



Glaukos to Outline Growth Strategy at Investor Day

2017-09-14

Company Revises 2017 Net Sales Guidance

SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, will provide an overview of its growth strategy and market opportunity, update progress of its innovative pipeline products and revise 2017 net sales guidance during its Investor Day meeting today in New York City.

"As the founder and pioneer of Micro-Invasive Glaucoma Surgery (MIGS), we see tremendous future potential for Glaukos to leverage our market-expanding portfolio of injectable *iStent*[®] MIGS devices and novel *iDose*[®] drug delivery system," said Thomas Burns, Glaukos president and chief executive officer. "With core competencies in micro-engineering design and manufacturability, drug formulation, regulatory strategy and commercial execution, we are building robust technology platforms to facilitate our transformation into a glaucoma-centric pharmaceutical-device company focused on important clinical needs aimed at driving sustained, longer-term growth."

Key Pipeline Developments

Among the topics Glaukos management will discuss today are the following updates about its *iDose Travoprost* and *iStent* pipeline products:

iDose Travoprost:

The company will provide an overview of the preliminary efficacy and safety results from the U.S. Investigational New Drug (IND) Phase II clinical trial to evaluate the reduction of intraocular pressure (IOP) by its Travoprost Intraocular Implant with the *iDose* delivery system in patients with open-angle glaucoma. Implanted during a micro-invasive procedure, the *iDose Travoprost* is designed to continuously elute therapeutic levels of medication from within the eye for extended periods of time. It is filled with a special formulation of travoprost, a prostaglandin analog used to reduce IOP, and capped with a membrane designed for continuous controlled drug elution into the anterior chamber. When depleted, the *iDose Travoprost* can be removed and replaced in a similar, subsequent procedure.

The purpose of the 154-patient, multi-center, randomized, double-blind Phase II trial is to evaluate two models of the *iDose* delivery system with different travoprost elution rates, compared to topical timolol maleate ophthalmic solution, 0.5%. Preliminary results showed that both models of the *iDose Travoprost* are currently achieving an approximate 8 mm Hg reduction in mean IOP in the cohort of

patients followed through nine months postoperative. In addition, the preliminary study results showed a favorable safety profile for *iDose Travoprost*, with no incidents of hyperemia reported.

“These preliminary results are very encouraging and illustrate the potential for *iDose Travoprost* to achieve significant duration of effect and provide a favorable safety profile, which are critical factors to effectively addressing the ubiquitous problem of patient non-adherence to topical glaucoma medication regimens,” said Mr. Burns. “We look forward to working with the FDA to continue the IND evaluation process.”

The Phase II *iDose Travoprost* trial design calls for subjects to be followed through three years. Glaukos expects to review the *iDose Travoprost* results with the FDA in the fourth quarter and to commence Phase III trials in early 2018.

iStent infinite[™]:

The company will announce plans to pursue U.S. FDA approval of *iStent infinite*, a three-stent trabecular bypass standalone solution for refractory open-angle glaucoma patients. In the fourth quarter of 2017, the company expects to submit an Investigational Device Evaluation (IDE) filing with the FDA, with plans to conduct a one-year clinical study of approximately 65 subjects, followed by a 510(k) submission.

“By addressing the needs of refractory glaucoma patients, the *iStent infinite* will round out our industry-leading portfolio of MIGS devices, designed to restore natural physiological outflow through an elegant, facile procedure,” said Mr. Burns. “We expect the *iStent infinite* to be an attractive alternative to invasive, late-stage glaucoma surgeries that often subject patients to high failure and complication rates.”

The *iStent infinite* will be intended for patients whose IOP is uncontrolled by maximal medication therapy or incisional surgeries such as trabeculectomies or tube shunt implantation. An international case series of 30 subjects – including 27 with prior trabeculectomies – showed that three trabecular bypass stents implanted in a standalone procedure provided a 52% reduction in mean IOP to 13.7 mm Hg at 12 months postoperative. Over the same one-year period, subjects achieved a 77% reduction in the mean number of topical medications used, to 0.43 postoperative vs. 1.83 preoperatively.

