



EyePoint Pharmaceuticals Reports Fiscal 2018 Fourth Quarter & Full Year Financial Results and Highlights Recent Progress

September 12, 2018

-Substantial progress made in the Company's accelerated transformation into a commercial entity

-YUTIQ™ PDUFA date of November 5, 2018

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

-Balance sheet strengthened by \$35 million of capital led by EW Healthcare Partners

-Conference call and webcast today, September 12th, at 8:30 AM ET-

WATERTOWN, Mass., Sept. 12, 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 2018 fourth quarter and full year ended June 30, 2018, and highlighted recent progress made to support its transformation into a commercial company.

"During EyePoint's fiscal fourth quarter, we made significant clinical, corporate and financial achievements that have contributed to the Company's rapid advancement towards commercialization," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "In preparation for the launch of DEXYCU and, if approved, YUTIQ, we added several key members to our management team, including David Price as Chief Financial Officer and Jack Weet as Senior Vice President Regulatory Affairs & Quality, each of whom has substantial experience in the launch and commercialization of pharmaceutical products."

Ms. Lurker continued, "Our clinical and research teams continue to add to the body of evidence supporting YUTIQ for the treatment of non-infectious posterior segment uveitis with multiple presentations at the 36th Annual Scientific Meeting of the American Society of Retina Specialists, and we look forward to the FDA's Prescription Drug User Fee Act (PDUFA) date of November 5, 2018 for this program. In support of our commercialization strategy, we also successfully strengthened our balance sheet with support from Essex Woodlands (EW) Healthcare Partners and Rosalind Advisors, Inc. (Rosalind Advisors), which have provided additional capital to support our commercialization plans and growth strategy for the future."

Recent Highlights

Key Commercial Preparations

- As EyePoint accelerates its transformation from a clinical-stage company into a commercial company ahead of future ophthalmic product launches, the Company has strengthened its infrastructure to support its growth across multiple functions, including finance, sales and marketing and regulatory, including the following personnel additions in newly created positions:
 - [David Price, Chief Financial Officer](#), brings more than 25 years of financial experience in the healthcare, investment banking and accounting sectors; and
 - [John \(Jack\) Weet, Ph.D., SVP, Regulatory Affairs & Quality](#), brings over 40 years of experience in regulatory affairs to EyePoint. He has extensive expertise in the oversight of FDA relations and negotiations across multiple therapeutic areas, including ocular disease.
- The Company has continued to execute on its four-pillar commercialization plan, which is to execute on a robust medical education road map, train and hire a top tier sales team, gain payor access and launch with a compelling marketing strategy. Notably, EyePoint has consummated an agreement with a premier contract sales organization to ensure a fully trained and highly seasoned field organization at launch. The Company has also established and begun executing its medical education, product marketing and market access plans ahead of product launch.

Strengthened Balance Sheet

- In June 2018, EW Healthcare Partners, an established healthcare-focused investment firm, Rosalind Advisors and another accredited investor contributed an aggregate of \$25.5 million of growth capital to EyePoint following stockholder approval of the financing. The closing of this financing, coupled with the closing, in March 2018, of the initial tranche of \$9.5 million of equity financing led by EW Healthcare Partners, resulted in total gross proceeds to the Company of \$35.0 million. Under the terms of the second tranche securities purchase agreement, funds affiliated with EW Healthcare Partners and the other second tranche investors received warrants to purchase an additional 20,184,224 shares of the Company's common stock, which, if exercised in full, would provide the Company with additional gross proceeds of up to approximately \$28.9 million to further strengthen its balance sheet. The warrants are cash-exercise only and are exercisable until the close of business on September 28, 2018.

