EyePoint Reports Second Quarter 2025 Financial Results and Highlights Recent Corporate Developments

Aug 6, 2025

– Completed Phase 3 enrollment for DURAVYU™ in wet AMD with over 800 patients enrolled and randomized –

– LUGANO and LUCIA trials each rapidly enrolled in seven months underscoring strong physician and patient interest –

– Topline 56-week data for LUGANO on track for readout in mid-2026 with LUCIA topline data to closely follow –

– Northbridge, MA commercial manufacturing facility on line with DURAVYU registration batches underway –

– $256 million of cash, cash equivalents and marketable securities as of June 30, 2025, provides cash runway into 2027, beyond topline data for both Phase 3 wet AMD trials –

WATERTOWN, Mass., Aug. 06, 2025 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (Nasdaq: EYPT), a company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases, today announced financial results for the second quarter ended June 30, 2025, and highlighted recent corporate developments.

"In recent months, we continued our track record of exceptional execution across all aspects of the business, most notably completing enrollment in both pivotal Phase 3 trials, LUGANO and LUCIA, in wet AMD in record time for this indication," said Jay S. Duker, M.D., President and Chief Executive Officer of EyePoint. "The noteworthy physician and patient enthusiasm we have seen for our Phase 3 program across U.S. and international sites—supported by DURAVYU's robust Phase 2 efficacy and safety data package and our patient-centric, well-understood trial design—has reinforced the clear need and global demand for more durable wet AMD therapies and the role that DURAVYU can play in meaningfully extending the wet AMD treatment paradigm."

Dr. Duker continued, "With topline LUGANO data anticipated in mid-2026, LUCIA data to closely follow, and registration batches underway at our state-of-the-art, commercial manufacturing facility in Northbridge, Massachusetts, we believe we are well-positioned for DURAVYU to be first-to-market among investigational sustained release treatments for wet AMD. We look forward to providing an update on our DURAVYU pivotal plan in DME in the coming months as we work to deliver innovative therapeutics for multiple serious retinal diseases."

R&D Highlights and Updates

- Completed enrollment of Phase 3 wet AMD pivotal program ahead of plan.
  - LUGANO and LUCIA are double-masked non-inferiority trials designed to support a clear approval pathway and potential commercial success.
  - Both Phase 3 trials experienced unprecedented enrollment exceeding observed recruitment rates of comparable historical and ongoing wet AMD clinical trials
  - The oversubscribed LUGANO trial randomized 432 patients in the U.S. in seven months with topline data anticipated in mid-2026.
  - LUCIA randomized over 400 patients in the U.S. and in ex-U.S. sites over a seven-month period, with topline data anticipated in the second half of 2026.
  - Enrolled the first ex-U.S. patient in the LUCIA trial in Israel with patient participation in sites throughout the Czech Republic, South America, Europe, Australia and India.
  - Investigator and patient enthusiasm for the trials underscores the retinal community's support and recognition of the clinical rigor underpinning the Phase 3 pivotal program.
- Announced that based on interim masked safety data, the safety profile observed in LUGANO and LUCIA is consistent with previous DURAVYU clinical trials. In parallel, an independent Data Safety Monitoring Committee ("DSMC") convened and recommended continuation of the program as planned.
- Received approval of the Phase 3 protocols for the LUGANO and LUCIA trials by the European Medicines Agency (EMA).
- Delivered multiple oral presentations at the American Society of Retina Specialists (ASRS) annual meeting supporting

DURAVYU's potentially best-in-class therapeutic profile as a sustained release tyrosine kinase inhibitor (TKI) being developed for multiple indications:
    - An assessment of the treatment burden in wet AMD treated with DURAVYU versus aflibercept from the Phase 2 DAVIO 2 clinical trial
    - Vision outcomes from the DAVIO 2 trial for the treatment of neovascular age-related macular degeneration
    - 24-week results from the Phase 2 VERONA clinical trial of DURAVYU versus aflibercept for the treatment of diabetic macular edema (DME)
- Completed a positive End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to discuss pivotal Phase 3 clinical trial plans for DURAVYU in DME. The Company will share details on its DME pivotal plan in the second half of 2025.
- Presented 24-week topline results from the Phase 2 VERONA study in DME at the Retina World Congress in May 2025, highlighting DURAVYU's potential to transform the treatment landscape in DME, the second largest retinal disease market, with its best-in-class safety and efficacy profile.
- Accepted to present the Phase 2 VERONA 24-week end-of-study results in DME at the Retina Society Annual Meeting in September, underscoring the broad treatment potential of DURAVYU and enthusiasm from the retinal community for new treatment options in multiple serious retinal diseases.

