EyePoint Pharmaceuticals Reports Fourth Quarter and Full-Year 2023 Financial Results and Highlights Recent Corporate Developments

March 7, 2024

– Announced positive topline efficacy and safety data from the Phase 2 DAVIO 2 trial of EYP-1901 in wet AMD achieving all primary and secondary endpoints; initiation of the first Phase 3 clinical trial expected in 2H 2024 –

– Dosed first patient in Phase 2 VERONA clinical trial of EYP-1901 in DME; topline data expected in 1Q 2025 –

– Phase 2 PAVIA clinical trial topline data of EYP-1901 in moderately severe-to-severe NPDR anticipated in 2Q 2024 –

– Announced appointment of Ramiro Ribeiro, M.D., Ph.D. as Chief Medical Officer –

– $331M of cash and investments on December 31, 2023, with cash runway through topline data of Phase 3 trials for EYP-1901 for wet AMD in 2026 –

– Management to host a conference call and webcast today at 8:30 a.m. ET –

WATERTOWN, Mass., March 07, 2024 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious retinal diseases, today announced financial results for the fourth quarter and year ended December 31, 2023, and highlighted recent corporate developments.

“2023 was an exceptional year of execution and results for EyePoint Pharmaceuticals. The highlights include positive data from our Phase 2 DAVIO 2 trial of EYP-1901 in wet AMD, the continued advancement of our ongoing Phase 2 trials in NPDR and DME and the strengthening of our balance sheet with a $230 million oversubscribed financing in December along with the sale of rights to YUTIQ® for $82.5 million plus future royalties last May,” said Jay Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. “The DAVIO 2 clinical trial for EYP-1901 achieved all primary and secondary endpoints, highlighting its potential to become a paradigm-altering maintenance treatment for patients with wet AMD. We look forward to discussing our Phase 3 plans with the U.S. Food and Drug Administration (FDA) at a planned end of Phase 2 meeting this April and initiating the first pivotal trial in the second half of this year.”

Dr. Duker continued, “We anticipate topline data for the Phase 2 PAVIA clinical trial of EYP-1901 in moderately severe-to-severe non-proliferative diabetic retinopathy (NPDR) in the second quarter of 2024. We are excited about the potential of EYP-1901 in NPDR, a chronic disease where over 90% of patients currently receive no course of treatment until they develop sight-threatening complications. 2024 promises to be another transformative year as we continue to advance EYP-1901 through clinical development across these three very significant indications.”

R&D Highlights and Updates

- Announced positive topline efficacy and safety data from the Phase 2 DAVIO 2 clinical trial of EYP-1901 in wet AMD in December 2023. DAVIO 2 met all primary and secondary endpoints with both EYP-1901 doses demonstrating a statistically non-inferior change in best corrected visual acuity (BCVA) compared to aflibercept control and a favorable safety profile with no EYP-1901-related ocular or systemic serious adverse events (SAEs).
- DAVIO 2 Phase 2 data and sub-group analyses which underscore the favorable clinical profile of EYP-1901, were presented at Angiogenesis, Exudation, and Degeneration 2024 Meeting and at the 47th Annual Meeting of the Macula Society in February 2024.
- The Company plans to conduct an end of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in April 2024, with the initiation of the first Phase 3 pivotal trial in wet AMD expected in the second half of 2024.
- Announced first patient dosed in the Phase 2 VERONA clinical trial of EYP-1901 for the treatment of diabetic macular edema (DME). Topline data are expected in the first quarter of 2025.
- Accepted to present at the upcoming 2024 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in May. The Company will be presenting an encore presentation of the DAVIO 2 clinical trial results, the design and function of EYP-1901, plasma PK data of EYP-1901, and the mechanism of action (MOA) of vorolanib and differentiation from other anti-VEGF TKIs.

Recent Corporate Highlights

- Announced the appointment of Ramiro Ribeiro, M.D., Ph.D. as Chief Medical Officer in March. Dr. Ribeiro joins EyePoint from Apellis Pharmaceuticals, where he served as Vice President, Head of Clinical Development.
- Completed an upsized underwritten public offering with gross proceeds of $230.0 million in December. The Company sold 13,529,411 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase an additional 1,764,705 shares of common stock. The shares of common stock were sold at a public offering price of $17.00 per share.

Review of Results for the Fourth Quarter Ended December 31, 2023

For the quarter ended December 31, 2023, total net revenue was $14.0 million compared to $10.5 million for the quarter ended December 31, 2022. Net product revenue for the quarter ended December 31, 2023, was $0.7 million, compared to net product revenue for the quarter ended December 31, 2022, of $9.9 million. The decrease in net product revenue resulted from the strategic exit from our commercial business in 1H 2023.

Net revenue from royalties and collaborations for the quarter ended December 31, 2023, totaled $13.3 million compared to $0.7 million in the corresponding period in 2022. The increase was primarily due to partial recognition of deferred revenue from the license of the YUTIQ franchise, which beginning in 2Q 2023 will be recognized over a 2-year period in connection with the delivery of YUTIQ supply units.

Operating expenses for the quarter ended December 31, 2023, totaled $30.4 million compared to $54.3 million in the prior year period. This decrease was primarily driven by the strategic exit from our commercial business in 1H 2023 and a one-time intangible asset impairment charge in 4Q 2022.

Net non-operating income totaled $2.3 million and net loss was $14.1 million, or ($0.33) per share, compared to a net loss of $43.5 million, or ($1.16) per share, for the prior year period.

