

IRIDEX CORP  
Form 424B4  
December 09, 2016  
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Filed Pursuant to Rule 424(b)(4)  
Registration No. 333-213094

**The information in this preliminary prospectus supplement is not complete and may be changed. A registration statement relating to these securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting offers to buy these securities, in any state where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED DECEMBER 8, 2016**

**PROSPECTUS SUPPLEMENT**

(to Prospectus dated August 26, 2016)

**Shares of Common Stock**

We are offering \_\_\_\_\_ shares of our common stock pursuant to this prospectus supplement and the accompanying prospectus.

Our common stock is listed on The NASDAQ Global Market under the symbol IRIX. On December \_\_\_\_\_, 2016, the last reported sale price of our common stock on The NASDAQ Global Market was \$ \_\_\_\_\_ per share.

**Investing in our common stock involves a high degree of risk. Please read Risk Factors beginning on page S-6 of this prospectus supplement and page 4 of the accompanying prospectus, as well as the documents incorporated by reference in this prospectus supplement.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**No Exercise of  
Over-Allotment**

**Full Exercise of  
Over-Allotment**

	<b>Per Share</b>	<b>Total</b>	<b>Per Share</b>	<b>Total</b>
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions(1)	\$	\$	\$	\$
Proceeds to IRIDEX, before expenses	\$	\$	\$	\$

(1) In addition, we have agreed to reimburse the underwriter for certain expenses. See Underwriting on page S-33 of this prospectus supplement for additional information.

The offering is being underwritten on a firm commitment basis. Delivery of the common stock is expected to be made on or about \_\_\_\_\_, 2016. We have granted the underwriter an option exercisable one or more times at any time or from time to time, in whole or in part, for a period of 30 days from the date of this prospectus supplement to purchase up to an additional \_\_\_\_\_ shares of our common stock, less underwriting discounts and commissions, solely to cover overallotments, if any.

*Sole Book-Running Manager*

**Roth Capital Partners**  
**Prospectus Supplement dated \_\_\_\_\_, 2016.**

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**You should rely only on the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. IRIDEX has not and the underwriter has not authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the United States. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an**

**offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.**

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**You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and in any free writing prospectus that we have authorized for use in connection with this offering, is accurate only as of the date of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering, in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled **Where You Can Find More Information** and **Incorporation of Certain Information by Reference**.**

### **About This Prospectus Supplement**

This document is in two parts. The first part is the prospectus supplement, which describes the specific terms of the securities being offered by us and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information, some of which may not apply to this offering of securities. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date—for example, a document incorporated by reference in the accompanying prospectus—the statement in the document having the later date modifies or supersedes the earlier statement.

Unless the context requires otherwise, references in this prospectus supplement and the accompanying prospectus to IRIDEX, the company, we, us and our refer to IRIDEX Corporation.

This prospectus supplement and the accompanying prospectus are part of a registration statement on Form S-3 that we filed on August 12, 2016, with the SEC using a shelf registration process with respect to up to \$50,000,000 in securities that may be sold by IRIDEX thereunder and up to 2,060,688 shares of common stock that may be sold by the selling stockholders thereunder. The shelf registration statement was declared effective by the SEC on August 26, 2016.

Under the shelf registration process, we may offer and sell any combination of securities described in the accompanying prospectus in one or more offerings. The accompanying prospectus provides you with a general description of the securities we may offer. The purpose of this prospectus supplement is to provide supplemental information regarding us in connection with this offering of common stock.

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**Prospectus Supplement Summary**

*This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider carefully the more detailed information in this prospectus supplement and the accompanying prospectus, including the factors described under the heading Risk Factors in this prospectus supplement and the financial and other information incorporated by reference in this prospectus supplement and the accompanying prospectus, as well as the information included in any free writing prospectus that we have authorized for use in connection with this offering, before making a decision to invest in our common stock.*

**Company Overview**

IRIDEX Corporation is a leading worldwide provider of therapeutic-based laser consoles, delivery devices and consumable instrumentation used to treat sight-threatening eye diseases in ophthalmology. Certain of our products are powered by our differentiated MicroPulse technology, which is a method of delivering laser energy using a mode which chops the continuous wave laser beam into short, microsecond-long laser pulses. Our products are sold in the United States predominantly through a direct sales force and internationally through independent distributors.

Our products consist of laser consoles, delivery devices and consumable instrumentation, including laser probes, and are used in the treatment of serious eye diseases, including glaucoma and retinal diseases. Our laser consoles consist of the following product lines:

**Glaucoma** This product line includes our recently introduced Cyclo G6 laser system used for the treatment of glaucoma;

**Medical Retina** Our medical retina product line includes our IQ 532 and IQ 577 laser photocoagulation systems, which are used for the treatment of diabetic macular edema and other retinal diseases; and

**Surgical Retina** Our surgical retina line of products includes our OcuLight TX, OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. These systems are often used in vitrectomy procedures, which are used to treat proliferative diabetic retinopathy, macular holes, retinal tears and detachments.

Our business generates recurring revenues through sales of consumable products, predominantly single-use laser probe devices and other instrumentation, as well as repair, servicing and extended service contracts for our laser systems. Our laser probes consist of the following product lines:

**Glaucoma** Probes used in our glaucoma product line include our recently patented MicroPulse P3 ( MP3 ) probe and G-Probe; and

**Surgical Retina** Our surgical retina probes include our EndoProbe family of products used in vitrectomy procedures.

Ophthalmologists typically use our laser systems in hospital operating rooms ( ORs ) and ambulatory surgical centers ( ASCs ), as well as their offices and clinics. In the ORs and ASCs, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a consumable, single use MP3 probe, G-Probe or EndoProbe.

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**Corporate Information**

IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In November 1995, we changed our name to IRIDEX Corporation and reincorporated in Delaware. Our executive offices are located at 1212 Terra Bella Avenue, Mountain View, California 94043-1824, and our telephone number is (650) 940-4700. We can also be reached at our website at [www.IRIDEX.com](http://www.IRIDEX.com). Any information on, or that can be accessed through, our website and social media channels is not part of this prospectus.

