EyePoint Pharmaceuticals Reports Second Quarter 2019 Financial Results and Highlights Recent Company Progress

August 7, 2019

– Company reports total revenue of $7.2 million –

– Two commercial product launches in U.S. are underway for DEXYCU® and YUTIQ® with 43 sales reps actively targeting uveitis specialists, cataract surgeons and ambulatory surgical centers –

– YUTIQ receives specific and permanent J Code, effective October 1, 2019 –

– Over 400 physicians have completed a certification program and are now certified to purchase and administer DEXYCU –

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

WATERTOWN, Mass., Aug. 07, 2019 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today reported financial results for the second quarter ended June 30, 2019 and highlighted recent commercial and corporate developments.

“The physician feedback to date from our two commercial product launches, YUTIQ® and DEXYCU®, has been very positive, and we have seen a solid uptake in treatment volume along with tremendous progress in market access,” said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. “Our field force has received similar reception and eagerness to meet from physicians in the office setting for YUTIQ and at ambulatory surgery centers (ASCs) for DEXYCU. Our efforts on training and certifying physicians during our phased launch of DEXYCU are generating sales momentum with a solid start in July, as evidenced by the number of ASCs purchasing product for the first time, as well as repeat purchases. YUTIQ continues to address a large unmet need for patients afflicted with chronic non-infectious posterior segment uveitis and July sales remain on a solid upward trajectory with the number of ordering physicians increasing month over month. With the recently accelerated October 1, 2019 effective date of a permanent and specific J code for YUTIQ, J7413, payor approval and reimbursement will soon become even easier and more streamlined.”

Ms. Lurker continued, “Physicians are now actively seeing the clinical results of both YUTIQ and DEXYCU with their patients and to date have experienced positive efficacy and safety results as seen in the pivotal clinical studies. We are very proud to have launched our two exciting ophthalmic products, YUTIQ and DEXYCU, and to bring these innovative products to patients in need.”

“In an effort to support our commercial activities we have enhanced our leadership team with the appointments of Scott Jones as Chief Commercial Officer and Said Saim, Ph.D., as Chief Technology Officer. We look forward to making further progress in growing the reach of our commercially available products and advancing the balance of our pipeline to deliver much-needed innovation to ophthalmic patients,” concluded Ms. Lurker.

Commercial Performance in Second Quarter 2019

YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for chronic non-infectious uveitis affecting the posterior segment of the eye

- 10 Key Account Managers (KAMs) are dedicated to calling predominantly uveitis specialists across the U.S.
- Since the February launch, approximately 95% of the top decile uveitis specialists have been visited by the 10 KAMs.
- YUTIQ has been included in more than 20 Academic Formularies and is pending inclusion for an additional 8.
- As of July 31, market access has been well established with 100% of Medicare patients being covered and benefit investigations being approved for over 95% of Medicare advantage and commercial plan patients.

DEXYCU (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following cataract surgery

- 33 KAMs dedicated to the promotion of DEXYCU have focused on a phased launch program to ensure proper physician training for the preparation, application and administration of DEXYCU.
- Since launch, over 400 surgeons in more than 275 ambulatory surgical centers (ASCs) have completed the training/certification program and are now able to purchase DEXYCU.
- Since launch, over 4,200 patients have been injected with DEXYCU via the Company’s sampling program.
- Since launch, over 3,000 medical professionals and office staff have been called on to discuss DEXYCU.
- As of July 31, our market access initiatives have resulted in 100% of Medicare Fee-For-Service lives being covered and benefit investigations being approved for over 90% of Medicare Advantage and commercial plan patients.

R&D Highlights

- At the 37th Annual Scientific Meeting of the American Society of Retina Specialists (ASRS) that took place July 26-30, 2019 in Chicago, three podium presentations highlighted data supporting YUTIQ for the treatment of non-infectious posterior segment uveitis. Highlights from each of the presentations include:
    - Results at the 36-month follow up of the Phase 3 trial of YUTIQ demonstrated that visual acuity gains of 3-lines

were more common with YUTIQ (33% vs 15%) and losses were more common with sham (9% vs 1%).
- At 36-months, the recurrence rate in YUTIQ randomized eyes was significantly lower than in sham treated eyes (56.3% vs. 92.9%, respectively; p<0.001). The number of eyes with at least 1 recurrence was 49 for YUTIQ and 39 for sham treated eyes, with total recurrences of 103 for YUTIQ and 166 for sham treated eyes. The median time to the first recurrence was 1,051 days for YUTIQ (95% CI 686, 1,125) and 95 days for sham-treated eyes (95% CI 71, 117).
- Safety data showed 19.5% of YUTIQ treated eyes needed the assistance of adjunctive intraocular/periocular injection medication for uveitic inflammation compared to 69.0% for sham treated eyes.

