstanding and recorded as cost of revenues.

The Company regularly reviews whether facts and circumstances exist which indicate that the carrying amounts of assets, may not be recoverable or that the useful life of assets are shorter or longer than originally estimated. The Company assesses the recoverability of its assets by comparing the projected undiscounted net cash flows associated with the related assets over their estimated remaining lives against their respective carrying amounts. The Company considers factors such as estimated usage and expected lives of its assets for lease in this analysis. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets. At December 31, 2022 and 2021, there were no impairment indicators.

Property and Equipment

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

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

At December 31, 2022 and 2021, capital assets are classified into one of the following categories:

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

At December 31, 2022 and 2021, capital assets are depreciated based on the following estimated useful life for each category:

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

The Company regularly reviews whether facts and circumstances exist which indicate that the carrying amounts of capital assets, may not be recoverable or that the useful life of assets are shorter or longer than originally estimated. The Company assesses the recoverability of its assets by comparing the projected fair value of the related asset over the estimated remaining life against the respective carrying amounts. The Company considers factors such as estimated usage and expected lives of its capital assets in this analysis. Impairment, if any, is based on the excess of the carrying amount over the fair value of those assets. The Company did not have any impairments to record during either the years ended December 31, 2022, or 2021.

Impairment of Long-Lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the asset's carrying amount may not be recoverable. The Company conducts its long-lived asset impairment analyses in accordance with ASC 360-10-15, "Impairment or Disposal of Long-Lived Assets." ASC 360-10-15 requires the Company to group assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities and evaluate the asset group against the sum of the undiscounted future cash flows. If the undiscounted cash flows do not indicate the carrying amount of the asset is recoverable, an impairment charge is measured as the amount by which the carrying amount of the asset group exceeds its fair value based on discounted cash flow analysis or appraisals.

Fair Value of Financial Instruments

Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of the fair value hierarchy under Financial Accounting Standards Board (the "FASB") Accounting Standards Codification ("ASC") 820, Fair Value Measurement, are described as follows:

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

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

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

The financial instruments of the Company consist primarily of cash, money market accounts, receivable, and accounts payable. These items are considered Level 1 due to their short-term nature and their market interest rates and are therefore considered a reasonable estimate of fair value at December 31, 2022 and 2021. The Company classifies short-term investments within Level 1 in the fair value hierarchy, because quoted prices for identical assets in active markets are used to determine fair value. The Company estimates the fair value of the investment in debt security using Level 3 inputs. See Note 8 for description of methodologies and significant assumptions used in those valuations. The Company also invested in non-convertible promissory note, prepayment for inventory and equity securities of two privately held companies, which were recorded on cost basis. See Note 6,8 and 9 to the financial statements for more information.

Investment Valuation

The Company's investments in equity in privately held companies without readily determinable fair values, which are generally recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, less impairments. As part of its assessment for impairment indicators, the Company considers significant deterioration in the earnings performance and overall business prospects of the investee as well as significant adverse changes in the external environment these investments operate. If its qualitative assessment indicates the investments are impaired, the fair value of these equity securities would be estimated, which would involve a significant degree of judgment and subjectivity.

No impairment charges were recorded during the year ended December 31, 2022 and 2021.

Deferred Revenue

Deferred revenue represents amounts billed to or collected from customers for which the related revenues have not been recognized because one or more of the revenue recognition criteria have not been met. The full amount is expected to be recognized as revenues within one year from the balance sheet date and, therefore, such deferred amounts have been classified as current liabilities in the balance sheets presented. The Company generally invoices its clients in advance of a rental period with payment due upon receipt of the invoice. Revenue recognized for the year ended December 31, 2022 from amounts included in deferred revenue as of December 31, 2021 was $921. Revenue recognized for the year ended December 31, 2021 from amounts included in deferred revenue as of December 31, 2020 was $963.

Research and Development

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

Stock-Based Compensation

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

Employee Benefit Plan

The Company has a savings plan that qualifies under Section 401(k) of the Internal Revenue Code of 1986, as amended (the "Code"). Effective January 1, 2022, the Company started to match 50% of employee's 401(k) deferral up to a maximum of 6% of the employee's eligible earnings.

Income Taxes

The Company uses the asset and liability method to account for income taxes. Deferred tax assets and liabilities are recognized for the expected tax consequences attributable to the differences between financial reporting and the tax bases of existing assets and liabilities and net operating loss ("NOL") carryforwards, and they are measured using enacted tax rates expected to be in effect when differences are expected to reverse.