IRIDEX, the IRIDEX logo, IRIS Medical, MicroPulse, OcuLight, SmartKey, and EndoProbe, are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, IQ 577, IQ 532, Cyclo G6, TxCell, OtoProbe, Symphony, EasyFit, Endoview, MoistAir and GreenTip product names are our trademarks. All other trademarks or trade names appearing in this prospectus are the property of their respective owners.





Except as otherwise indicated, all information in this prospectus assumes no exercise by the underwriter of their overallotment option.

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**Table of Contents****Summary Financial Data**

The table below presents financial data for the periods indicated. The summary financial data as of January 2, 2016 and January 3, 2015 and for the years ended January 2, 2016, January 3, 2015 and December 28, 2013 are derived from our audited financial statements and related notes for those periods that are incorporated by reference in this prospectus supplement and accompanying prospectus. The summary financial data as of October 1, 2016 and for the nine months ended October 1, 2016 and October 3, 2015 have been derived from our unaudited condensed consolidated financial statements and related notes for those periods that are incorporated by reference in this prospectus supplement and accompanying prospectus. In the opinion of management, such unaudited interim financial data contains all adjustments necessary for the fair statement of our financial position and results of operations as of and for such periods. Historical results are not necessarily indicative of results that may be expected or attained for future periods.

The following information is only a summary. You should read this data in conjunction with our historical financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report filed on Form 10-K, Quarterly Reports filed on Form 10-Q and other information on file with the SEC that is incorporated by reference in this prospectus supplement and the accompanying prospectus. For more details on how you can obtain our SEC reports and other information, you should read the section of this prospectus supplement entitled Where You Can Find More Information. Our results of operations are for historical periods and are not necessarily indicative of results of operations for future periods.

**Consolidated Statements of Operations Data:**

	Fiscal Year Ended			Nine Months Ended	
	January 2, 2016	January 3, 2015	December 28, 2013	October 1, 2016	October 3, 2015
	(Unaudited)				
	(in thousands, except share and per share data)				
Total revenues	\$ 41,757	\$ 42,814	\$ 38,273	\$ 33,628	\$ 29,644
Cost of revenues	21,804	21,409	19,686	18,352	15,176
Gross profit	19,953	21,405	18,587	15,276	14,468
Operating expenses:					
Research and development	5,214	4,629	3,684	4,007	4,000
Sales and marketing	8,901	8,155	7,720	7,212	6,463
General and administrative	5,550	6,034	5,023	5,546	4,206
Proceeds from demutualization of insurance carrier			(473)		
Total operating expenses	19,665	18,818	15,954	16,765	14,669
Income (loss) from operations	288	2,587	2,633	(1,489)	(201)
Other income (expense), net	3	(1,255)	(371)	(83)	134

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Income (loss) before (benefit from) provision for income taxes	291	1,332	2,262	(1,572)	(67)
(Benefit from) provision for income taxes	(183)	(8,706)	31	(674)	(103)
Net income (loss)	\$ 474	\$ 10,038	\$ 2,231	\$ (898)	\$ 36
Net income (loss) per share:					
Basic	\$ 0.05	\$ 1.01	\$ 0.24	\$ (0.09)	\$ 0.00
Diluted	\$ 0.05	\$ 0.97	\$ 0.22	\$ (0.09)	\$ 0.00
Weighted average shares used in computing net income (loss) per common share:					
Basic	9,962	9,892	9,245	10,083	9,956
Diluted	10,128	10,357	10,104	10,083	10,142

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	<b>January 3, 2015</b>	<b>As of January 2, 2016</b>	<b>October 1, 2016 (Unaudited)</b>
		<b>(in thousands)</b>	
Cash and cash equivalents	\$ 13,303	\$ 9,995	\$ 9,577
Total assets	41,818	41,823	42,714
Deferred revenue	1,179	1,311	1,305
Total liabilities	8,082	8,135	8,162
Total stockholders' equity	33,736	33,688	34,552

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**Risk Factors**

*An investment in our common stock involves a high degree of risk. Prior to making a decision about investing in our common stock, you should carefully consider the specific factors discussed below, the risk factors beginning on page 4 of the accompanying prospectus, as well as the risk factors discussed under the section entitled Risk Factors contained in our Quarterly Report on Form 10-Q for the quarter ended October 1, 2016 as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended, or the Exchange Act, each of which is incorporated by reference in this prospectus supplement and accompanying prospectus in their entirety, together with all of the other information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and therein, and any related free writing prospectus. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations. The occurrence of any of these known or unknown risks might cause you to lose all or part of your investment in the offered common stock.*

**Risks Relating to our Business**

***We face quality control and other production issues that could materially and adversely impact our sales and financial results and the acceptance of our products.***

The manufacture of our infrared and visible laser consoles and related delivery devices is a highly complex and precise process. We assemble critical subassemblies and substantially all of our final products at our facility in Mountain View, California. We may experience manufacturing difficulties, quality control issues or assembly constraints, particularly with regard to new products that we may introduce.

If our sales increase substantially, we may need to increase our production capacity and may not be able to do so in a timely, effective or cost-efficient manner. We may not be able to manufacture sufficient quantities of our products, which may require that we qualify other manufacturers for our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations.

In the recent past, we have experienced supply chain, production and training issues as we have expanded our product lines and sales volumes. For example, in our third quarter of fiscal 2016, we experienced certain supply chain and sales force training issues in certain of our medical retina products. As a result of these issues, we reduced the shipment of these products in that fiscal quarter. In fiscal 2015, we experienced quality issues with certain of our products, which caused us to reduce shipments, particularly to international distributors.

While we have taken steps to address these issues, there is no assurance that these steps will be effective in rectifying or preventing similar issues in the future. If we are unable to address these supply chain, production and training issues in a timely and cost-effective manner, product shipments to our customers could be delayed, our sales levels may suffer and manufacturing and operational costs may increase, any of which would negatively impact our net revenues.