Review of Results for the Full Year Ended December 31, 2023

For the full year ended December 31, 2023, total net revenue was $46.0 million compared to $41.4 million for the year ended December 31, 2022. Net product revenue for the full year ended December 31, 2023, was $14.2 million, compared to net product revenues for the full year ended December 31, 2022, of $39.9 million. The decrease in net product revenue resulted from the Company's strategic exit from its commercial business in 1H 2023.

Net revenue from royalties and collaborations for the full year ended December 31, 2023, totaled $31.8 million compared to $1.5 million in the corresponding period in 2022.

Operating expenses for the full year ended December 31, 2023, totaled $121.1 million versus $141.0 million in the prior year period. This decrease was primarily driven by the strategic exit from our commercial business in 1H 2023 and a one-time intangible asset impairment charge in 4Q 2022.

Net non-operating expense totaled $4.4 million and net loss was $70.8 million, or ($1.82) per share, compared to a net loss of $102.3 million, or ($2.74) per share, for the prior year period.

Cash, cash equivalents and investments in marketable securities on December 31, 2023, totaled $331.1 million compared to $144.6 million as of December 31, 2022.

Financial Outlook

We expect that our cash, cash equivalents, and investments on December 31, 2023, will enable us to fund operations through topline data for the planned Phase 3 clinical trials of EYP-1901 for wet AMD in 2026.

Conference Call Information

EyePoint will host a conference call today at 8:30 a.m. ET to discuss the results for the fourth quarter and year ended December 31, 2023 and recent corporate developments. To access the live conference call, please register at https://register.vevent.com/register/BI91be5d0e320646e887cf4047c70fe73c. A live audio webcast of the event can be accessed via the Investors section of the Company website at www.eyepointpharma.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology for sustained intraocular drug delivery. The Company's lead product candidate, EYP-1901, is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with Durasert E™. Pipeline programs include EYP-2301, a promising TIE-2 agonist, razuprotafib, f/k/a AKB-9778, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases. The proven Durasert® drug delivery technology has been safely administered to thousands of patient eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

Vorolanib is licensed to EyePoint exclusively by Equinox Sciences, a Betta Pharmaceuticals affiliate, for the localized treatment of all ophthalmic diseases outside of China, Macao, Hong Kong and Taiwan.

EYEPOINT PHARMACEUTICALS SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the use of proceeds for the offering and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint's actual results to be materially different than those expressed in or implied by EyePoint's forward-looking statements. For EyePoint, this includes uncertainties regarding the timing and clinical development of our product candidates, including EYP-1901 and EYP-2301; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration (wet AMD) and non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME); the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals including potential U.S. Food and Drug Administration (FDA) regulatory approval of EYP-1901 and EYP-2301; the success of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; the success of Durasert® as a drug delivery platform in FDA approved products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; and other factors described in our filings with the Securities and Exchange Commission. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-

looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements. Our forward-looking statements speak only as of the dates on which they are made. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

Investors:

Christina Tartaglia
Stern IR
Direct: 212-698-8700
christina.tartaglia@sternir.com

Media Contact:

Amy Phillips
Green Room Communications
Direct: 412-327-9499
aphillips@greenroompr.com

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 281,263	$ 95,633
Marketable securities	49,787	48,928
Accounts and other receivables, net	805	15,503
Other current assets	9,039	9,858
Inventory	3,906	2,886
Total current assets	344,800	172,808
Operating lease right-of-use assets	4,983	6,038
Other assets	5,401	1,510
Total assets	$ 355,184	$ 180,356
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 24,025	$ 22,278
Deferred revenue	38,592	1,205
Short-term borrowings	-	10,475
Other current liabilities	646	579
Total current liabilities	63,263	34,537
Long-term debt	-	29,310
Deferred revenue, less current portion	20,692	13,557
Operating lease liabilities - noncurrent	4,906	5,984
Other long-term liabilities	-	600
Total liabilities	88,861	83,988
Stockholders' equity:		
Capital	1,007,605	766,933
Accumulated deficit	(742,146)	(671,351)
Accumulated other comprehensive income	864	786
Total stockholders' equity	266,323	96,368
Total liabilities and stockholders' equity	$ 355,184	$ 180,356

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 749	$ 9,857	$ 14,232	$ 39,905
License and collaboration agreements	13,029	202	30,797	362
Royalty income	250	474	989	1,137
Total revenues	14,028	10,533	46,018	41,404
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	998	3,410	4,632	8,326
Research and development	17,951	15,543	64,662	49,642
Sales and marketing	185	5,915	11,689	25,507
General and administrative	11,248	8,496	40,102	34,817
Amortization of acquired intangible assets	-	205	-	2,050
Impairment of acquired intangible assets	-	20,699	-	20,699
Total operating expenses	30,382	54,268	121,085	141,041
Loss from operations	(16,354)	(43,735)	(75,067)	(99,637)
Other income (expense):				
Interest and other income, net	2,338	1,064	6,949	2,131
Interest expense	-	(781)	(1,247)	(3,189)
Gain (loss) on extinguishment of debt	-	-	(1,347)	(1,559)
Total other expense, net	2,338	283	4,355	(2,617)
Net loss	$ (14,016)	$ (43,452)	$ (70,712)	$ (102,254)
Provision for income taxes	$ (83)	$ -	$ (83)	$ -
Net loss	$ (14,099)	$ (43,452)	$ (70,795)	$ (102,254)
Net loss per common share - basic and diluted	$ (0.33)	$ (1.16)	$ (1.82)	$ (2.74)
Weighted average common shares outstanding - basic and diluted	42,168	37,352	38,904	37,317

Source: EyePoint Pharmaceuticals, Inc.