



Glaukos Corporation Announces Third Quarter 2022 Financial Results

2022-11-02

ALISO VIEJO, 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 third quarter ended September 30, 2022. Key highlights include:

- Net sales of \$71.3 million in Q3 2022.
- Glaucoma net sales of \$53.7 million and Corneal Health net sales of \$17.5 million in Q3 2022.
- Gross margin of approximately 76% and non-GAAP gross margin of approximately 84% in Q3 2022.
- Updated 2022 net sales guidance to \$278 million to \$280 million, compared to \$275 million to \$280 million previously.

"Our solid third quarter performance reflects our teams' ongoing commitment to advance our key strategic priorities and execute our plans while navigating a dynamic macro environment," said Thomas Burns, Glaukos chairman and chief executive officer. "We are now in the midst of several exciting new product launches and continue to successfully invest in and advance our robust pipeline of novel, dropleless platform technologies designed to meaningfully advance the standard of care and improve outcomes for patients suffering from chronic eye diseases."

Third Quarter 2022 Financial Results

Net sales in the third quarter of 2022 of \$71.3 million declined 4.6% on a reported basis, or 1.6% on a constant currency basis, compared to \$74.7 million in the same period in 2021.

Gross margin for the third quarter of 2022 was approximately 76%, compared to approximately 79% in the same period in 2021. Non-GAAP gross margin for the third quarter of 2022 was approximately 84%, compared to approximately 87% in the same period in 2021.

Selling, general and administrative (SG&A) expenses for the third quarter of 2022 increased 6% to \$47.1 million, compared to \$44.5 million in the same period in 2021. Non-GAAP SG&A expenses for the third quarter of 2022 increased 13% to \$46.4 million, compared to \$41.2 million in the same period in 2021.

Research and development (R&D) expenses for the third quarter of 2022 were \$28.9 million, compared to \$28.8 million in the same period in 2021. Non-GAAP R&D expenses for the third quarter of 2022 increased 1% to \$28.9 million, compared to \$28.7 million in the same period in 2021.

Loss from operations in the third quarter of 2022 was \$21.6 million, compared to operating income of \$11.0 million in the third quarter of 2021. Non-GAAP loss from operations in the third quarter of 2022 was \$15.3 million, compared to non-GAAP operating loss of \$9.9 million in the third quarter of 2021.

Net loss in the third quarter of 2022 was \$27.6 million, or (\$0.58) per diluted share, compared to net income of \$6.2 million, or \$0.13 per diluted share, in the third quarter of 2021. Non-GAAP net loss in the third quarter of 2022 was \$21.3 million, or (\$0.45) per diluted share, compared to non-GAAP net loss of \$14.7 million, or (\$0.31) per diluted share, in the third quarter of 2021.

Included in operating income, net income and earnings per share (EPS) for the third quarter of 2021 is a \$30 million payment receipt related to the company's settlement of patent litigation with Ivantis, Inc., which was recorded as an offset to GAAP operating expenses.

Included in non-GAAP loss from operations, non-GAAP net loss and non-GAAP EPS for the third quarter of 2021 is an in-process R&D (IPR&D) charge of \$5.0 million associated with an upfront payment related to the execution of a licensing arrangement with Atillaps Holdings, which caused the non-GAAP loss per diluted share to have an additional loss of (\$0.10) in the prior year period. This charge was previously excluded in the prior year reporting period from non-GAAP operating expenses and has been adjusted to account for a change in the company's methodology to now include similar IPR&D transactions for non-GAAP disclosure and reporting purposes.

The company ended the third quarter of 2022 with approximately \$371 million in cash and cash equivalents, short-term investments and restricted cash.

2022 Revenue Guidance

The company expects 2022 net sales to be in the range of \$278 million to \$280 million.

Webcast & Conference Call

The company will host a conference call and simultaneous webcast today at 1:30 p.m. PT (4:30 p.m. ET) 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 888-210-2212 (U.S.) or 646-960-0390 (international) and enter Conference ID 7935742. A replay of the webcast will be archived on the company's website following completion of the call.

Quarterly Summary Document

The company has posted a document on its Investor Relations website under the "Financials & Filings – Quarterly Results" section titled "Quarterly Summary." This Quarterly Summary document is designed to provide the investment community with a summarized and easily accessible reference document that details the key facts associated with the quarter, the state of the company's business objectives and strategies and any forward statements or guidance the company may make. Going forward, this document will be provided alongside the company's earnings press release and is designed to be read by investors before the regularly scheduled quarterly conference call. As such, today's conference call will be in a format primarily consisting of a questions and answers session, during which Glaukos will address any queries investors have regarding the company's results. It is the company's goal that this format will make its quarterly earnings process more efficient and impactful for the investment community going forward.