Recently Issued Accounting Pronouncements

Accounting Pronouncements Recently Adopted

In May 2021, the financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2021-04, *Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40) Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. This update provides guidance for a modification or an exchange of a freestanding equity-classified written call option that is not within the scope of another Topic. This update is effective for the Company's fiscal years beginning after December 15, 2021. The Company adopted this ASU prospectively effective January 1, 2022 and determined that the adoption of this new accounting standard did not have a material impact on its financial statements.

In July 2021, the FASB issued ASU No. 2021-05, *Leases (Topic 842): Lessors — Certain Leases with Variable Lease Payments*. This update addresses stakeholders' concerns by amending the lease classification requirements for lessors to align them with practice under Topic 840. Lessors should classify and account for a lease with variable lease payments that do not depend on a reference index or a rate as an operating lease if both of the following criteria are met: i) The lease would have been classified as a sales-type lease or a direct financing lease in accordance with the classification criteria in paragraphs 842-10-25-2 through 25-3, ii) the lessor would have otherwise recognized a day-one loss. This update is effective for the Company's fiscal years beginning after December 15, 2021. The Company adopted this ASU prospectively to the leases that commence or modified on or after January 1, 2022 and determined that the adoption of this new accounting standard did not have a material impact on its financial statements.

Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("Topic 326"). This ASU requires timelier recording of credit losses on loans and other financial instruments held. Instead of reserves based on a current probability analysis, Topic 326 requires the measurement of all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. All organizations will now use forward-looking information to better inform their credit loss estimates. Topic 326 requires enhanced disclosures regarding significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an organization's portfolio. These disclosures include qualitative and quantitative requirements that provide information about the amounts recorded in the financial statements. In addition, Topic 326 amends the accounting for credit losses on available-for-sale debt securities and purchased financial assets with credit deterioration. In April 2019, the FASB issued ASU No. 2019-04, *Codification Improvements to Topic 326 Financial Instruments — Credit*

Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments, to introduce amendments which will affect the recognition and measurement of financial instruments, including derivatives and hedging. In May 2019, the FASB issued ASU No. 2019-05, *Financial Instruments — Credit Losses (Topic 326);* Targeted Transition Relief. The amendments in this ASU provide entities that have certain instruments within the scope of Subtopic 326-20 with an option to irrevocably elect the fair value option in Subtopic 825-10, applied on an instrument-by-instrument basis for eligible instruments upon adoption of Topic 326. This standard and related amendments are effective for the Company's fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company will adopt the new standard in the first quarter of fiscal year 2023. The Company does not expect adoption of this standard will have a material impact on its financial statements on the adoption date. However, subsequently the impact will largely depend on the composition and credit quality of the Company's portfolio of financial assets and the economic conditions at the time of adoption.

In March 2020, FASB issued ASU No. 2020-03, *Codification Improvements to Financial Instruments*. This ASU improves and clarifies various financial instruments topics, including the current expected credit losses standard issued in 2016 (ASU No. 2016-13). The ASU includes seven different issues that describe the areas of improvement and the related amendments to GAAP, intended to make the standards easier to understand and apply by eliminating inconsistencies and providing clarifications. The amendments have different effective dates. The issues 1-5 are conforming amendments, which are effective upon issuance of this final update. The Company determined that issues 1-5 have no impact on its financials. The amendments related to issue 6 and 7 effect ASU No. 2016-13, *Financial instruments — credit losses (Topic 326): measurement of credit losses on financial statements*. Effective dates of issue 6 and 7 are the same as the effective date of ASU No. 2016-13. The Company will adopt the new standard in the first quarter of fiscal year 2023. The Company does not expect adoption of this standard will have a material impact on its financial statements.

In October 2021, the FASB issued ASU No.2021-08, *Business Combinations (Topic 805):* A*ccounting for Contract Assets and Contract Liabilities from Contracts with Customers*. This ASU improves the accounting for acquired revenue contracts with customers in a business combination by addressing diversity in practice and inconsistency related to recognition of an acquired contract liability and payment terms and their effect on subsequent revenue recognized by the acquirer. For public business entities, this guidance will be effective for fiscal years beginning after December 15, 2022 and for interim periods within those fiscal years. This ASU should be applied prospectively to all business combinations in the year of adoption. The Company will adopt the new standard in the first quarter of fiscal year 2023. The Company does not expect the adoption of this standard will have a material impact on its financial statements.