Corporate Updates

- Scott Jones was appointed Chief Commercial Officer in June 2019 and will lead the Company's sales and marketing efforts for the Company's two ophthalmic commercial products. Mr. Jones brings significant experience commercializing drugs and devices globally to EyePoint. Most recently, he served as Chief Commercial Officer and Vice President, Business Development at Notal Vision, where he developed the commercial and growth strategy for the organization.
- Also in June 2019, Said Saim, Ph.D., was appointed Chief Technology Officer, a newly created position at the Company, where he will be responsible for advancing EyePoint's pipeline products and technology for ocular treatments from formulation, preclinical research up to clinical development, as well as pharmaceutical sciences, manufacturing and operations. Dr. Saim has more than 25 years of product development experience. He most recently served as Vice President, Pharmaceutical Development at Collegium Pharmaceutical, where his responsibilities included managing formulation development, clinical trial manufacturing, and commercial manufacturing for immediate, delayed and controlled release dosage forms.
- In July 2019, Wendy DiCicco, CPA, was appointed to the Company's Board of Directors and Audit Committee, where she serves as Chair of the Committee. Ms. DiCicco most recently was Chief Operating and Financial Officer of Centinel Spine, a privately-held designer, developer and worldwide distributor of spinal implants, where she established the Company's international operations, and was instrumental in both the recapitalization of the Company's financial structure as well as active in corporate development initiatives.

Review of Second Quarter Results Ended June 30, 2019

For the three months ended June 30, 2019, total revenue was $7.2 million. Net product revenue was $6.7 million generated from sales of YUTIQ. Due to adequate inventory stocking by the Company's distributor, Cardinal Health, ahead of the mid-March launch prior to the end of the first quarter, DEXYCU did not generate product revenue during the second quarter of 2019. Neither of these products had net revenue in the corresponding quarter in 2018.

Net revenue from royalties and collaborations for the three months ended June 30, 2019 totaled $505,000 compared to $715,000 in the corresponding quarter in 2018.

Operating expenses for the three months ended June 30, 2019 increased to $17.4 million from $10.5 million in the prior year period, due primarily to investments in sales and marketing infrastructure and program costs, professional services, stock-based compensation and cost of sales related to product revenue. Non-operating expense, net, for the three months ended June 30, 2019 totaled $1.3 million of net interest expense. Net loss for the three months ended June 30, 2019 was $11.5 million, or $0.11 per share, compared to a net loss of $34.4 million, or $0.62 per share, for the prior year quarter.

Review of Six Months Results Ended June 30, 2019

For the six months ended June 30, 2019, total net product revenue was $7.9 million. Neither product had net revenue in the corresponding period in 2018. Net revenue from royalties and collaborations for the six months ended June 30, 2019 totaled $1.3 million compared to $1.6 million in the corresponding period in 2018.

Operating expenses for the six months ended June 30, 2019 increased to $34.0 million from $16.1 million in the prior year period, due primarily to investments in sales and marketing infrastructure and program costs, professional services, stock-based compensation, cost of sales related to product revenue and amortization of the DEXYCU intangible asset. Non-operating expense, net, for the six months ended June 30, 2019 totaled $5.9 million and consisted of $2.1 million of net interest expense and $3.8 million from the loss on extinguishment of debt related to the payoff of the SWK term loan. Net loss for the six months ended June 30, 2019 was $30.7 million, or $0.30 per share, compared to a net loss of $41.4 million, or $0.82 per share, for the prior year period.

Cash and cash equivalents at June 30, 2019 totaled $44.2 million compared to $45.3 million at December 31, 2018.

Financial Outlook

Given that the Company's two commercial products, YUTIQ and DEXYCU, have not yet established a consistent sales trajectory, guidance regarding the timing of positive cash flow is not being provided at this time. We expect that the Company's existing cash and cash equivalents at June 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our operating plan into 2020.

Conference Call Information

EyePoint will host a conference call today, Wednesday, August 7, 2019 at 8:30 AM ET to discuss the results for the second quarter ended June 30 and recent operational developments. To access the conference call, please dial (877) 312-7507 from the U.S. and Canada or (631) 813-4828 (international) at least 10 minutes prior to the start time and refer to conference ID 5175125. A live webcast will be available on the Investor Relations