About Glaukos

Glaukos (www.glaukos.com) is an ophthalmic medical technology and pharmaceutical company focused on developing and commercializing novel therapies for the treatment of glaucoma, corneal disorders and retinal diseases. Glaukos first developed Micro-Invasive Glaucoma Surgery (MIGS) as an alternative to the traditional glaucoma treatment paradigm, launching its first MIGS device commercially in 2012, and continues to develop a portfolio of technologically distinct and leverageable platforms to support ongoing pharmaceutical and medical device innovations. Products or product candidates for each of these platforms are designed to advance the standard of care through better treatment options across the areas of glaucoma, corneal disorders and retinal diseases.

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 impact of the COVID-19 pandemic or other future public health crises on our business; the impact of general macroeconomic conditions; the reduced physician fee and ASC facility fee reimbursement rate finalized by CMS for 2022 and 2023 for procedures utilizing the Company's iStent family of products and its impact on our U.S. combo-cataract glaucoma revenue; our ability to continue to generate sales of our commercialized products and develop and commercialize additional products; 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, or other disruption at our primary facility, which may materially affect our manufacturing capacity and operations; securing or maintaining adequate coverage or reimbursement by third-party payors for procedures using the *iStent*, the *iStent inject*, the *iStent inject W*, *iAccess*, *iPRIME*, *iStent infinite*, 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 compete effectively in the medical device industry and against current and future technologies (including MIGS technologies); our compliance with federal, state and foreign laws and regulations for the approval and sale and marketing of our products and of our manufacturing processes; the lengthy and expensive clinical trial process and the uncertainty of timing and outcomes from any particular clinical trial or regulatory approval processes; 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 and the impact of any claims against us for infringement or misappropriation of third party intellectual property rights and any related litigation; and our ability to service our indebtedness. 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 (SEC), including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, which was filed with the SEC on August 5, 2022, and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, which is expected to be filed with the SEC by November 9, 2022. Our filings with the SEC 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.

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 external acquisition-related costs incurred to effect a business combination; amortization of intangible assets acquired in a business combination, asset purchase transaction or other contractual relationship; impairment of goodwill and intangible assets; certain in-process R&D charges; fair value adjustments to contingent consideration liabilities and pre-acquisition contingencies arising from a business combination; integration and transition costs related to business combinations; fair market value adjustments to inventories acquired in a business combination or asset purchase transaction; restructuring charges, duplicative operating expenses, or asset write-offs (or reversals) associated with exiting or significantly downsizing a business; gain or loss from the sale of a business; gain or loss on the mark-to-market adjustment, impairment, or sale of long-term investments; mark-to-market adjustments on derivative instruments that hedge income or expense exposures in a future period; significant legal litigation costs and/or settlement expenses or proceeds legal and other associated expenses that are both unusual and significant related to governmental or internal inquiries; and significant discrete income and other 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.

In addition, in order to remove the impact of fluctuations in foreign currency exchange rates, the Company also presents certain net sales information on a constant currency basis, which represents the outcome that would have resulted had exchange rates in the current period been the same as the average exchange rates in effect in the comparable prior period. See page 9 of this press release for a presentation of certain net sales information on a reported, GAAP and a constant currency basis.