***Some of our laser systems are complex in design and may contain defects that are not detected until deployed by our customers, which could increase our costs and reduce our revenues.***

Laser systems are inherently complex in design and require ongoing regular maintenance. The manufacture of our lasers, laser products and systems involves a highly complex and precise process. As a result of the technical complexity of our products, changes in our or our suppliers' manufacturing processes or the inadvertent use of defective materials by us or our suppliers could result in a material adverse effect on our ability to achieve acceptable

manufacturing yields and product reliability. To the extent that we do not achieve such yields or product reliability, our business, operating results, financial condition and customer relationships would be adversely affected. We provide warranties on certain of our product sales, and allowances for estimated warranty

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costs are recorded during the period of sale. The determination of such allowances requires us to make estimates of failure rates and expected costs to repair or replace the products under warranty. We currently establish warranty reserves based on historical warranty costs. If actual return rates and/or repair and replacement costs differ significantly from our estimates, adjustments to recognize additional cost of revenues may be required in future periods.

Our customers may discover defects in our products after the products have been fully deployed and operated under peak stress conditions. In addition, some of our products are combined with products from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

loss of customers;

increased costs of product returns and warranty expenses;

damage to our brand reputation;

failure to attract new customers or achieve market acceptance;

diversion of development and engineering resources; and

legal actions by our customers.

The occurrence of any one or more of the foregoing factors could seriously harm our business, financial condition, results of operations and the price of our common stock.

***We depend on international sales for a significant portion of our operating results.***

We derive, and expect to continue to derive, a large portion of our revenues from international sales. For the third quarter of fiscal 2016, our international ophthalmology sales were \$3.9 million, or 40% of total revenues. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. None of our international revenues and costs for the quarter ended October 1, 2016 have been denominated in foreign currencies. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our products more expensive and thus less competitive in foreign markets and may negatively affect our reported revenue in any particular reporting period. Our international operations and sales are subject to a number of risks and potential costs, including:

fluctuations in foreign currency exchange rates;



quality and production issues;

performance of our international channel of distributors;

longer accounts receivable collection periods;

impact of recessions in global economies and availability of credit;

political and economic instability;

trade sanctions and embargoes;

impact of international conflicts, terrorist and military activity, and civil unrest;

foreign certification requirements, including continued ability to use the CE mark in Europe, and other local regulatory requirements;

differing local product preferences and product requirements;

cultural differences;

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changes in foreign medical reimbursement and coverage policies and programs;

reduced or limited protections of intellectual property rights in jurisdictions outside the United States;

potentially adverse tax consequences;

protectionist, adverse and changing foreign governmental laws and regulations;

greater risk of our employees failing to comply with both U.S. and foreign laws, including anti-trust regulations, the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010 and any trade regulations designed to ensure fair trade practices; and

compliance costs and risks of non-compliance with multiple regulatory regimes governing the production, marketing, sale and use of our products.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations.

As we expand our existing international operations we may encounter new risks in addition to the above factors. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing these relationships, we may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenues, profitability and the price of our common stock.

***We are exposed to risks associated with worldwide economic slowdowns and related uncertainties.***

We are subject to macro-economic fluctuations in the U.S. and worldwide economy. Concerns about consumer and investor confidence, volatile corporate profits and reduced capital spending, international conflicts, terrorist and military activity, civil unrest and pandemic illness could reduce customer orders or cause customer order cancellations. In addition, political and social turmoil related to international conflicts and terrorist acts may put further pressure on economic conditions in the United States and abroad.

Weak economic conditions and declines in consumer spending and consumption may harm our operating results. Purchases of our products are often discretionary. During uncertain economic times, customers or potential customers may delay, reduce or forego their purchases of our products and services, which may impact our business in a number of ways, including lower prices for our products and services and reducing or delaying sales. There could be a number of follow-on effects from economic uncertainty on our business, including insolvency of key suppliers resulting in product delays, delays in customer payments of outstanding accounts receivable and/or customer insolvencies, counterparty failures negatively impacting our operations, and increasing expense or inability to obtain future financing.

If economic uncertainty persisted, or if the economy entered a prolonged period of decelerating growth, our results of operations may be harmed.

*Our operating results may fluctuate from quarter to quarter and year to year.*

Our sales and operating results may vary significantly from quarter to quarter and from year to year in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

changes in the prices at which we can sell our products, including the impact of changes in exchange rates;

general economic uncertainties and political concerns;

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introduction of new products, product enhancements and new applications by our competitors, including new drugs, entry of new competitors into our markets, pricing pressures and other competitive factors;

the timing of the introduction and market acceptance of new products, product enhancements and new applications;

changes in demand for our existing line of ophthalmology products;

the cost and availability of components and subassemblies, including the willingness and ability of our sole or limited source suppliers to timely deliver components at the times and prices that we have planned;

our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;

fluctuations in our product mix within ophthalmology products and foreign and domestic sales;

the effect of regulatory approvals and changes in domestic and foreign regulatory requirements;

our long and highly variable sales cycle;

changes in customers' or potential customers' budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products;

variances in shipment volumes as a result of quality, supply chain and training issues; and

increased product innovation costs.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors. For example, our European sales during the third quarter are generally lower due to many businesses being closed for the summer vacation season.

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarter. Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

***If we fail to develop and successfully introduce new products and applications, our business prospects and operating results may suffer.***

Our ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, which may include clinical trials that lead to the development of new products and new applications using our products. Our research and development process is expensive, prolonged, and entails considerable uncertainty. Due to the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully.

Successful commercialization of new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications

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and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns.

Our ability to market and sell new products is subject to government regulation, including approval or clearance by the Food and Drug Administration ( FDA ) and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

***We rely on continued market acceptance of our existing products and any decline in sales of our existing products would adversely affect our business and results of operations.***

We currently market visible and infrared medical laser systems and delivery devices to the ophthalmology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent upon a number of factors including the following:

acceptance of product performance, features, ease of use, scalability and durability, including with respect to our MicroPulse laser photocoagulation systems;

recommendations and opinions by ophthalmologists, other clinicians, and their associated opinion leaders;

marketing study outcomes;

price of our products and prices of competing products and technologies, particularly in light of the current macro-economic environment where healthcare systems and healthcare operators are becoming increasingly price sensitive;

availability of competing products, technologies and alternative treatments; and

level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales in the form of recurring revenues from selling consumable instrumentation, including our EndoProbe devices and service. Our ability to increase recurring revenues from the sale of consumable products will depend primarily upon the features of our current products and product innovation, the quality of our products, ease of use and prices of our products, including the relationship to prices of competing products. The level of our service revenues will depend on the quality of service we provide and the responsiveness and the willingness of our customers to request our services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices, consumables or services may have a material adverse effect on our business, results of operations

and financial condition.