In March 2022, the FASB issued ASU No.2022-02, *Financial Instruments-Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures,* which eliminates the troubled debt restructuring accounting model in Accounting Standards Codification ("ASC") 310-40 for creditors that have adopted the guidance on measurement of credit losses in ASU 2016-13. Additionally, the ASU requires the public business entities to disclose current period gross writeoffs by year of origination for financing receivables and net investments in leases as part of their vintage disclosures under ASC 326. For entities that have adopted the amendments in ASU 2026-13, the amendments are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. For entities that have not yet adopted the amendments in ASU 2016-13, the effective dates are the same as effective dates in ASU 2016-13. The Company will adopt this ASU along with ASU 2016-13 in the first quarter of 2023. The Company does not expect the adoption of this standard will have a material impact on its financial statements.

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

3. Assets for Lease, net

The Company provides financing of certain equipment through operating leases (see Note 12 to the financial statements). Assets for lease consist of the following:

	As of December 31,	
	2022	2021
Assets for lease	$ 3,702	$ 3,241
Less: accumulated depreciation	(1,224)	(1,598)
Assets for lease, net	$ 2,478	$ 1,643

Depreciation expense amounted to $386 and $442 for the years ended December 31, 2022 and 2021, respectively. Reduction to accumulated depreciation for returned items was $352 and $310 for the years ended December 31, 2022 and December 31, 2021, respectively. The Company recognized a loss on disposal of assets for lease in the amount of $463 and $362 for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022 and 2021, total assets for lease, net, in use at customer locations were $518 and $631, respectively.

4. Inventory

As of December 31, 2022 and 2021, the inventory balance was $469 and $550, respectively. Inventory includes finished goods of light blocking bags and heel warmers.

5. Property and Equipment, net

Capital assets consist of the following:

	As of December 31,	
	2022	2021
Capital assets	$1,206	$ 882
Less: accumulated depreciation	(539)	(488)
Capital assets, net	$ 667	$ 394

Depreciation expense amounted to $203 and $180 for the years ended December 31, 2022 and 2021, respectively.

6. Long-Term Investments

Carrying value of non-marketable securities is measured as the total initial cost plus the cumulative net gain (loss). Carrying value of non-marketable equity investments consist of the following for the periods presented:

	As of December 31,	
	2022	2021
Investments in SYNAPS Dx	$512	$512
Investments in Mellitus Health Inc.	309	309
Total initial cost	$821	$821

In September 2020, the Company acquired a promissory note from NeuroDiagnostics Inc., which is doing business as SYNAPS Dx, in the principal amount of $500, $100 of which was retained for expense reimbursement. Subsequently, in December 2020, the Company agreed to convert the promissory note,

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

together with all accrued interest thereon, into shares of preferred stock of SYNAPS Dx as repayment in full of the promissory note. The value of the note exchanged for the shares of preferred stock of SYNAPS Dx held by the Company as of December 31, 2022 and 2021 was approximately $512.

In October 2020, the Company acquired from a seller a convertible promissory note previously issued by Mellitus Health Inc., ("Mellitus") to such seller for a purchase price of $59, which represented the $50 principal amount of the note and all accrued and unpaid interest thereon.

Subsequently, in October 2020, the Company purchased $250 of shares of preferred stock of Mellitus, and in connection with such transaction, the convertible promissory note, together with all accrued interest thereon, also converted pursuant to its terms into shares of preferred stock of Mellitus as repayment in full of such convertible promissory note. The value of consideration exchanged for the shares of preferred stock of Mellitus held by the Company as of December 31, 2022 and 2021 was approximately $309.

The investments in SYNAPS Dx and Mellitus securities that were retained by the Company as of December 31, 2022 were recorded in accordance with ASC 321, *Investments — equity securities,* which provides that investments in equity securities in privately-held companies without readily determinable fair values are generally recorded at cost, plus or minus subsequent observable price changes in orderly transactions for identical or similar investments, less impairments. The Company elected the practical expedient permitted by ASC 321 and recorded the above investments on a cost basis. As a part of the assessment for impairment indicators, the Company considers significant deterioration in the earnings performance and overall business prospects of the investee as well as significant adverse changes in the external environment these investments operate. If qualitative assessment indicates the investments are impaired, the fair value of these equity securities would be estimated, which would involve a significant degree of judgement and subjectivity.

The Company qualitatively assessed both investments for impairment in accordance with ASC 321. As of December 31, 2022, the Company determined that there was no impairment for the investment in SYNAPS Dx and the investment in Mellitus.

7. Fair Value Measurements

The following table presents fair value hierarchy of the Company's financial assets measured at fair value on a recurring basis:

	Fair Value Hierarchy			
	Level 1	Level 2	Level 3	Total
As of December 31,2022				
U.S. Treasury bill	$20,073	$ —	$ —	$20,073
(Included in short-term investments)				
Investment in debt Security	—	—	3,679	3,679
(Included in notes held for investment)				
Total Assets	$20,073	$ —	$3,679	$23,752

There were no debt securities that were measured at fair value as of December 31,2021.