section of the corporate website at http://www.eyepointpharma.com. A replay of the webcast will also be available on the corporate website.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals, Inc. (www.eyepointpharma.com), headquartered in Watertown, MA, is a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products in indications with high unmet medical need to help improve the lives of patients with serious eye disorders. With the approval by the FDA on October 12, 2018 of the YUTIQ® three-year treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, the Company has developed five of the six FDA-approved sustained-release treatments for eye diseases. The most common adverse reactions reported for YUTIQ were cataract development and increases in intraocular pressure. DEXYCU® was approved by the FDA on February 9, 2018. DEXYCU, administered as a single intraocular dose at the end of ocular surgery for the treatment of postoperative inflammation, is the first and only FDA-approved intraocular product with this indication. The most common adverse reactions reported by 5-15% of patients were increased intraocular pressure, corneal edema and iritis. DEXYCU employs the Verisome® extended-release drug delivery technology, which encompasses a broad number of related, but distinct drug delivery systems with the potential of incorporating an extensive range of active agents, including small molecules, proteins and monoclonal antibodies. ILUVIEN® (fluocinolone acetonide intravitreal implant), a micro-insert for diabetic macular edema, licensed to Alimera Sciences, Inc. (“Alimera”), is currently sold directly in the U.S. and several EU countries. Retisert ® (fluocinolone acetonide intravitreal implant), for non-infectious posterior segment uveitis, is licensed to and sold by Bausch & Lomb, Inc. The Company's pre-clinical development program is focused on using its core Durasert™ and the Verisome platform technologies to deliver drugs to treat wet age-related macular degeneration, glaucoma, and other diseases. To learn more about the Company, please visit www.eyepointpharma.com and connect on Twitter and LinkedIn.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our commercialization of YUTIQ and DEXYCU, the potential for our products to alter the treatment landscape for ocular diseases; the expected use of proceeds from our debt refinancing and equity offering and our expectation that the Company’s existing cash and cash equivalents at June 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our operating plan into 2020, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for YUTIQ and DEXYCU; the regulatory approval and successful release of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; potential off-label sales of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye; consequences of fluocinolone acetonide side effects for YUTIQ; consequences of dexamethasone side effects for DEXYCU; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema, or DME; Alimera’s ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; Alimera’s ability to commercialize ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in the territories in which Alimera is licensed to do so; declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; our dependence on contract research organizations, contract sales organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; 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. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

Contacts

Investors:
Argot Partners
Kimberly Minarovich
(646) 368-8014
kimberly@argotpartners.com

Joseph Rayne
(617) 340-6075
joseph@argotpartners.com

Media:
Thomas Gibson
201-476-0322
tom@tomgibsoncommunications.com

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

(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues:				
Product sales, net	$ 6,705	$ -	$ 7,932	$ -
Collaborative research and development	5	218	70	742
Royalty income	500	497	1,220	901
Total revenues	7,210	715	9,222	1,643
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	706	-	1,035	-
Research and development	3,955	4,765	7,753	8,090
Sales and marketing	7,284	1,512	14,595	1,512
General and administrative	4,815	4,220	9,425	6,501
Amortization of acquired intangible assets	615	-	1,230	-
Total operating expenses	17,375	10,497	34,038	16,103
Loss from operations	(10,165)	(9,782)	(24,816)	(14,460)
Other income (expense), net				
Interest and other income	266	27	509	52
Interest expense	(1,599)	(720)	(2,619)	(720)
Loss on extinguishment of debt	-	-	(3,810)	-
Change in fair value of derivative liability	-	(23,953)	-	(26,278)
Total other expense, net	(1,333)	(24,646)	(5,920)	(26,946)
Net loss	$ (11,498)	$ (34,428)	$ (30,736)	$ (41,406)
Net loss per common share:				
Basic and diluted	$ (0.11)	$ (0.62)	$ (0.30)	$ (0.82)
Weighted average common shares outstanding:				
Basic and diluted	106,238	55,387	100,847	50,542

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 44,161	$ 45,261
Accounts receivable	9,598	627
Other current assets	4,814	1,713
Total current assets	58,573	47,601
Operating lease right-of-use assets	3,291	-
Intangible assets, net	28,899	30,129
Other assets	567	438
Total assets	$ 91,330	$ 78,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,280	$ 6,429
Accrued development milestone	-	15,000
Operating lease liabilities - current	441	-
Deferred revenue	-	30
Total current liabilities	10,721	21,459
Long-term debt	46,250	17,621
Operating lease liabilities - noncurrent	3,149	-
Other long-term liabilities	3,000	1,455
Total liabilities	63,120	40,535
Stockholders' equity:		
Capital	466,599	445,287
Accumulated deficit	(439,229)	(408,493)
Accumulated other comprehensive income	840	839
Total stockholders' equity	28,210	37,633
Total liabilities and stockholders' equity	$ 91,330	$ 78,168

EYEPOINT PHARMACEUTICALS

Source: EyePoint Pharmaceuticals, Inc.