***We face strong competition in our markets and expect the level of competition to grow in the foreseeable future.***

Competition in the market for devices used for ophthalmic treatment procedures is intense and is expected to increase. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Alcon Inc. (Novartis AG), Carl Zeiss Meditec AG, Nidek Co. Ltd., Synergetics (Bausch and Lomb), Topcon Corporation, Ellex Medical Lasers, Ltd., Quantel Medical SA, and Lumenis Ltd. Most of these companies currently offer a competitive, semiconductor-based laser system for ophthalmology. Also within ophthalmology, pharmaceutical alternative treatments for AMD and DME such as Lucentis/Avastin (Genentech),

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Eylea (Regeneron), Macugen (OSI Pharmaceuticals), Ozurdex (Allergan) and ILUVIEN (Alimera Sciences), and to a lesser extent Visudyne (Valeant Pharmaceuticals), compete rigorously with traditional laser procedures. A number of these competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do, including greater name recognition, and benefit from long-standing customer relationships. Some medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

***Our operating results may be adversely affected by uncertainty regarding healthcare reform measures and changes in third-party coverage and reimbursement policies.***

Our ophthalmology products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as governmental programs and private insurance plans, for the health care services provided to their patients. Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding reimbursement of medical procedures using our products and any healthcare reform measures. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care and Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the Affordable Care Act). At this time, it remains unclear whether there will be any changes made to or any repeal of the Affordable Care Act, with respect to certain of its provisions or in its entirety. Various healthcare reform proposals have also emerged at the state level.

We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Furthermore, existing legislation and regulation related to the health care industry and third-party coverage reimbursement, including the Affordable Care Act, has been subject to judicial challenge, and may be subject to similar challenges from time to time in the future. Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition.

Third-party payers are increasingly scrutinizing and continue to challenge the coverage of new products and the level of reimbursement for covered products. Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective.

***If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.***

While we do not bill directly to Medicare, Medicaid or other third-party payors, because payment is in many cases available for our products from such payors, many healthcare laws place limitations and requirements on the manner in which we conduct our business (including our sales and promotional activities and interactions with healthcare professionals and facilities) and could result in liability and exposure to us. The laws that may affect our ability to



operate include, among others: (i) the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal

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healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us if we provide coding and billing advice to customers, or under theories of implied certification where the government and qui tam relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted off-label, lacked necessary clearance or approval, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and disclosures requirements such as the federal Sunshine Act, now known as Open Payments; and/or (iv) state law equivalents of each of the above federal laws, including, without limitation anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Open Payments, commonly known as the Sunshine Act, is a relatively new law, and compliance with this law has presented a number of challenges to companies such as ours, in terms of interpretation of the law and its implementation. Under the Sunshine Act, CMS has the potential to impose penalties of up to \$1.15 million per year for violations, depending on the circumstances, although enforcement has been negligible to date. Payments reported under the Sunshine Act also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the Anti-Kickback Statute and other healthcare laws. The risk that we are our being found in violation of these laws may be increased by the fact that we do not have a formal healthcare compliance program in place. Further, while safe harbors may in some instances be available and utilized by companies to reduce risks associated with the Anti-Kickback Statute and certain other healthcare laws, we have not necessarily utilized such safe harbors nor fully followed all elements required to claim the benefit of such safe harbors in all possible instances. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

***We depend on collaborative relationships to develop, introduce and market new products, product enhancements and new applications.***

We depend on both clinical and commercial collaborative relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and innovation and clinical testing of our products. Commercially, we currently have a distribution and licensing agreement with Alcon for our GreenTip SoftTip Cannula. Sales of and royalties from the GreenTip Soft Tip Cannula are dependent upon the sales performance of Alcon, which depends on their efforts and is beyond our control. The failure to obtain any additional future clinical or commercial collaborations and the resulting failure or success of such arrangements of any current or future clinical or commercial collaboration relationships could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

***If we cannot increase our sales volumes, reduce our costs or introduce higher margin products to offset anticipated reductions in the average unit price of our products, our operating results may suffer.***

The average unit price of our products may decrease in the future in response to changes in product mix, competitive pricing pressures, new product introductions by our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes or through new product introductions, our net revenues will decline. In addition, to maintain our gross margins we must continue

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to reduce the manufacturing cost of our products. If we cannot maintain our gross margins our business could be seriously harmed, particularly if the average selling price of our products decreases significantly without a corresponding increase in sales.

***We rely on our direct and independent sales forces and network of international distributors to sell our products and any failure to maintain our sales force and distributor relationships could harm our business.***

Our ability to sell our products and generate revenues depends upon our direct and independent sales forces within the United States and relationships with independent distributors outside the United States. Currently our direct and independent sales forces within the United States consist of approximately 16 employees and 13 independent representatives, respectively. Our international independent distributors are managed by a team of five people. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are entirely dependent on the efforts of these third parties. If any distributor breaches the terms of its distribution agreement with us or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, which may harm our revenues and our ability to maintain market share. Similarly, our independent and distributor agreements are generally terminable at will by either party and independents and distributors may terminate their relationships with us, which would affect our sales and results of operations.

***Our promotional practices are subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion, and marketing that have a significant negative effect on our business.***

We are subject to governmental oversight and associated civil and criminal enforcement relating to drug and medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. In the United States, we are subject to potential enforcement from the FDA, the U.S. Federal Trade Commission, the Department of Justice, the CMS, other divisions of the Department of Health and Human Services and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against pharmaceutical and medical device companies, alleging off-label marketing and other violations. We may be subject to liability based on the actions of individual employees and contractors carrying out activities on our behalf, including sales representatives who may interact with healthcare professionals.

***If we fail to manage growth effectively, our business could be disrupted which could harm our operating results.***

We have experienced and may in the future experience growth in our business, both organically and through the acquisition of businesses and products. We have made and expect to continue to make significant investments to enable our future growth through, among other things, new product innovation and clinical trials for new applications and products. We must also be prepared to expand our work force and to train, motivate and manage additional employees as the need for additional personnel arises. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to effectively manage future growth could have a material adverse effect on our business, results of operations and financial condition.