Treasury bill was purchased on November 30, 2022 at a cost of $19,996 and fair value accretes to maturity date at an interest rate of 4.245%. As of December 31, 2022, the interest income recorded on this bill was $77. The fair value of the investments in the debt securities were determined by the Company to be equivalent to the initial purchase price, as the transactions were negotiated with an unrelated third parties. There were no material changes in the fair value of the debt securities identified between the acquisition date of securities, and the year end of December 31, 2022, the reporting date.

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

8. Notes held for investment

Notes receivable consist of the following for the periods presented:

	As of December 31,	
	2022	**2021**
Senior secured promissory notes	$1,000	$ —
Secured convertible promissory notes	3,679	—
Total notes held for investment	$4,679	$ —

In June 2022, the Company loaned Mellitus an aggregate of $1,000 through the purchase of two senior secured promissory notes that bear interest at a rate of 5% per annum, and mature in three years unless accelerated due to an event of default as provided in the notes. Repayment of notes is secured by a first priority interest in all of Mellitus' assets.

In May 2022, to facilitate the subordination of such notes in connection with the purchase of the senior secured notes, the Company acquired $179 aggregate principal amount of outstanding convertible notes of Mellitus, which, as amended, mature July 5, 2025, if not automatically converted into preferred stock prior thereto. This note bears an interest rate of 10% per annum.

In December 2022, the Company entered in a senior convertible promissory note arrangement with Monarch, providing Monarch with up to $5,000 in available funding, of which $3,500, in principle was drawn on the issuance date (the "Debt Security"). The remaining $1.5 million is available to be drawn at any time unless there is an Event of Default that is continuing. The Debt Security accrues interest at 10% per annum, payable monthly commencing January 5, 2023, and the principal balance is due December 6, 2024. The note along with up to $100 of transaction expenses is due and payable on the occurrence of an event of default or change of control unless accelerated due to the conversion into preferred stock prior thereto at the option of the Company. The Company has the option to extend the maturity date for two consecutive one-year terms. The Debt Security can be converted into Monarch's shares at the Company's option upon (a) an equity financing at Monarch, (b) upon a change of control at Monarch, or (c) at the Company's option at any time prior to the maturity date. If converted upon a change of control, the Company has the right to receive a cash payment equal to the balance of the Debt Security or the amount payable upon conversion into Monarch's shares. The Debt Security is redeemable at any time at Monarch's option or automatically upon an Event of Default.

The Company made an irrevocable election to account for the Debt Securities using the fair value option under ASC 825 — *Financial Instruments* ("ASC 825") and will measure the fair value of the Debt Securities in accordance with ASC 820. The Company made the fair value option election to present the Debt Securities in its entirety at fair value, which it believes to be preferable to recognizing the host instrument at fair value under ASC 320 and potentially separately recognizing certain embedded features as bifurcated derivatives under ASC 815. As of December 31, 2022, the Company estimated the fair value of the Debt Securities of Monarch to be $3,500 and Mellitus $179, which are equivalent of the outstanding principal balances at December 31, 2022.

The Company recognizes interest income as it accrues on the Debt Securities, which is included in interest income in the statements of income. For the year ended December 31, 2022, the Company recognized $62 of interest income from Monarch and Mellitus notes, which is included in prepaid and other current assets. The Company recognizes changes in fair value of the Debt Securities in the statements of income separately from the interest income. For the year ended December 31, 2022, there was no change in fair value recorded.

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

9. Other non-current assets

Other non-current assets consist of the following for the periods presented:

	As f December 31,	
	2022	2021
Prepaid licenses	$2,490	$ —
Other	352	332
Total other non-current assets	$2,842	$332

In April 2021, the Company entered into a five-year agreement, as amended in December 2022, with Mellitus to exclusively market and distribute its product line in the United States, including Puerto Rico, except for selected accounts. The Company is currently developing a marketing plan, including hiring dedicated sales and marketing personnel, conducting webinars and attending trade shows and etc. Under this distribution agreement and its amendments, the Company agreed to purchase $2,500 of product licenses and prepaid $2,500 for the license purchases. This prepayment, which was reclassed to a long-term asset in 2022 due to the change in the estimation of the recoverability period is expected to be more than one year. The long-term portion of the prepaid licenses are included in the Other non-current assets. Unless early terminated in accordance with its terms, the exclusive distribution agreement will remain in full force and effect until April 1, 2026, and for renewal periods of one year each upon its anniversary date, unless terminated by at least 60 days written notice prior to such an anniversary date. Either party may terminate the agreement by written notice to the other party upon or after the breach of any material provision of this agreement by the other party, if the other party has not cured such breach within 60 days after written notice thereof from the non-breaching party.