Recent Corporate Highlights

- Initiated DURAVYU registration batches in support of a potential NDA filing at EyePoint's commercial manufacturing facility in Northbridge, Massachusetts. The 41,000-square-foot facility was built to meet both FDA and EMA standards and will have capacity to support the anticipated significant demand for DURAVYU, if approved.

Review of Results for the Second Quarter Ended June 30, 2025

For the second quarter ended June 30, 2025, total net revenue was $5.3 million compared to $9.5 million for the quarter ended June 30, 2024.

Net revenue from license and royalties for the second quarter ended June 30, 2025, totaled $5.3 million compared to $8.4 million in the corresponding period in 2024. The decrease was primarily driven by lower recognition of deferred revenue related to the Company's 2023 agreement for the license of YUTIQ ® product rights.

Operating expenses for the second quarter ended June 30, 2025, totaled $67.6 million versus $44.0 million in the prior year period. This increase was primarily driven by an increase in clinical trial costs related to ongoing DURAVYU™ Phase 3 clinical trials (LUGANO and LUCIA) for wet AMD. Net non-operating income totaled $2.9 million and net loss was $59.4 million, or ($0.85) per share, compared to a net loss of $30.8 million, or ($0.58) per share, for the corresponding period in 2024.

Cash, cash equivalents, and marketable securities as of June 30, 2025 totaled $256 million compared to $371 million as of December 31, 2024.

Financial Outlook

EyePoint expects its cash, cash equivalents, and marketable securities as of June 30, 2025 will enable the Company to fund operations into 2027 beyond topline Phase 3 data for DURAVYU in wet AMD expected in 2026.

Conference Call Information

EyePoint management will host a conference call today at 8:30 a.m. ET to discuss the results for the second quarter ended June 30, 2025, and recent corporate developments. To access the live conference call, please register using the audio conference link: https://register-conf.media-server.com/register/BI2f02d8b4966b40da83f2ef4135b2ba78. 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

EyePoint Pharmaceuticals, Inc. (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases. The Company's lead product candidate, DURAVYU ™, is an innovative investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor (TKI), in next-generation bioerodible Durasert E ™ technology. Supported by robust safety and efficacy data to date, DURAVYU is currently being evaluated in two Phase 3 pivotal trials for wet age-related macular degeneration (wet AMD) with topline data anticipated in 2026. DURAVYU also completed a positive Phase 2 clinical trial in diabetic macular edema (DME) with Phase 3 pivotal planning underway. Despite current therapies, patients with wet AMD and DME still tend to lose vision in the long term and wet AMD is the leading cause of vision loss among people 50 years of age and older in the United States.

The Company is committed to partnering with the retina community to improve patient lives while creating long-term value, with four approved drugs over three decades and tens of thousands of eyes treated with EyePoint innovation.

EyePoint is headquartered in Watertown, Massachusetts, with a commercial manufacturing facility in Northbridge, 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.

DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product candidate; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.