***We rely on patents and proprietary rights to protect our intellectual property and business.***

Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual

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agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued 29 United States patents and 17 foreign patents on the technologies related to our products and processes. We have 7 pending patent applications in the United States and 20 foreign pending patent applications that have been filed. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Patents have a limited lifetime and once a patent expires competition may increase.

In addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain industry standard provisions requiring such individuals to assign to us without additional consideration any inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. Proprietary information agreements with employees, consultants and others may be breached, and we may not have adequate remedies for any breach. Also, our trade secrets may become known to or independently developed by competitors.

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage.

Numerous patents are held by others, including academic institutions and our competitors. Patent applications filed in the United States after November 2000 generally will be published eighteen months after the filing date. However, since patent applications continue to be maintained in secrecy for at least some period of time, both within the United States and with regards to international patent applications, we cannot assure you that our technology does not infringe any patents or patent applications held by third parties. We have, from time to time, been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable.

Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop non-infringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition.

***If we lose key personnel or fail to integrate replacement personnel successfully, our ability to manage our business could be impaired.***

Our future success depends upon the continued service of our key management, technical, sales, and other critical personnel. Our officers and other key personnel are employees-at-will, and we cannot assure you that we will be able to retain them. Key personnel have left our company in the past, and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and

completion of company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. Competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic

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markets in which we recruit, is intense and characterized by increasing salaries, which may increase our operating expenses or hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

***If we fail to accurately forecast demand for our product and component requirements for the manufacture of our product, we could incur additional costs or experience manufacturing delays and may experience lost sales or significant inventory carrying costs.***

We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. If we underestimate demand for our product and consequently, our component and materials requirements, we may have inadequate inventory, which could interrupt our manufacturing, delay delivery of our product to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

***We depend on sole source or limited source suppliers.***

We rely on third parties to manufacture substantially all of the components used in our products, including optics, laser diodes and crystals. We have some long term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. Some of our suppliers and manufacturers are sole or limited sources. In addition, some of these suppliers are relatively small private companies whose operations may be disrupted or discontinued at any time. There are risks associated with the use of independent manufacturers, including the following:

unavailability of shortages or limitations on the ability to obtain supplies of components in the quantities that we require;

delays in delivery or failure of suppliers to deliver critical components on the dates we require;

failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and

inability to obtain components at acceptable prices.

Our business and operating results may suffer from the lack of alternative sources of supply for critical sole and limited source components. The process of qualifying suppliers is complex, requires extensive testing with our products, and may be lengthy, particularly as new products are introduced. New suppliers would have to be educated in our production processes. In addition, the use of alternate components may require design alterations to our products and additional product testing under FDA and relevant foreign regulatory agency guidelines, which may delay sales and increase product costs. Any failures by our vendors to adequately supply limited and sole source components may impair our ability to offer our existing products, delay the submission of new products for regulatory approval and market introduction, materially harm our business and financial condition and cause our stock price to



decline. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. Our business, results of operations and financial condition would be adversely affected if we are unable to continue to obtain components in the quantity and quality desired and at the prices we have budgeted.

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***If our facilities were to experience catastrophic loss, our operations would be seriously harmed.***

Our facilities could be subject to catastrophic loss such as fire, flood or earthquake. All of our research and development activities, manufacturing, our corporate headquarters and other critical business operations are located near major earthquake faults in Mountain View, California. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

***If we fail to maintain our relationships with health care providers, customers may not buy our products and our revenue and profitability may decline. At the same time, relationships with these individuals and entities are the subject of heightened scrutiny and may present the potential for healthcare compliance risks.***

We market our products to numerous health care providers, including physicians, hospitals, ASCs, government affiliated groups and group purchasing organizations. We have developed and strive to maintain close relationships with members of each of these groups who assist in product research and development and advise us on how to satisfy the full range of surgeon and patient needs. We rely on these groups to recommend our products to their patients and to other members of their organizations. The failure of our existing products and any new products we may introduce to retain the support of these various groups could have a material adverse effect on our business, financial condition and results of operations. In addition, our interactions, communications, and financial relationships with these individuals and entities present potential healthcare compliance risks.

***We are subject to government regulations which may cause us to delay or withdraw the introduction of new products or new applications for our products.***

The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the Food, Drug and Cosmetic Act ( FDCA ) and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the product must be shown to meet regulatory requirements established by the FDCA and implemented by the FDA. Unless otherwise exempt, a device manufacturer must obtain marketing clearance through the 510(k) premarket notification process, or approval through the lengthier premarket approval application ( PMA ) process. Not all devices are eligible for the 510(k) clearance process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the FDA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory clearance or approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes a broad range of additional requirements on medical device companies. Our products must be produced in compliance with the Quality System Regulation ( QSR ) and our manufacturing facilities are subject to establishment registration and device listing requirements from the FDA, and similar requirements from certain state authorities, and ongoing periodic inspections by the FDA, including unannounced inspections for compliance with applicable requirements. We are subject to monitoring, recordkeeping, and reporting obligations for medical device adverse events and malfunctions; notification of our products' defects or failure to comply with the FDA's laser regulations; and reporting of recalls, corrections, or removals of our products. The FDA also imposes requirements for the labeling of our products, and places limitations on claims we are permitted to make about our products in promotional labeling. The Federal Trade Commission has jurisdiction over the advertising of all of our products, which are non-restricted devices, and exercises oversight in coordination with the FDA.



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Noncompliance with the applicable requirements can result in, among other things, regulatory citations (including 483 Observations ) and Warning Letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Any of these actions by the FDA would materially and adversely affect our ability to continue operating our business and the results of our operations. Such enforcement action can also result in negative publicity.

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products CE marked, an international symbol affixed to all products demonstrating compliance with the European Medical Device Directive and all applicable standards. While currently all of our released products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition.

***If required, clinical trials necessary to support a 510(k) or PMA application will be an expensive, lengthy, costly, and uncertain process, and could result in delays in new product introductions or even an inability to release a product.***

The clinical trials often required to obtain regulatory approvals for products such as ours are complex and expensive and their outcomes are uncertain. If we were to embark upon clinical trials, we would incur substantial expense for, and devote significant time to, these trials but could not be certain that the trials would ever support the commercial sale of a product. We could suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products could produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA, or another regulatory authority could suspend or terminate clinical trials at any time if they or we believed the trial participants faced unacceptable health risks.

