Glaukos Corporation Announces First Quarter 2020 Financial Results

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SAN CLEMENTE, Calif.--(BUSINESS WIRE)-- Glaukos Corporation (NYSE: GKOS), an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases, today announced financial results for the first quarter ended March 31, 2020. Key highlights include:

- Q1 2020 net sales of $55.3 million, compared to $54.0 million in Q1 2019.
- Glaucoma Q1 2020 net sales of $44.1 million, compared to $54.0 million in Q1 2019.
- Corneal Health Q1 2020 net sales of $11.2 million.
- In March 2020, Glaukos withdrew its annual net sales guidance for 2020 due to continued uncertainties related to the COVID-19 pandemic.

“I want to recognize the dedication and resiliency of our employees who continue to move our company forward despite unique challenges associated with the COVID-19 pandemic. I also want to express our deep gratitude for the healthcare workers and first responders who are selflessly serving on the frontlines to take care of those in need,” said Thomas Burns, Glaukos president and chief executive officer. “In response to COVID-19, Glaukos immediately reviewed and implemented numerous measures to prioritize the health and safety of our employees and their families, support our customers, preserve jobs globally, protect core research and development programs and maintain our strong financial and operating position following the COVID-19 pandemic. While our near-term business trends have been and continue to be materially impacted due to the shift of healthcare systems resources to the treatment of COVID-19 and government restrictions on elective procedures, I am confident the longer-term fundamental prospects of our business remain strong as we advance our mission to transform the treatment of chronic eye diseases with novel therapies that provide sustainable solutions to important clinical needs. We remain well-positioned to provide our essential ophthalmic therapies to customers and their patients as deferred procedures ultimately return in the future as the COVID-19 pandemic subsides.”

First Quarter 2020 Financial Results

Net sales rose 2% in the first quarter of 2020 to $55.3 million, compared to $54.0 million in the same period in 2019. The growth reflected contribution from the Avedro acquisition offset primarily by disruptions associated with COVID-19.

Gross margin for the first quarter of 2020 was approximately 41%, compared to approximately 87% in the same period in 2019. Non-GAAP gross margin for the first quarter of 2020 was approximately 84%, compared to approximately 87% in the same period in 2019.

Selling, general and administrative (SG&A) expenses for the first quarter of 2020 rose 45% to $50.5 million, compared to $34.9 million in the same period in 2019. Non-GAAP SG&A expenses for the first quarter of 2020 rose 29% to $41.1 million, compared to $31.9 million in the same period in 2019.

Research and development (R&D) expenses in the first quarter of 2020 rose 79% to $24.9 million, compared to $13.9 million in the same period in 2019. Non-GAAP R&D expenses for the first quarter of 2020 rose 64% to $22.9 million, compared to $13.9 million in the same period in 2019.

Loss from operations in the first quarter of 2020 was $52.6 million, compared to an operating loss of $1.9 million in the first quarter of 2019. Non-GAAP loss from operations in the first quarter of 2020 was $17.8 million, compared to non-GAAP operating income of $1.1 million in the first quarter of 2019.

Net loss in the first quarter of 2020 was $54.1 million, or ($1.24) per diluted share, compared to a net loss of $1.3 million, or ($0.04) per diluted share, in the first quarter of 2019. Non-GAAP net loss in the first quarter of 2020 was $19.2 million, or ($0.44) per diluted share, compared to non-GAAP net income of $1.7 million, or $0.04 per diluted share, in the first quarter of 2019.

The company ended the first quarter of 2020 with $173.0 million in cash and cash equivalents, short-term investments and restricted cash. Additionally, the company does not carry any outstanding debt obligations.

2020 Revenue Guidance

As previously announced in a press release issued on March 24, 2020, due to the rapidly evolving environment and continued uncertainties from the impact of COVID-19, Glaukos has withdrawn its previously announced annual guidance for 2020, which was issued on February 27, 2020. At this date, Glaukos cannot predict the specific extent, or duration, of the impact of the COVID-19 outbreak on its financial and operating results.

Webcast & Conference Call

The company will host a conference call and simultaneous webcast today at 1:30 p.m. PDT (4:30 p.m. EDT) to discuss the results and provide additional information about the company's financial outlook. A link to the webcast is available on the company's website at http://investors.glaukos.com. To participate in the conference call, please dial 833-979-2546 (U.S.) or 236-714-2218 (international) and enter Conference ID 6256058. A replay of the webcast will be archived on the company's website following completion of the call.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical company focused on novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. 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 launched its next-generation *iStent inject*® device in the United States in September 2018. In corneal health, Glaukos' proprietary suite of single-use, bio-activated pharmaceuticals are designed to strengthen, stabilize and reshape the cornea through a process called corneal collagen cross-linking to treat corneal ectatic disorders and correct refractive conditions. Glaukos is leveraging its platform technology to build a comprehensive and proprietary portfolio of micro-scale surgical and pharmaceutical therapies in glaucoma, corneal health and retinal disease.