Revenue from these product licenses will be recognized in accordance with ASC 606, *Revenue from Contracts with Customers*. The Company did not generate significant revenue from these product licenses during the year ended December 31, 2022 and 2021.

Other includes right-of-use asset ("ROU") of $233, miscellaneous receivables of $100 and long-term deposits of $19 as of December 31, 2022. As of December 31, 2021, ROU asset and miscellaneous deposits balances were $314 and $18 respectively.

10. Accrued Expenses

Accrued expenses consist of the following:

	As of December 31,	
	2022	2021
Compensation	$2,467	$1,754
Accrued Taxes	1,923	1,159
Miscellaneous Accruals	358	523
Total Accrued Expenses	$4,748	$3,436

11. Concentration of Credit Risk

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

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

The Company maintains cash with major financial institutions. The Company's cash consists of bank deposits held with banks that, at times, exceed federally insured limits. The cash and cash equivalents also include short term treasury bills with original maturities of three months or less. As of December 31,2022, the Company held deposits of $12,960, which exceeded federal deposit corporation limits. The Company also invested in U.S. treasury bills in the amount of $30,127. The Company limits its credit risk by dealing with counterparties that are considered to be of high credit quality and by performing periodic evaluations of the relative credit standing of these financial institutions.

Management periodically monitors the creditworthiness of its customers and believes that it has adequately provided for any exposure to potential credit loss. For the year ended December 31, 2022, two customers accounted for 40.4% and 29.0% of the Company's revenue. For the year ended December 31, 2021, two customers accounted for 40.8%, and 28.6% of the Company's revenue. As of December 31, 2022, three customers accounted for 26.8%, 25.9% and 16.8% of the Company's accounts receivable. As of December 31, 2021, three customers accounted for 21.9%, 20.1% and 16.6% of the Company's accounts receivable.

As of December 31, 2022 and 2021 the allowance for doubtful accounts was $109 and $61, respectively.

As of December 31, 2022, two vendors accounted for 25.8% and $10.8% of the Company's accounts payable. As of December 31, 2021, one vendor accounted for 14.0% of the Company's accounts payable.

12. Leases

Lessee Arrangements

On July 31, 2020, the Company entered into a 61-month lease agreement for office space to use, as necessary, for office administration, lab space and assembly and storage purposes, located in Santa Clara, California. The Company took possession of the leased office space in September 2020, and the lease is effective through September 30, 2025.

As of December 31, 2022, the remaining lease term is three years and nine months with no options to renew. The Company recognized facilities lease expenses of $88 and $112 for the years ended December 31, 2022 and 2021, respectively. The following table summarizes the future minimum rental payments required under operating leases that had initial or remaining non-cancelable lease terms greater than one year as of December 31, 2022:

	Total
2023	90
2024	93
2025	71
Total undiscounted future minimum lease payments	254
Less: present value discount	(9)
Total lease liabilities	245
Lease expense in excess cash payment	(12)
Total ROU asset	$233

As of December 31, 2022, the Company's ROU asset was $233, which is recorded on the Company's balance sheet as other non-current assets, and the Company's current and noncurrent lease liabilities were $85 and $160, respectively, which were recorded on the Company's balance sheet as other short-term liabilities and other long-term liabilities, respectively.

Lessor Arrangements

The Company enters into contracts with customers for the Company's QuantaFlo® product. The Company has determined these contracts meet the definition of a lease under Topic 842. The lease portfolio primarily consists of operating leases that are short-term in nature (monthly, quarterly or one year, all of which have renewal options). The Company allocates the consideration in a bundled contract with its customers based on relative standalone selling prices of the lease and non-lease components. The Company made an accounting policy election to apply the practical expedient to not separate lease and eligible non-lease components. The lease component is the predominant component and consists of fees charged for use of the equipment over the period of the arrangement. The nature of the eligible non-lease component is primarily software support. The assets associated with these leasing arrangements are separately identified in the Balance Sheet as Assets for Lease and separately disclosed in Note 3 to the financial statements. During the year ended December 31, 2022 and 2021, the Company recognized approximately $34,039 and $30,561, respectively, in lease revenue related to these arrangements, which is included in revenue on the Statements of Income.