***If we fail to comply with the FDA's quality system regulation and laser performance standards, our manufacturing operations could be halted, and our business would suffer.***

We are currently required to demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. Our failure to take satisfactory corrective action in response to an adverse QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, which would cause our sales and business to suffer.

***If we modify one of our FDA approved devices, we may need to submit a new 510(k), or potentially a PMA, and if clearance or approval is not obtained, it would prevent us from selling our modified products or cause us to redesign our products.***

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for

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modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenues and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

### ***Our products may be misused, which could harm our reputation and our business.***

We market and sell our products for use by highly skilled physicians with specialized training and experience in the treatment of eye-related disorders. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions, nor do we supervise the procedures performed with our products. The physicians who operate our products are responsible for their use and the treatment regime for each individual patient. In addition, non-physicians, particularly in countries outside of the United States, or poorly trained or inexperienced physicians, may make use of our products. Our efforts to market our MicroPulse systems as a Fovea-friendly alternative to traditional continuous wavelength systems or alternative treatment methods may result in users failing to implement adequate safety precautions and thereby increase the risks associated with the misuse of our product. The lack of training and the purchase and use of our products by non-physicians or poorly trained or inexperienced physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation, or otherwise cause our business to suffer.

### ***Inability of customers to obtain credit or material increases in interest rates may harm our sales.***

Some of our products are sold to health care providers in general practice. Many of these health care providers purchase our products with funds they secure through various financing arrangements with third-party financial institutions, including credit facilities and short-term loans. If availability of credit becomes more limited, or interest rates increase, these financing arrangements may be harder to obtain or become more expensive for our customers, which may decrease demand for our products. Any reduction in the sales of our products would cause our business to suffer.

### ***Our products could be subject to recalls even after receiving FDA approval or clearance. A recall would harm our reputation and adversely affect our operating results.***

The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in the design or manufacture of our products, or in other cases we may determine that we will recall a product because we have determined that the product is violative, in order to avoid further enforcement action and protect the public health. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales.

### ***If product liability claims are successfully asserted against us, we may incur substantial liabilities that may adversely affect our business or results of operations.***

We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat extremely delicate eye tissue. We believe we maintain adequate levels of product liability insurance. However, product liability insurance is expensive and we might not be able to obtain product liability insurance in the future on

acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

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***Efforts to acquire additional companies or product lines may divert our managerial resources away from our business operations, and if we complete additional acquisitions, we may incur or assume additional liabilities or experience integration problems.***

Since 1989, we have completed six acquisitions. As part of our growth strategy we seek to acquire businesses or product lines for various reasons, including adding new products, adding new customers, increasing penetration with existing customers, adding new manufacturing capabilities or expanding into new geographic markets. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These efforts could divert the attention of our management and key personnel from our business operations. If we complete future acquisitions, we may also experience:

difficulties integrating any acquired products into our existing business;

difficulties in integrating an acquired company's technologies, services, employees, customers, partners, business operations and administrative and software management systems with ours;

delays in realizing the benefits of the acquired products;

diversion of our management's time and attention from other business concerns;

adverse customer reaction to the product acquisition; and

increases in expenses.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations. Furthermore, acquisitions could materially impair our operating results by causing us to amortize acquired assets, incur acquisition expenses and add debt.

***We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties. Additionally, challenges to or investigation into our practices could cause adverse publicity and be costly to respond to and thus could harm our business.***

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of certain metals used in manufacturing which may stem from minerals (so called "conflict minerals") which originate in the Democratic Republic of the Congo or adjoining regions. These metals include tantalum, tin, gold and tungsten. These metals are central to the technology industry and are present in some of our products as component parts. In most cases no acceptable alternative material exists which has the necessary properties. It is not possible to determine the source of the metals by analysis but instead a good faith description of the source of the intermediate components and raw materials must be obtained. The components which incorporate those metals may originate from many sources and we purchase fabricated products from manufacturers who may have a long and difficult-to-trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used, and components and assemblies which we buy may have a mix of sources as their origin. We are



required to carry out a diligent effort to determine and disclose the source of these materials. There can be no assurance we can obtain this information from intermediate producers who are unwilling or unable to provide this information or further identify their sources of supply or to notify us if these sources change. These metals are subject to price fluctuations and shortages which can affect our ability to obtain the manufactured materials we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products.

***If we fail to comply with environmental requirements, our business, financial condition, operating results and reputation could be adversely affected.***

Our products and operations are subject to various federal, state, local and foreign environmental laws and regulations, including those governing the use, storage, handling, exposure to, and disposal of hazardous

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materials and a large and growing body of international standards which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use and disposal of our products. We must continually keep abreast of these standards and requirements and integrate compliance to these with the development and regulatory documentation for our products. Failure to meet these standards could limit the ability to market our products in those regions which require compliance to such standards or subject us to fines and penalties. Examples of such standards include laws governing the hazardous material content of our devices and products, such as the European Union ( EU ) Directive 2011/65/EU relating to Restrictions on the Use of Certain Hazardous Substances RoHS Directive, and the EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment or WEEE Directive . Similar laws and regulations have been passed or are pending in several other jurisdictions and may be enacted in other regions, including in the United States, and we are, or may in the future be, subject to these laws and regulations.

Our failure to comply with past, present and future similar laws could result in reduced sales of our devices and products, inventory write-offs, reputational damage, penalties and other sanctions, any of which could harm our business and financial condition. We also expect that our devices and products will be affected by new environmental laws and regulations on an ongoing basis. New environmental laws and regulations will likely result in additional costs and may increase penalties associated with violations or require us to change the content of our devices and products or how they are manufactured, which could have a material adverse effect on our business, operating results and financial condition.

### **Risks Relating to Our Ownership of Our Common Stock and this Offering**

*Our stock price has been and may continue to be volatile and an investment in our common stock could suffer a decline in value.*

The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including changes in foreign currency exchange rates, quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. For the fiscal quarter ended October 1, 2016, the trading price of our common stock fluctuated from a low of \$13.39 per share to a high of \$16.64 per share. For the four fiscal quarters ended October 1, 2016, the trading price of our common stock fluctuated from \$7.50 per share to a high of \$16.64 per share. There can be no assurance that our common stock trading price will not suffer declines. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes and therefore broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

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

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways with which you may not agree. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the proceeds will be invested or otherwise used in a way that does not yield a favorable, or any, return for our company.