Forward-Looking Statements

This communication contains "forward-looking statements" within the meaning of federal securities laws. 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 statements are based on management's current expectations, assumptions, estimates and beliefs. 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 that could cause actual results to differ materially from those described in forward-looking statements include, without limitation, uncertainties regarding the duration and severity of the COVID-19 pandemic and its impact on our business or the economy generally; uncertainties about our dependence on the success and market acceptance of the *iStent* and the *iStent inject*; our ability to reach sustained profitability; our ability to leverage our sales and marketing infrastructure to increase market penetration and acceptance of our products both in the United States and internationally; our ability to bring our pipeline products to market; our dependence on a limited number of third-party suppliers, some of which are single-source, for components of our products; the occurrence of a crippling accident, natural disaster, pandemic (including an outbreak of COVID-19) or other disruption 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,* the *iStent inject*, our corneal cross-linking products 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 are large public companies or divisions of publicly traded companies that have competitive advantages; the timing, effect, expense and uncertainty 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 timing and outcomes from any particular clinical trial; the risk of recalls or serious safety issues with our products and the uncertainty of patient outcomes; 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; the market's perception of our limited operating history as a public company; and potential disruptions from the acquisition of Avedro that may divert management attention from other important business objectives. 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 2019, which was filed with the Securities and Exchange Commission (SEC) on March 2, 2020, and will also be included in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which we expect to file on or before May 11, 2020. 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.

In addition, with respect to COVID-19, we are currently unable to reasonably estimate the specific extent, or duration, of the impact of the COVID-19 outbreak on our financial and operating results. We are also unable to predict how the outbreak will continue to affect restrictions and advisories on elective procedures and therapies, the availability of physicians and/or their treatment prioritizations or the impact of the outbreak on the overall healthcare infrastructure. In addition to an impact on procedure volumes, we are experiencing and may experience other disruptions as a result of the COVID-19 outbreak. For example, it is possible our suppliers will incur challenges supplying the materials needed for the manufacture of our product. In addition, our clinical trials may be adversely affected. Other disruptions or potential disruptions include restrictions on the ability of Company personnel to travel and access customers for training and case support; delays in approvals by regulatory bodies; delays in product development efforts; and additional government requirements to “shelter at home” or other incremental mitigation efforts that may further impact our capacity to manufacture, sell and support the use of our products. The total impact of these disruptions could have a material impact on the Company’s financial condition, cash flows and results of operations.

Statement Regarding Use of Non-GAAP Financial Measures

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles ("GAAP"), the Company uses certain non-GAAP historical financial measures. Management makes adjustments to the GAAP measures for items (both charges and gains) that (a) do not reflect the core operational activities of the Company, (b) are commonly adjusted within the Company's industry to enhance comparability of the Company's financial results with those of its peer group, or (c) are inconsistent in amount or frequency between periods (albeit such items are monitored and controlled with equal diligence relative to core operations). The Company uses the term "Non-GAAP" to exclude intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, costs and expenses associated with acquisitions and integration, costs associated with enterprise system upgrades, certain inventory write-off charges, in-process R&D charges, significant discrete income tax adjustments related to transactions as well as changes in estimated acquisition-date tax effects associated with business combinations, and the impact from implementation of tax law changes and settlements. See “GAAP to Non-GAAP Reconciliations” for a reconciliation of each non-GAAP measure presented to the comparable GAAP financial measure.

GLAUKOS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2020	**2019**
Net sales	$ 55,336	$ 54,026
Cost of sales	32,529	7,111
Gross profit	22,807	46,915
Operating expenses:		

Selling, general and administrative	50,546	34,925
Research and development	24,873	13,930
Total operating expenses	75,419	48,855
Loss from operations	(52,612)	(1,940)
Non-operating income (expense):		
Interest income	696	788
Interest expense	(881)	-
Other expense, net	(1,711)	(68)
Total non-operating (expense) income	(1,896)	720
Loss before taxes	(54,508)	(1,220)
Income tax (benefit) provision	(450)	122
Net loss	$ (54,058)	$ (1,342)
Basic and diluted net loss per share	$ (1.24)	$ (0.04)
Weighted average shares used to compute basic and diluted net loss per share	43,766	36,205

GLAUKOS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except par values)