Variable-fee Revenue

The Company recognizes revenues from variable-fee licenses (e.g., fee per test) and sales of hardware equipment and accessories in accordance with Topic 606. Total revenues from variable-fee licenses were approximately $21,277 and $21,510 for the years ended December 31, 2022 and 2021, respectively. Total revenues from sales of hardware and equipment accessories were approximately $1,358 and $956 for the years ended December 31, 2022 and 2021, respectively. The remainder of the revenue is earned from leasing the Company's testing product for a fixed fee, which is not subject to Topic 606.

13. Commitments and Contingencies

Senior Secured Convertible Note

In December 2022, the Company committed a loan of $5,000 to Monarch through the purchase of a senior secured convertible promissory note that bears interest at a rate of 10% per annum and matures on the second anniversary from the issue date, which can be extended for up to two additional consecutive one-year terms in the Company's sole discretion. The note along with up to $100 of transaction expenses is due and payable on the occurrence of an event of default or change of control unless accelerated due to the conversion into preferred stock prior thereto at the option of the Company. Monarch borrowed $3,500 out of the committed amount of $5,000 as of December 31, 2022 and has agreed to reimburse the Company for up to $100 of transaction expense. Repayment of the note is secured by a first priority interest in all of Monarchs' assets. In January 2023, Monarch borrowed an additional $500 leaving a balance of $1,000 available to be borrowed in the future. See Note 8 to financial statements.

Indemnification Obligations

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

under these indemnities. The Company believes that the likelihood of conditions arising that would trigger these indemnities is remote and, historically, the Company had not made any significant payment under such indemnification provisions. Accordingly, the Company has not recorded any liabilities relating to these agreements. In certain cases, the Company has recourse against third parties with respect to the aforesaid indemnities, and the Company believes it maintains adequate levels of insurance coverage to protect the Company with respect to potential claims arising from such agreements.

Other

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") provides for an employee retention payroll tax credit for certain employers, which is a refundable tax credit against certain employment taxes equal to 50% of the qualified wages an eligible employer pays to employees after March 12, 2020 and before December 31, 2021. For each employee, wages (including health plan costs) up to $10,000 can be counted to determine the amount of the 50% credit. The Company started claiming this credit on its July 2020 payroll until mid-April 2021 when it determined that it no longer qualified given the change in government restrictions on travel that had impacted its sales activities. The Company's determination that it qualified to claim the employee retention payroll tax credit is subjective and subject to audit by the Internal Revenue Service ("IRS"). If the IRS were to disagree with the Company's tax position, it could be required to pay the retention credit claimed, along with penalties. As of December 31, 2021, the Company claimed $1.24 million in this retention credit. No credit was claimed for the year ended December 31, 2022.

Legal Matter

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

14. Stockholders' Equity

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

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

Treasury Stock Acquired

On March 14, 2022, the Company's Board of Directors authorized a share repurchase program under which it may repurchase up to $20.0 million of its outstanding common stock. Under this program the Company may purchase shares on a discretionary basis from time to time through open market purchases, privately negotiated transactions or other means, including through Rule 10b5-1 trading plans or through the use of other techniques such as accelerated share repurchases. The timing and amount of any transactions will be subject to the discretion of the Company based upon market conditions and other opportunities that it may have for the use or investment of its cash balances. The repurchase program has no expiration date, does not require the purchase of any minimum number of shares and may be suspended, modified or discontinued at any time without prior notice. The Company purchased 148,500 shares at a cost of approximately $4,991 during the year ended December 31, 2022.

For the years ended December 31, 2022 and 2021, a total of 1,548,545 and 1,433,120 shares of common stock, respectively, were reserved for issuance upon (i) exercise of common stock warrants, and (ii) the exercise of outstanding stock options, as follows:

	Year ended December 31,	
	2022	2021
Common stock warrants	76,875	76,875
Stock options	1,471,670	1,356,245
Total	1,548,545	1,433,120

15. Stock Option Plan

The Company's stock-based compensation program is designed to attract and retain employees while also aligning employees' interests with the interests of its stockholders. Stock options have been granted to employees under the stockholder-approved 2007 Key Person Stock Option Plan ("2007 Plan") or the stockholder-approved 2014 Stock Incentive Plan ("2014 Plan"). Stockholder approval of the 2014 Plan became effective in September 2014. The 2014 Plan originally provided that the aggregate number of shares of common stock that may be issued pursuant to awards granted under the 2014 Plan may not exceed 450,000 shares (the "Share Reserve"), however in October 2015, the stockholders approved a 1,500,000 increase to the Share Reserve. In addition, the Share Reserve automatically increases on January 1st of each year, for a period of not more than 10 years, beginning on January 1st of the year following the year in which the 2014 Plan became effective and ending on (and including) January 1, 2024, in an amount equal to 4% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. The Company's board of directors may act prior to January 1st of a given year to provide that there will be no January 1st increase in the Share Reserve for such year or that the increase in the Share Reserve for such year will be a lesser number of shares of common stock than would otherwise occur. The Share Reserve is currently 3,315,203 shares for the year ending December 31, 2022.