*Future sales and issuances of securities could negatively affect our stock price and dilute the ownership interest of our existing investors.*

Future sales or issuances of securities by us could decrease the value of our common stock, dilute stockholders' voting power and reduce future potential earnings per share.

To raise capital, we may sell common stock, convertible securities or other equity-linked securities in one or more transactions at prices and in a manner we determine from time to time. If we sell additional equity

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securities, our existing stockholders may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. We may also issue debt securities, which may impose restrictive covenants on our operations or otherwise adversely affect the holdings or the rights of our stockholders.

Sales or issuances of a substantial amount of securities, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock. As of October 1, 2016, we had 10,146,235 shares of common stock outstanding, all of which shares, other than shares held by our directors, our executive officers and certain investment funds affiliated with BlueLine Partners, L.L.C. were, and continue to be, eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. All of the shares offered under this prospectus supplement and the accompanying prospectus will be freely tradable without restriction or further registration upon issuance. Future resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

As of October 1, 2016, holders of an aggregate of 2,060,688 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. In addition, the shares of common stock subject to outstanding options and RSUs under our 2008 Equity Incentive Plan and the shares reserved for future issuance under the Incentive Plan will become eligible for sale in the public markets in the future, subject to certain legal and control limitations.

We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this 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 additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

***Because we do not intend to pay dividends, stockholders will benefit from an investment in our common stock only if it appreciates in value.***

We expect to retain any earnings for use to further develop our business, and do not expect to declare cash dividends on our common stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon our earnings, financial condition, capital needs and other factors deemed relevant by the board of directors, and may be restricted by future agreements with lenders. In addition, our loan facility with Silicon Valley Bank restricts us from paying any dividends or making any other distribution or payment on account of our common stock. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

***If securities or industry analysts do not continue to publish research or publish incorrect or unfavorable research about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our market and our competitors. If no or few securities or industry analysts cover our company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes incorrect or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price or trading volume to decline.



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***Ownership of our common stock is concentrated among a few investors, which may affect the ability of a third party to acquire control of us. Substantial sales by such investors could cause our stock price to decline.***

Our directors, executive officers, current five percent or greater stockholders and affiliated entities together beneficially own a significant portion of our common stock outstanding as of October 1, 2016. Having such a concentration of ownership may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding common stock or control of our board of directors through a proxy solicitation.

Shares held by our directors, our executive officers and certain investment funds affiliated with BlueLine Partners, L.L.C. under this prospectus supplement and the accompanying prospectus, are subject to a 90-day contractual lock-up, subject to certain exceptions, as described in the section entitled Underwriting. The sale, or perceived sale, of a substantial number of our shares by any such investor or our other stockholders, before or after the expiration of the 90-day contractual lock-up period, could cause the trading price of our common stock to decline, make it more difficult for us to raise funds through future offerings of our common stock or acquire other businesses using our common stock as consideration.

***Our ability to raise capital in the future may be limited, and our failure to raise capital when needed could prevent us from growing.***

Our business and operations may consume resources faster than we anticipate. In the future, we may need to raise additional funds to invest in future growth opportunities. Additional financing may not be available on favorable terms, if at all. If adequate funds are not available on acceptable terms, we may be unable to invest in future growth opportunities, which could seriously harm our business and operating results.

***As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.***

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We may experience difficulty in meeting these reporting requirements in a timely manner, particularly if material weaknesses or significant deficiencies persist. In July 2, 2016, we became an accelerated filer and effective with our Annual Report covering our fiscal year 2016, our independent registered public accounting firm will be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 as defined in the Exchange Act. If we are unable to comply with the requirements of Section 404 in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the NASDAQ Stock Market, the SEC or other regulatory authorities, which could require additional financial and management resources.

Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which could likely have a negative effect on the trading price of our common stock.

Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining

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the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes-Oxley Act in a timely manner, that our internal controls are perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline.

***Our charter documents, anti-takeover provisions of Delaware law, and contractual provisions could delay or prevent an acquisition or sale of our company.***

Our Certificate of Incorporation empowers the board of directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. These provisions give the board of directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock. Our certificate of incorporation and bylaws contain other provisions that could have an anti-takeover effect, including the following:

allow the authorized number of directors to be changed only by resolution of our board of directors;

only our board of directors is authorized to fill vacant directorships, including newly created seats;

special meetings of our stockholders may be called only by our board of directors or by a committee of our board of directors, thus prohibiting a stockholder from calling a special meeting;

stockholders must give advance notice to nominate directors or propose other business; and

stockholders are not permitted to cumulate votes in the election of directors.

In addition, we are generally subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock or prevent changes in our management.



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**Cautionary Statements Regarding Forward-Looking Statements**

This prospectus, any related prospectus supplement and the registration statement of which they are a part contain or incorporate by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. These forward-looking statements include, but are not limited to, statements about:

the effectiveness of procedures implemented to address recent supply chain and sales force training issues;

anticipated levels of future sales and operating results, and long term growth prospects;

market acceptance and adoption of our products and our outlook for system sales;

our gross margin goals and performance;

the success of our efforts to reduce costs and manage cash flows;

general economic conditions, including changes in foreign currency rates, and levels of international sales;

corporate strategy;

effects of seasonality;

inspections by and approvals required by the FDA;

our current and future liquidity and capital requirements; levels of future investment in research and development and sales and marketing efforts;

our product distribution strategies with Alcon, Inc.; and

compliance of our devices and products with various environmental laws and regulations.