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

Three Months Ended **September 30,** **Nine Months Ended** **September 30,**

	2022	2021	2022	2021
Net sales	\$ 71,269	\$ 74,710	\$ 211,635	\$ 220,771
Cost of sales	16,861	15,370	51,757	49,762
Gross profit	54,408	59,340	159,878	171,009
Operating expenses:				
Selling, general and administrative	47,149	44,470	140,998	131,691
Research and development	28,870	28,846	87,459	74,321
In-process research and development	-	5,000	10,000	10,000
Litigation-related settlement	-	(30,000)	(30,000)	(30,000)
Total operating expenses	76,019	48,316	208,457	186,012
(Loss) income from operations	(21,611)	11,024	(48,579)	(15,003)
Non-operating expense:				
Interest income	744	291	1,415	1,016
Interest expense	(3,481)	(3,413)	(10,311)	(9,948)
Other expense, net	(2,981)	(1,470)	(9,792)	(3,097)
Total non-operating expense	(5,718)	(4,592)	(18,688)	(12,029)
(Loss) income before taxes	(27,329)	6,432	(67,267)	(27,032)
Income tax provision	247	202	468	689
Net (loss) income	<u>\$ (27,576)</u>	<u>\$ 6,230</u>	<u>\$ (67,735)</u>	<u>\$ (27,721)</u>
Basic and diluted net (loss) income per share	<u>\$ (0.58)</u>	<u>\$ 0.13</u>	<u>\$ (1.43)</u>	<u>\$ (0.60)</u>
Weighted average shares used to compute basic net (loss) income per share	<u>47,614</u>	<u>46,737</u>	<u>47,346</u>	<u>46,255</u>
Weighted average shares used to compute diluted net (loss) income per share	<u>47,614</u>	<u>49,320</u>	<u>47,346</u>	<u>46,255</u>

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

September 30, **December 31,**
2022 **2021**
(unaudited)

Assets

Current assets:		
Cash and cash equivalents	\$ 104,018	\$ 100,708
Short-term investments	257,600	313,343
Accounts receivable, net	34,766	33,438
Inventory	34,182	23,011
Prepaid expenses and other current assets	18,275	15,626
Total current assets	448,841	486,126
Restricted cash	9,078	9,416
Property and equipment, net	87,307	68,969
Operating lease right-of-use asset	26,049	28,142
Finance lease right-of-use asset	47,206	49,022
Intangible assets, net	314,097	332,781
Goodwill	66,134	66,134
Deposits and other assets	9,756	9,108
Total assets	<u>\$ 1,008,468</u>	<u>\$ 1,049,698</u>

Liabilities and stockholders' equity

Current liabilities:		
Accounts payable	\$ 11,465	\$ 7,333
Accrued liabilities	49,150	56,027
Total current liabilities	60,615	63,360
Convertible senior notes	281,056	280,026

Operating lease liability	29,129	29,650
Finance lease liability	72,319	72,699
Deferred tax liability, net	7,301	7,318
Other liabilities	9,494	9,494
Total liabilities	459,914	462,547
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; 47,693 and 46,993 shares issued and 47,665 and 46,965 shares outstanding at September 30, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	985,407	952,432
Accumulated other comprehensive (loss) income	(3,823)	15
Accumulated deficit	(432,946)	(365,211)
Less treasury stock (28 shares as of September 30, 2022 and December 31, 2021)	(132)	(132)
Total stockholders' equity	548,554	587,151
Total liabilities and stockholders' equity	\$ 1,008,468	\$ 1,049,698

GLAUKOS CORPORATION
GAAP to Non-GAAP Reconciliations
(in thousands, except per share amounts and percentage data)
(unaudited)

	Q3 2022			Q3 2021		
	GAAP	Adjustments	Non-GAAP	GAAP	Adjustments	Non-GAAP
Cost of sales	\$ 16,861	\$ (5,536)	(a) \$ 11,325	\$ 15,370	\$ (5,703)	(a) \$ 9,667
Gross Margin	76.3%	7.8%	84.1%	79.4%	7.7%	87.1%
<u>Operating expenses:</u>						
Selling, general and administrative	\$ 47,149	\$ (787)	(b) \$ 46,362	\$ 44,470	\$ (3,278)	(b)(d) \$ 41,192
Research and development	\$ 28,870	\$ -	\$ 28,870	\$ 28,846	\$ (136)	(c) \$ 28,710
Litigation-related settlement	\$ -	\$ -	\$ -	\$ (30,000)	\$ 30,000	(e) \$ -
(Loss) income from operations	\$ (21,611)	\$ 6,323	\$(15,288)	\$ 11,024	\$ (20,883)	\$ (9,859)
Net (loss) income	\$ (27,576)	\$ 6,323	(f) \$(21,253)	\$ 6,230	\$ (20,883)	(f) \$(14,653)
Basic and diluted net (loss) income per share	\$ (0.58)	\$ 0.13	\$ (0.45)	\$ 0.13	\$ (0.44)	\$ (0.31)

(a) Cost of sales adjustments related to the acquisition of Avedro, Inc. (Avedro), including amortization of developed technology intangible assets and stock-based compensation expense related to replacement awards, totaling \$5.5 million in Q3 2022 and \$5.7 million in Q3 2021.