In light of stockholder approval of the 2014 Plan, the Company no longer grants equity awards under the 2007 Plan. As of December 31, 2022, there were no shares available for future stock-based compensation grants under the 2007 Plan and 1,471,670 shares of an aggregate total of 3,315,203 shares available for future stock-based compensation grants under the 2014 Plan.

Aggregate intrinsic value represents the difference between the closing market value as of December 31, 2022 of the underlying common stock and the exercise price of outstanding, in-the-money options. A summary of the Company's stock option activity and related information for 2022 and 2021 is as follows:

	Options Outstanding			
	Number of Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (In Thousands)
Balance, December 31, 2020	**1,451,420**	**$ 3.25**	**4.91**	**$131,714**
Options exercised	(95,175)	2.55	—	—
Balance, December 31, 2021	**1,356,245**	**$ 3.30**	**3.97**	**$119,830**
Options exercised	(73,398)	**2.58**	—	—
Options granted	5,000	**30.48**	**4.00**	—
Balance, December 31, 2022	**1,287,847**	**$ 3.44**	**3.03**	**$ 38,053**
Exercisable as of December 31, 2021	**1,356,245**	**$ 3.30**	**3.97**	**$119,830**
Exercisable as of December 31, 2022	**1,282,847**	**$ 3.34**	**3.00**	**$ 38,053**

On May 17, 2022 the Company awarded 5,000 options to an employee as compensation pursuant to the 2014 Plan with an exercise price of $30.48 and Black-Scholes options pricing model value of $22.27. In

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

applying the Black-Scholes options pricing model, the following assumptions were used: 1) expected price volatility of 78.6%; risk-free interest rate of 2.884%; weighted average expected life of 7 years; zero forfeiture rate and no dividend yield; 1/4th of these options is vested one year after the grant date and 1/48th for each month thereafter contingent upon the participant's continued service beginning on the initial vesting date and ending when the Vested Ratio equals 1/1. The total estimated grant date fair value of options vested during the years ended December 31, 2022 and 2021 was $0 and $192, respectively. As of December 31, 2022, unrecognized stock-based compensation expense of $94 is expected to be recorded over a weighted average period of 3.4 years. Actual forfeitures are recognized as they occur.

There were no options granted or forfeited during the year ended December 31, 2021.

Stock grants

The Company granted 9,421 and 5,516 shares of fully vested stock to a consultant, employees and board of directors in the year ended December 31, 2022 and 2021, respectively. Grant date fair value of the stock was $723 and $557 for the year ended December 31, 2022 and 2021, respectively.

The Company has recorded an expense of $741 and $749 as it relates to stock-based compensation for the years ended December 31, 2022 and 2021, respectively, which was allocated as follows based on the role and responsibility of the recipient in the Company:

	December 31 2022	December 31 2021
Engineering and Product Development	$ 45	$ 32
Sales and Marketing	173	125
General and Administrative	523	592
Total	$741	$749

16. Income Taxes

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

	2022	2021
Current tax provision:		
Federal	$3,201	$1,397
State	517	428
Total current tax provision	3,718	1,825
Deferred tax provision:		
Federal	(373)	456
State	22	(48)
Total deferred tax provision	(351)	408
Total income tax provision	$3,367	$2,233

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

A summary of the differences between the Company's effective income tax rate and the federal statutory income tax rate for the years ended December 31, 2022 and 2021 are as follows:

	2022	2021
Federal statutory rate	21.00%	21.00%
State income tax rate, net of federal benefit	2.57%	1.55%
Stock-based compensation	(4.03)%	(10.62)%
Permanent items	(0.93)%	(1.16)%
Other	0.35%	0.68%
Effective income tax rate	18.96%	11.45%

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

	2022	2021
Net operating loss carryforwards	$ 303	$ 446
Deferred revenue	278	220
Stock based compensation	529	556
Accrual and reserves	297	529
Research and development credits	254	228
Other	2	14
Depreciation and amortization	633	—
Lease liability	59	77
Total gross deferred tax assets	2,355	2,070
Less valuation allowance	—	—
Net deferred tax assets	2,355	2,070
Deferred tax liabilities:		
Depreciation and amortization	—	(49)
Right of use assets	(56)	(75)
Total deferred tax liabilities	(56)	(124)
Net deferred tax assets	$2,299	$1,946

Federal and California tax laws imposes significant restrictions on the utilization of net operating loss ("NOL") carryforwards in the event of a change in ownership of the Company, as defined by Section 382 of the Code ("Section 382"). The Company has completed a formal 382 study for the period from January 1, 2012 through June 30, 2019 and believes a change in ownership has occurred. The Company has no NOL carryforwards for Federal income tax purposes and approximately $4,234 for California income tax purposes as of December 31, 2022. The state NOL carryforwards, if not utilized, will expire beginning in 2036.