Forward-looking statements involve a number of risks and uncertainties, many of which are outside of our control. Factors that might cause actual results to differ include, but are not limited to, those set forth under Risk Factors in this prospectus supplement and the documents incorporated by reference herein. In particular, factors that could cause

actual results to differ materially from projected results include, but are not limited to:

quality control, production and product assembly issues;

defects in product design;

risks associated with international sales;

general economic and political conditions globally or regionally;

business and economic conditions in the industries in which we operate;

the ability to successfully develop new products;

the ability of new and existing products to achieve and maintain market acceptance;

increases in and effects of competition;

uncertainty regarding healthcare reform measures and changes in third-party coverage and reimbursement policies;

changes in collaborative relationships;

changes in our costs and unit pricing of products;

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changes in sales force or distributor relationships;

any failure to manage growth in our business, including growth through acquisitions;

any failure to maintain or successfully protect intellectual property rights;

any loss of key personnel;

any failure to accurately forecast demand for our products;

reliance on sole and limited source suppliers and manufacturers;

any catastrophic loss of our facilities;

any failure to maintain our relationships with health care providers;

the impact of FDA, environmental and other regulations on business;

any failure to comply with regulatory and legal requirements;

loss of reputation, including as a result of any misuse of products;

the inability of customers to obtain credit or increases in interest rates;

any recalls of products;

product liability and other legal claims;

the ability to successfully manage the acquisition and integration of additional companies or product lines;  
and

our ability to comply with federal, state and foreign laws governing our business practices.

Although we believe that the assumptions underlying our forward-looking statements are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in our forward-looking statements, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. IRIDEX disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any additional disclosures we have made or will make in our reports to the SEC on Forms 10-K, 10-Q and 8-K. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in this prospectus.

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We estimate that the net proceeds from the sale of the \_\_\_\_\_ shares of common stock that we are offering, will be approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ million if the underwriter exercise their over-allotment option in full, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We expect the net proceeds to us from the sale of the common stock offered by this prospectus supplement and the accompanying prospectus will be used for working capital and other general corporate purposes. We may also use a portion of the net proceeds for licensing or acquiring intellectual property or technologies to incorporate in our products, capital expenditures, to fund possible investments in and acquisitions of complementary businesses, partnerships, minority investments or to repay indebtedness.

We have not determined the amounts we plan to spend on the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion in the application of the net proceeds of this offering. We have no current plans, commitments or agreements with respect to any material licenses, acquisitions, investments or similar transactions as of the date of this prospectus. Pending the application of the net proceeds, we expect to invest the net proceeds of this offering in investment-grade, interest-bearing securities.

**Price Range of Our Common Stock**

Our common stock is listed on The NASDAQ Global Market under the symbol IRIX. The following table sets forth, for the periods indicated, the high and low closing sales prices of our common stock as reported on The NASDAQ Global Market:

	<b>High</b>	<b>Low</b>
<b>Fiscal Year ended January 3, 2015</b>		
First Quarter	\$ 10.80	\$ 8.12
Second Quarter	\$ 9.47	\$ 8.02
Third Quarter	\$ 8.35	\$ 6.51
Fourth Quarter	\$ 8.81	\$ 6.63
<b>Fiscal Year ended January 2, 2016</b>		
First Quarter	\$ 10.79	\$ 8.66
Second Quarter	\$ 10.70	\$ 8.29
Third Quarter	\$ 8.35	\$ 6.51
Fourth Quarter	\$ 9.86	\$ 7.37
<b>Fiscal Year ended December 31, 2016</b>		
First Quarter	\$ 10.70	\$ 8.80
Second Quarter	\$ 15.51	\$ 10.02
Third Quarter	\$ 16.39	\$ 13.52
Fourth Quarter (through December 7, 2016)	\$ 16.26	\$ 12.70

As of December 7, 2016, there were 42 holders of record of our common stock. On December 7, 2016, the last sale price reported on The NASDAQ Global Market for our common stock was \$14.90 per share.



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**Dividend Policy**

We have never declared or paid any dividends on our capital stock. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, our loan facility with Silicon Valley Bank restricts us from paying any dividends or making any other distribution or payment on account of our common stock.

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**Description of Securities**

In this offering, we are offering \_\_\_\_\_ shares of common stock. The material terms and provisions of our common stock are described under the caption Description of Capital Stock starting on page 7 of the accompanying prospectus.

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**Material U.S. Federal Income Tax Consequences to Non-U.S. Holders of our Common Stock**

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock, but does not purport to be a complete analysis of all the potential tax considerations relating thereto. This summary is based upon the provisions of the Code, Treasury regulations promulgated thereunder, administrative rulings and judicial decisions, all as of the date hereof. These authorities may be changed, possibly retroactively, and any changes may result in U.S. federal income tax consequences different from those set forth below. We have not sought any ruling from the Internal Revenue Service, or the IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions.

This summary also does not address the tax considerations arising under the laws of any state, local or non-U.S. jurisdiction or under U.S. federal non-income tax laws, except to the limited extent set forth below. In addition, this discussion does not address the potential application of the Medicare contribution tax on net investment income or any tax considerations applicable to an investor's particular circumstances or to investors that may be subject to special tax rules, including, without limitation:

banks, insurance companies or other financial institutions;

persons subject to the alternative minimum tax;

tax-exempt organizations or accounts;

controlled foreign corporations, passive foreign investment companies or corporations that accumulate earnings to avoid U.S. federal income tax;

dealers in securities or currencies;

traders in securities that elect to use a mark-to-market method of accounting for their securities holdings;

persons that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);

certain former citizens or long-term residents of the United States;

persons who hold our common stock as a position in a hedging transaction, straddle, conversion transaction or other risk reduction transaction;

persons who do not hold our common stock as a capital asset within the meaning of Section 1221 of the Code (generally property held for investment); or

persons deemed to sell our common stock under the constructive sale provisions of the Code.

In addition, if a partnership (or entity or arrangement classified as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a person treated as a partner for such purposes generally will depend on the status of the partner and upon the activities of the partnership. Accordingly, partnerships that hold our common stock, and partners in such partnerships, should consult their tax advisors.

***You are urged to consult your tax advisor with respect to the application of the U.S. federal income tax laws to your particular situation, as well as any tax consequences of the purchase, ownership and disposition of our common stock arising under the U.S. federal estate or gift tax rules or under the laws of any state, local, non-U.S. or other taxing jurisdiction or under any applicable tax treaty.***

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**Non-U.S. Holder Defined**

For purposes of this discussion, you are a non-U.S. holder if you are a beneficial owner of our common stock that is not, for U.S. federal income tax purposes, any of the following:

an entity or arrangement treated as a partnership;

an individual who is a citizen or resident of the United States;