Forward Looking Statements

EYEPOINT 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 our expectations regarding our clinical development and regulatory plans of DURAVYU; our belief that DURAVYU is on track to be the first-to-market of the current investigational sustained release treatments for wet AMD; our belief that DURAVYU has two potential blockbuster indications; our belief that DURAVYU's potential real-world application in multiple retinal disease indications and de-risked trial designs position DURAVYU for clinical and commercial success; our expectations regarding timing for the completion of clinical trial enrollment and the timing of the availability and release of clinical data; our belief that rapid trial enrollment in LUGANO and LUCIA highlights physician and patient enthusiasm for DURAVYU, which we believe is driven by an established and familiar trial design, robust Phase 2 data, and a strong safety profile; our expectations regarding cash runway; our optimism that that DURAVYU has the potential to shift the treatment paradigm in wet AMD and DME and improve patient outcomes; our expectations regarding clinical development of our other product candidates, including EYP-2301; our belief that we are well positioned as the leader in ocular sustained drug delivery; our business strategies and objectives; and other statements regarding the Company's future plans, objectives, strategies and beliefs, as identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," or 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, these risks and uncertainties include the timing, progress and results of the Company's clinical development activities, including DURAVYU; uncertainties and delays relating to communications with the U.S. Food and Drug Administration and the ability to obtain regulatory approval from FDA for the commercialization of DURAVYU; unanticipated costs and expenses; the Company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the risk that results of clinical trials may not be predictive of future results, and interim and preliminary data are subject to further analysis and may change as more data becomes available; unexpected safety or efficacy data observed during clinical trials; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for approval of the Company's product candidates; changes in the regulatory environment; disruptions at the FDA, including due to a reduction in the FDA's workforce and/or inadequate funding for the FDA; changes in U.S. and international trade policies; changes in expected or existing competition; the success of current and future license agreements; our dependence on contract research organizations, and other outside vendors and service providers; product liability; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; delays, interruptions or failures in the manufacture and supply of our product candidates; the availability of and the need for additional financing; the Company's ability to obtain additional funding to support its clinical development programs; uncertainties regarding the timing and results of the August 2022 subpoena from the U.S. Attorney's Office for the District of Massachusetts; uncertainties regarding the FDA warning letter pertaining to the Company's Watertown, MA manufacturing facility; 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. A more complete discussion of the risks and uncertainties that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K, in our other filings with the Securities and Exchange Commission (SEC) and in our future reports to be filed with the SEC, which are available at www.sec.gov. 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:

Tanner Kaufman / Jenni Lu
FTI Consulting
Direct: 203-722-8743 / 667-321-6018
tanner.kaufman@fticonsulting.com / jenni.lu@fticonsulting.com

Media Contact:

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

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

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 71,143	$ 99,704
Marketable securities	184,590	271,209
Accounts and other receivables, net	625	607
Prepaid expenses and other current assets	6,215	9,481
Inventory	2,678	2,305
Total current assets	265,251	383,306
Operating lease right-of-use assets	21,089	21,000
Other assets	14,807	14,159
Total assets	$ 301,147	$ 418,465
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 31,163	$ 29,824
Deferred revenue	—	17,784
Other current liabilities	2,012	1,440
Total current liabilities	33,175	49,048
Deferred revenue - noncurrent	—	10,853
Operating lease liabilities - noncurrent	21,815	21,858
Other noncurrent liabilities	148	205
Total liabilities	55,138	81,964
Stockholders' equity:		
Capital	1,222,814	1,208,489
Accumulated deficit	(977,637)	(873,016)
Accumulated other comprehensive income	832	1,028
Total stockholders' equity	246,009	336,501
Total liabilities and stockholders' equity	$ 301,147	$ 418,465

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenues:				
Product sales, net	$ —	$ 1,068	$ 715	$ 1,726
License and collaboration agreements	5,333	7,782	16,382	18,345
Royalty income	—	627	12,689	1,090
Total revenues	5,333	9,477	29,786	21,161

Operating expenses:				
Cost of sales	165	1,401	970	2,160
Research and development	55,498	29,822	114,072	60,011
Sales and marketing	35	50	70	56
General and administrative	11,862	12,750	25,738	26,801
Total operating expenses	67,560	44,023	140,850	89,028
Loss from operations	(62,227)	(34,546)	(111,064)	(67,867)
Other income (expense):				
Interest and other income, net	2,894	3,720	6,536	7,757
Total other income, net	2,894	3,720	6,536	7,757
Net loss before provision for income taxes	$ (59,333)	$ (30,826)	$ (104,528)	$ (60,110)
Provision for income taxes	(93)	—	(93)	—
Net loss	$ (59,426)	$ (30,826)	$ (104,621)	$ (60,110)
Net loss per common share - basic and diluted	$ (0.85)	$ (0.58)	$ (1.50)	$ (1.13)
Weighted average common shares outstanding - basic and diluted	69,926	53,206	69,847	53,059

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Source: EyePoint Pharmaceuticals, Inc.