



## EyePoint Pharmaceuticals Reports Fiscal First Quarter 2019 Financial Results and Highlights Recent Clinical and Operational Developments

November 6, 2018

*-YUTIQ™ approved by U.S. FDA; anticipated launch in calendar 1Q19-*

*-Exclusive license granted to Ocumension Therapeutics to develop and commercialize EyePoint's three-year micro-insert product using the Durasert™ technology for posterior segment uveitis in Greater China-*

*-Commercial preparations underway for anticipated launch of DEXYCU™ in the first half of calendar year 2019-*

*-Cash injection of \$28.9 million from warrant exercise-*

*-Conference call and webcast today, November 6<sup>th</sup>, at 8:00 AM ET-*

WATERTOWN, Mass., Nov. 06, 2018 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today reported operating and financial results for its fiscal 2019 first quarter ended September 30, 2018 and highlighted recent clinical and operational developments.

"The approval of YUTIQ™ by the U.S.FDA in October marked a significant achievement for EyePoint and validates the Company's innovation and ability to develop an effective treatment to decrease recurrence of uveitic flares from non-infectious posterior segment uveitis that can result in blindness," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "Following the positive reception by retina and uveitis specialists of the clinical data presented for YUTIQ at the American Academy of Ophthalmology 2018 Annual Meeting, we believe that we are well-positioned for a successful product launch planned in the first quarter of calendar 2019. In addition, we are scaling up our manufacturing of DEXYCU™ ahead of an anticipated launch in the first half of calendar 2019."

### Recent Clinical & Operational Highlights

- In October 2018, the U.S. Food and Drug Administration (FDA) approved YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, a three-year micro-insert for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. YUTIQ utilizes the Company's Durasert™ drug delivery technology and is an intravitreal micro-insert designed to deliver drug consistently over 36 months. The approval occurred 24 days in advance of the PDUFA date of November 5<sup>th</sup>.
- At the American Academy of Ophthalmology (AAO) 2018 Annual Meeting in Chicago, IL, 24-month efficacy and safety data supporting YUTIQ was presented during the Retina Subspecialty day at a breakthrough presentation entitled, "24-month Evaluation of Fluocinolone Acetonide Intravitreal Insert Treatment for Non-Infectious Posterior Uveitis". These data demonstrated that the recurrence rate in randomized eyes treated with YUTIQ was significantly lower than in sham eyes (59.8% vs. 97.6%, respectively;  $p < 0.001$ ) at 24-months of the three-year trial. Safety and side effects were consistent with those reported for previous analyses of earlier timepoints.
- In August, safety and efficacy data from the Phase 3 clinical trial of DEXYCU compared to prednisolone acetate 1.0% ophthalmic drops for the treatment of inflammation post-cataract surgery were published in the *Journal of Cataract & Refractive Surgery*. In this open label trial, results demonstrated similar safety and efficacy between both products in treating inflammation post cataract surgery with a patient preference of DEXYCU compared to drops.
- EyePoint granted Ocumension Therapeutics, a China-based ophthalmology company, an exclusive license to develop and commercialize EyePoint's three-year micro insert product using the Durasert technology for chronic, non-infectious uveitis affecting the posterior segment of the eye in the greater China territory, which is comprised of China, Hong Kong, Macau and Taiwan. EyePoint will receive a one-time upfront payment of \$1.75 million and is eligible to receive up to an additional \$10.0 million if certain future prespecified development, regulatory and commercial sales milestones are achieved by Ocumension. Ocumension will be responsible for funding the clinical development of EyePoint's three-year micro-insert product using the Durasert technology for chronic, non-infectious posterior segment uveitis in Greater China. EyePoint will supply product for the clinical trials.
- John Landis, Ph.D., M.S., was appointed to the EyePoint Board of Directors in October 2018. Dr. Landis brings more than 30 years of pharmaceutical research and development experience from senior level roles held at Schering-Plough Corporation, Pharmacia Corporation and The Upjohn Company.
- EyePoint's Board of Directors approved a change of the Company's fiscal year-end to December 31 from the current fiscal

year-end of June 30. The Company believes this change will align its financial reporting periods to that of its peer group in the industry and better facilitate assessment of the Company's financial performance. The Company will file transitional audited financial statements on Form 10-KT for the six-month period ending December 31, 2018.

### **Fiscal First Quarter 2019 Results**

Revenue for the three months ended September 30, 2018 totaled \$486,000 compared to \$385,000 for the prior year quarter. Revenues in both periods were primarily derived from royalty income under existing collaboration agreements.