2017 Guidance

At today's Investor Day, Glaukos management will also discuss revisions to its 2017 net sales guidance. The company is revising its guidance for third quarter and full year 2017 net sales to a range of \$38 million to \$40 million and \$155 million to \$160 million, respectively. This compares to prior guidance of \$41 million to \$43 million for the third quarter and \$162 million to \$167 million for the full year 2017. The revised guidance reflects the company's current assessment of certain transitory impacts to *iStent* procedure volumes, including commercial carrier reimbursement, recent hurricanes and reimbursement changes in Australia, together with less transitory factors, including new MIGS competition entering the market.

Investor Day and Webcast Information

The company will host its Investor Day meeting today in New York City, beginning at 8 a.m. EDT and concluding at approximately 11:30 a.m. EDT. A live webcast of the meeting, including slide presentations, will be available on the Glaukos website at <http://investors.glaukos.com>. An archived replay will also be available on the website following the meeting.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, one of the world's leading causes of blindness. The company pioneered Micro-Invasive Glaucoma Surgery, or MIGS, to revolutionize the traditional glaucoma treatment and management paradigm. Glaukos launched the *iStent*[®], its first MIGS device, in the United States in July 2012 and is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale injectable therapies designed to address the complete range of glaucoma disease states and progression. The company believes the *iStent*, measuring 1.0 mm long and 0.33 mm wide, is the smallest medical device ever approved by the FDA.

Forward-Looking Statements

All statements other than statements of historical facts included in this press release that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. These forward-looking statements include our expectations about our *iDose Travoprost* and *iStent infinite* pipeline products and our financial guidance for the third quarter and full year 2017. Although we believe that we have a reasonable basis for forward-looking statements contained herein, we caution you that they are based on current expectations about future events affecting us and are subject to risks, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control, that may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this press release. These potential risks and uncertainties include, without limitation, uncertainties about our ability to maintain profitability; our dependence on the success and market acceptance of the *iStent*; our ability to leverage our sales and marketing infrastructure to increase market penetration and acceptance both in the United States and internationally of our products; our dependence on a limited number of third-party suppliers for components of our products; the occurrence of a crippling accident, natural disaster or other disruption of our business and at our primary facility, which may materially affect our manufacturing capacity and operations; maintaining adequate coverage or reimbursement by third-party payors for procedures using the *iStent* or other products in development; our ability to properly train, and gain acceptance and trust from, ophthalmic surgeons in the use of our products; our ability to successfully develop and commercialize additional products; our ability to compete effectively in the highly competitive and rapidly changing medical device industry and against current and future competitors (including MIGS competitors) that, in some cases, are large public companies or divisions of publicly traded companies that have competitive advantages; the timing, effect and expense of navigating different regulatory approval processes as we develop additional products and penetrate foreign markets; the impact of any product liability claims against us and any related litigation; the effect of the extensive and increasing federal and state regulation in the healthcare industry on us and our suppliers; the lengthy and expensive clinical trial process and the uncertainty of outcomes from any particular clinical trial; our ability to protect, and the expense and time-consuming nature of protecting, our intellectual property against third parties and competitors that could develop and commercialize similar or identical products; the impact of any claims against us of infringement or misappropriation of third party intellectual property rights and any related litigation; and the market's perception of our limited operating history as a public company. These and other known risks, uncertainties and factors are described in detail under the caption "Risk Factors" and elsewhere in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for 2016 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. Our filings with the Securities and Exchange Commission are available in the Investor Section of our website at www.glaukos.com or at www.sec.gov. In addition, information about the risks and benefits of our products is available on our website at www.glaukos.com. All forward-looking statements included in this press release are

expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on the forward-looking statements in this press release, which speak only as of the date hereof. We do not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

View source version on
businesswire.com: <http://www.businesswire.com/news/home/20170914005466/en/>

Source: Glaukos Corporation

Glaukos Corporation

Sheree Aronson

VP, Investor Relations

(949) 481-0361

saronson@glaukos.com