(b) Avedro acquisition-related expenses, including amortization expense of customer relationship intangible assets and stock-based compensation expense related to replacement awards of \$0.8 million in Q3 2022 and \$1.2 million in Q3 2021.

(c) Stock-based compensation expense related to replacement awards from the acquisition of Avedro.

(d) Expenses related to the Company's patent infringement litigation and related matters of \$2.1 million in Q3 2021.

(e) Settlement proceeds received related to the Company's patent infringement litigation.

(f) 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 2022 and 2021.

Note: Beginning in the second quarter of 2022, we are no longer excluding certain in-process R&D charges for non-GAAP reporting and disclosure purposes in response to and in accordance with the Securities and Exchange Commission's latest industry correspondence on this matter. We have conformed all prior period amounts included herein to this new presentation.

GLAUKOS CORPORATION

GAAP to Non-GAAP Reconciliations
(in thousands, except per share amounts and percentage data)
(unaudited)

	Year-to-Date Q3 2022			Year-to-Date Q3 2021		
	GAAP	Adjustments	Non-GAAP	GAAP	Adjustments	Non-GAAP
Cost of sales	\$ 51,757	\$ (16,633) (a)	\$ 35,124	\$ 49,762	\$ (16,893) (a)	\$ 32,869
Gross Margin	75.5%	7.9%	83.4%	77.5%	7.6%	85.1%
<u>Operating expenses:</u>						
Selling, general and administrative	\$ 140,998	\$ (2,533) (b)	\$ 138,465	\$ 131,691	\$ (6,163) (b)(e)	\$ 125,528
Research and development	\$ 87,459	\$ (127) (c)	\$ 87,332	\$ 74,321	\$ (426) (c)	\$ 73,895
Litigation-related settlement	\$ (30,000)	\$ 30,000 (d)	\$ -	\$ (30,000)	\$ 30,000 (d)	\$ -
Loss from operations	\$ (48,579)	\$ (10,707)	\$ (59,286)	\$ (15,003)	\$ (6,518)	\$ (21,521)
Net loss	\$ (67,735)	\$ (10,707) (f)	\$ (78,442)	\$ (27,721)	\$ (6,518) (f)	\$ (34,239)
Basic and diluted net loss per share	\$ (1.43)	\$ (0.23)	\$ (1.66)	\$ (0.60)	\$ (0.14)	\$ (0.74)

(a) Cost of sales adjustments related to the acquisition of Avedro, Inc. (Avedro), including amortization of developed technology intangible assets and stock-based compensation expense related to replacement awards, totaling \$16.6 million year-to-date Q3 2022 and \$16.9 million year-to-date Q3 2021.

(b) Avedro acquisition-related expenses, including amortization expense of customer relationship intangible assets and stock-based compensation expense related to replacement awards of \$2.5 million year-to-date Q3 2022 and \$3.2 million year-to-date Q3 2021.

(c) Stock-based compensation expense related to replacement awards from the acquisition of Avedro of \$0.1 million year-to-date Q3 2022 and \$0.4 million year-to-date Q3 2021.

(d) Settlement proceeds received related to the Company's patent infringement litigation.

(e) Expenses related to the Company's patent infringement litigation and related matters of \$3.0 million year-to-date Q3 2021.

(f) 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 2022 and 2021.

Note: Beginning in the second quarter of 2022, we are no longer excluding certain in-process R&D charges for non-GAAP reporting and disclosure purposes in response to and in accordance with the Securities and Exchange Commission's latest industry correspondence on this matter. We have conformed all prior period amounts included herein to this new presentation.

Reported Sales vs. Prior Periods (in thousands)									
				Year-over-Year Percent Change			Quarter-over-Quarter Percent Change		
	3Q 2022	3Q 2021	2Q 2022	Reported	Operations (1)	Currency (2)	Reported	Operations (1)	Currency (2)
International Glaucoma	\$ 16,532	\$ 15,099	\$ 17,867	9.5%	24.2%	(14.7%)	(7.5%)	(2.5%)	(5.0%)
Total Net Sales	\$ 71,269	\$ 74,710	\$ 72,685	(4.6%)	(1.6%)	(3.0%)	(1.9%)	(0.7%)	(1.2%)

(1) Operational growth excludes the effect of translational currency

(2) Calculated by converting the current period numbers using the prior period's average foreign exchange rates

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Source: Glaukos Corporation