	March 31, 2020	**December 31, 2019**
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 53,614	$ 62,430
Short-term investments	110,096	111,553
Accounts receivable, net	28,885	38,417
Inventory, net	27,699	42,578
Prepaid expenses and other current assets	11,092	7,900

Total current assets	231,386	262,878
Restricted cash	9,326	9,326
Property and equipment, net	22,760	22,056
Operating lease right-of-use asset	15,059	15,704
Finance lease right-of-use asset	53,441	54,048
Intangible assets, net	376,377	382,605
Goodwill	66,134	66,134
Deposits and other assets	5,237	5,649
Total assets	$ 779,720	$ 818,400
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 12,943	$ 5,781
Accrued liabilities	38,134	51,919
Total current liabilities	51,077	57,700
Operating lease liability	13,601	14,195
Finance lease liability	59,316	58,435
Deferred tax liability, net	9,936	9,632
Other liabilities	4,491	5,166
Total liabilities	138,421	145,128
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized; no shares issued and outstanding	-	-
Common stock, $0.001 par value; 150,000 shares authorized; 44,119 and 43,530 shares issued and 44,091 and 43,502 shares outstanding as of March 31, 2020 and December 31, 2019, respectively	44	44
Additional paid-in capital	883,136	861,740
Accumulated other comprehensive income	2,019	1,330
Accumulated deficit	(243,768)	(189,710)

Less treasury stock (28 shares as of March 31, 2020 and December 31, 2019)	(132)	(132)
Total stockholders' equity	641,299	673,272
Total liabilities and stockholders' equity	$779,720	$818,400

GLAUKOS CORPORATION
GAAP to Non-GAAP Reconciliations
(in thousands, except per share amounts)
(Unaudited)

	Q1 2020			**Q1 2019**		
	GAAP	Adjustments	Non-GAAP	**GAAP**	Adjustments	Non-GAAP
Cost of sales	**$32,529**	$ (23,439) (a)(b)(f)	$9,090	**$7,111**	-	$7,111
Gross profit	**$22,807**	$ 23,439	$46,246	**$46,915**	-	$46,915
Operating expenses:						
Selling, general and administrative	**$50,546**	$ (9,448) (c)(d)(e)(f)	$41,098	**$34,925**	$ (3,071) (h)(i)	$31,854
Research and development	**$24,873**	$ (1,970) (c)(f)	$22,903	**$13,930**	-	$13,930
Total operating expenses	**$75,419**	$ (11,417)	$64,002	**$48,855**	$ (3,071)	$45,784
(Loss) income from operations	**$(52,612)**	$ 34,856	$(17,756)	**$(1,940)**	$ 3,071	$1,131
Net (loss) income	**$(54,058)**	$ 34,856 (g)	$(19,202)	**$(1,342)**	$ 3,071 (g)	$1,729
Diluted net (loss) income per share	**$(1.24)**		$(0.44)	**$(0.04)**		$0.04

(a) Cost of sales adjustments related to the inventory fair value step up and amortization of developed technology intangible assets from the Avedro, Inc. acquisition in the amount of $9.7 million and $5.5 million, respectively.

(b) Inventory write-off charges and COVID-19 related excess and obsolete reserves, a portion of which includes the associated fair-value step up of acquired Avedro inventory, totaling $7.9 million.

(c) Restructuring expenses of $0.2 million in selling, general and administrative and $0.1 million in research and development.

(d) Expenses related to the Company's patent infringement litigation and related matters, consisting of $2.5 million.

(e) Costs of $0.5 million associated with the Company's implementation of its new enterprise systems and other technology optimizations.

(f) Expenses related to the Avedro, Inc. acquisition:

• Integration expenses of $0.8 million consisting primarily of legal fees, accounting fees and other costs in selling, general and administrative.

• Restructuring expenses of $0.2 million in cost of sales, $0.5 million in selling, general and administrative and $0.1 million in research and development.

• Amortization expense of customer relationship intangible assets in the amount of $0.7 million in selling, general and administrative.

• Stock-based compensation expense related to replacement awards in the amount of $0.2 million in cost of sales, $4.2 million in selling, general and administrative and $1.8 million in research and development.

(g) Includes total tax effect for non-GAAP pre-tax adjustments. For non-GAAP adjustments associated with the U.S., the tax effect is $0 given the Company's U.S. taxable loss positions in both 2020 and 2019.

(h) Expenses related to the Company's patent infringement litigation and related matters of $1.7 million.

(i) Costs of $1.4 million associated with the Company's implementation of its new enterprise systems and other technology optimizations.

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Chris Lewis
Director, Investor Relations, Corporate Strategy & Development
(949) 481-0510
clewis@glaukos.com

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