As of December 31, 2022 and 2021, the Company had $401 and $476, respectively, of unrecognized tax benefits, excluding interest and penalties. The following table summarizes the activity related to the Company's gross unrecognized tax benefits:

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

	Gross Unrecognized Tax Benefits 2022	Gross Unrecognized Tax Benefits 2021
Unrecognized tax benefits – January 1	$ 476	$341
Gross increases related to prior tax positions	—	41
Gross decreases related to prior tax positions	(120)	—
Gross increases related to current tax positions	45	94
Unrecognized tax benefits – December 31	$ 401	$476

The Company's policy is to recognize interest and penalty expenses related to uncertain tax positions in income tax expense, which was $30 and none for the years ended December 31, 2022 and 2021, respectively. The Company files income tax returns in the U.S. federal and various state tax jurisdictions.

The Company's tax years beginning in 2018 remain open for examination by the state tax authorities for four years. The Company's tax years beginning in 2019 remain open for examination by the federal tax authorities for three years. Tax years beginning in 2016 will remain open for examination from the date of utilization of any NOL or credits. The Company does not have any tax positions for which it is reasonably possible the total amount of gross unrecognized tax benefits will increase or decrease within 12 months of the year-ended December 31, 2022.

On August 16, 2022, the CHIPS and Science Act of 2022 or Creating Helpful Incentives to Produce Semiconductors for America Act, and Inflation Reduction Act (IRA Act) was signed into law in the United States. Among other things, CHIPS and Science Act provides incentives and tax credits for the global chip manufacturers who choose to set-up or expand existing operations in the United States. The IRA Act imposes a 15% corporate alternative minimum tax for tax years beginning after December 31, 2022, levies a 1% excise tax on net stock repurchases after December 31, 2022, and provides tax incentives to promote clean energy. This act is primarily applicable to large corporations with an annual revenue of $1 billion or over. Implementation of this act has no impact on the Company's financial statements as of December 31, 2022.

17. Net Income Per Share, Basic and Diluted

Basic earnings per share ("EPS") represent net income attributable to common shareholders divided by the weighted average number of common shares outstanding during the measurement period. Diluted EPS represents net income attributable to common shareholders divided by the weighted average number of common shares outstanding during the measurement period while also giving effect to all potentially dilutive common shares that were outstanding during the period using the treasury stock method. 5,000 options related to stock awards were granted and unvested. As of December 31, 2022, these options were considered anti-dilutive for the computation of diluted net income per share.

Basic and diluted net EPS is calculated as follows:

	For the year ended December 31,					
	2022			2021		
	Shares	Net Income	EPS	Shares	Net Income	EPS
Basic EPS	6,726,687	$14,325	$2.13	6,731,693	$17,222	$2.56
Common stock warrants	68,588	—	—	73,767	—	—
Common stock options	1,204,475	—	—	1,333,148	—	—
Diluted EPS	7,999,750	$14,325	$1.79	8,138,608	$17,222	$2.12

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 23, 2023

Semler Scientific, Inc.

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

POWER OF ATTORNEY

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

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

Name	Title	Date
/s/ Douglas Murphy-Chutorian, M.D. Douglas Murphy-Chutorian, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2023
/s/ Andrew B. Weinstein Andrew B. Weinstein	Senior Vice President, Finance and Accounting (Principal Financial Officer)	March 23, 2023
/s/ Daniel E. Conger Daniel E. Conger	Vice President, Finance (Principal Accounting Officer)	March 23, 2023
/s/ Arthur N. Leibowitz, M.D., F.A.A.P. Arthur N. Leibowitz, M.D., F.A.A.P.	Director	March 23, 2023
/s/ Daniel S. Messina Daniel S. Messina	Director	March 23, 2023
/s/ Cindy H. Moon Cindy H. Moon	Director	March 23, 2023
/s/ Wayne T. Pan, M.D., Ph.D. Wayne T. Pan, M.D., Ph.D.	Director	March 23, 2023

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Semler Scientific