Operating expenses for the quarter ended September 30, 2018 increased to \$14.0 million from \$6.4 million a year earlier, due primarily to initial investments in sales and marketing infrastructure and program costs, amortization of the DEXYCU intangible asset, professional services and stock-based compensation. Non-operating expense, net in the quarter ended September 30, 2018 totaled \$19.6 million and consisted primarily of a non-cash change in fair value of derivative liability and interest expense on our term loan. Net loss for the quarter ended September 30, 2018 was \$33.1 million, or \$0.44 per share, compared to a net loss of \$6.0 million, or \$0.15 per share, for the prior year quarter.

Cash and cash equivalents at September 30, 2018 totaled \$55.8 million compared to \$38.8 million at June 30, 2018. The cash balance of September 30, 2018 reflects proceeds of \$28.9 million from the exercise of warrants in the quarter.

### **Conference Call Information**

EyePoint will host a conference call today, Tuesday, November 6, 2018, at 8:00 AM ET, to discuss the fiscal first quarter 2019 financial results and recent clinical and operational developments. To access the conference call, please dial (877) 312-7507 (local) or (631) 813-4828 (international) at least 10 minutes prior to the start time and refer to conference ID 3098959. 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. (formerly pSivida Corp.) ([www.eyepointpharma.com](http://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 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. 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. 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® (flucinolone acetonide intravitreal implant), a micro-insert for diabetic macular edema, licensed to Alimera Sciences, Inc., is currently sold directly in the U.S. and several EU countries. Retisert® (flucinolone acetonide intravitreal implant), for posterior 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](http://www.eyepointpharma.com) and connect on Twitter, LinkedIn, Facebook and Google+.

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 plans to commercialize YUTIQ and DEXYCU, the expected timing of release of the 24-month and 36-month patient follow-up data for YUTIQ and our expectations regarding the timing of a filing of an application for approval of a next-generation, shorter-duration treatment for posterior segment uveitis, 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 include uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce commercial supply of YUTIQ and DEXYCU and commercialize YUTIQ and DEXYCU in the U.S.; our ability to successfully build a commercial infrastructure and enter into and maintain commercial agreements for the launch of DEXYCU and YUTIQ; the development of our next-generation YUTIQ short-acting treatment for uveitis; potential off-label sales of ILUVIEN for non-infectious posterior segment uveitis ("NIPU"); consequences of flucinolone acetonide side effects; successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema ("DME") which depends on the ability of Alimera Sciences, Inc. ("Alimera") to continue as a going concern; 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 obtain marketing approval for ILUVIEN in its licensed territories for NIPU; potential declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; 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; effects of the potential exit of the United Kingdom from the European Union; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements in light of these risks. 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.

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FINANCIAL TABLES FOLLOW

**EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**  
**(In thousands, except per share amounts)**

	Three Months Ended September 30,	
	2018	2017
Revenues:		
Collaborative research and development	\$ 56	\$ 140
Royalty income	430	245
Total revenues	<u>486</u>	<u>385</u>
Operating expenses:		
Research and development	6,233	3,819
Sales and marketing	3,646	-
General and administrative	4,161	2,572
Total operating expenses	<u>14,040</u>	<u>6,391</u>
Loss from operations	(13,554)	(6,006)
Interest and other income, net	129	23
Interest expense	(815)	-
Change in fair value of derivative liability	(18,886)	-
Net loss	<u>\$ (33,126)</u>	<u>\$ (5,983)</u>
Net loss per common share:		
Basic and diluted	<u>\$ (0.44)</u>	<u>\$ (0.15)</u>
Weighted average common shares outstanding:		
Basic and diluted	<u>75,170</u>	<u>39,430</u>

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

	<u>September 30,</u> <u>2018</u>	<u>June 30,</u> <u>2018</u>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 55,764	\$ 38,776
Other current assets	1,878	1,133
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Total current assets	57,642	39,909
Intangible assets, net	30,744	31,358
Other assets	469	403
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<b>Total assets</b>	<u>\$ 88,855</u>	<u>\$ 71,670</u>
 <b>Liabilities and stockholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 7,418	\$ 6,663
Accrued development milestone	15,000	15,000
	<hr/>	<hr/>
Total current liabilities	22,418	21,663
Long-term debt	17,463	17,309
Derivative liability	-	19,780
Other long-term liabilities	1,269	1,231
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<b>Total liabilities</b>	<u>41,150</u>	<u>59,983</u>
 <b>Stockholders' equity:</b>		
Capital	443,766	374,840
Accumulated deficit	(396,899)	(363,991)
Accumulated other comprehensive income	838	838
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Total stockholders' equity	<u>47,705</u>	<u>11,687</u>
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<b>Total liabilities and stockholders' equity</b>	<u>\$ 88,855</u>	<u>\$ 71,670</u>



Source: EyePoint Pharmaceuticals, Inc.