Clinical Highlights

- At the 36th Annual Scientific Meeting of the American Society of Retina Specialists that took place from July 20-25, 2018 in Vancouver, three presentations highlighted twelve-month efficacy and safety data supporting YUTIQ for the treatment of non-infectious posterior segment uveitis. Highlights from each of the presentations include:
 - **Confirmatory 1-Year Study Results of an Injectable Fluocinolone Acetonide Intravitreal Insert (FAi) to Treat Non-infectious Posterior Segment Uveitis.** Efficacy results from this three-year prospective, Phase 3 study showed a decrease in recurrence of uveitis in FAi versus sham eyes at twelve months. Safety results demonstrated that 23.8% and 7.7% of FAi and sham subjects, respectively, experienced intraocular pressure (IOP) increases of greater than or equal to 12mm Hg, with one of the FAi study eyes requiring IOP lowering surgery. The results of this study support previous findings that the FAi is safe and effective to both treat and prevent recurrent uveitis.
 - **Controlling Uveitic Recurrences: Results From a Phase 3 Study of 0.18 mg Fluocinolone Acetonide Insert in Non-infectious Posterior Uveitis.** Data from the first year of this three-year study showed a lower inflammation recurrence rate in FAi randomized eyes than in sham eyes (37.9% vs. 97.6%, respectively). A total of 63 recurrences were reported in FAi-treated eyes, versus 105 recurrences in the sham-treated eyes. This data adds to the growing body of evidence evaluating the role of FAi in decreasing the rate of inflammation occurrence.
 - **Injectable Fluocinolone Acetonide Intravitreal Insert Reduces the Need for Adjunctive Treatment in Non-infectious Posterior Segment Uveitis.** Analysis of the full intent-to-treat cohort at one year indicated that a single intravitreal injection of FAi provided effective anti-inflammatory treatment for one year and significantly reduced the need for adjunctive therapies. 6.9% of FAi eyes, versus 61.9% of sham eyes, received at least one intra/peri-ocular steroid injection. Of the 6 FAi eyes that required intra/peri-ocular steroid injection, four required only a single injection through twelve months while half of the 26 sham eyes required multiple injections up to a maximum of five.

Corporate Highlights

- [Göran Ando, M.D. was added to EyePoint's Board of Directors](#) in June 2018 and was appointed Chairman of the Board on September 7, 2018. Dr. Ando is the former Chairman of the Board of Novo Nordisk A/S (NYSE:NVO), a global pharmaceutical company, and brings more than 35 years of successful global drug development and general management experience to EyePoint.
- EyePoint completed its delisting from the Australian Securities Exchange (ASX) on May 7, 2018. The Company's decision to delist from the ASX was due to, among other things, a lower proportion of the Company's common stock held by Australian shareholders, low trading volume on the ASX and the costs of maintaining the listing.
- EyePoint secured transitional pass-through reimbursement from the Centers for Medicare & Medicaid Services (CMS) for DEXYCU and was assigned a C-code. The code, C9034, will become effective on October 1, 2018. Approximately 40% of patients who undergo cataract surgery are covered by Medicare Part B. Drugs that are administered as part of the cataract surgery procedures can be covered under a CMS administered transitional-pass-through payment.

Anticipated Milestones

- **YUTIQ PDUFA date of November 5, 2018.** YUTIQ has been accepted for filing by the FDA and is currently under standard review with a PDUFA date of November 5, 2018. Posterior segment uveitis is a high unmet need area with limited treatment options and the third leading cause of blindness in the U.S. If approved, the Company plans to launch YUTIQ in the U.S. in the first half of 2019.
- **Launch DEXYCU and YUTIQ - subject to YUTIQ FDA approval and successful production of commercial supply of DEXYCU - in the first half of 2019.** The Company anticipates two potential near-term product launches, including DEXYCU, a dropless, long-acting therapeutic for the treatment of postoperative inflammation, which was approved by the FDA, and YUTIQ, a three-year treatment of non-infectious posterior segment uveitis, which is currently under standard review with a PDUFA date of November 5, 2018.

Fiscal Fourth Quarter and Full Year 2018 Results

Revenue for the quarter ended June 30, 2018 totaled \$715,000 compared to \$701,000 for the prior year quarter. Revenues in both periods were derived from feasibility study agreements and royalty income.

Operating expenses for the quarter ended June 30, 2018 increased to \$10.5 million from \$6.8 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 in the quarter ended June 30, 2018 totaled \$24.6 million, which included a \$24.0 million non-cash charge for the change in fair value of derivative liability primarily associated with the revaluation of the second tranche transaction immediately prior to the June 25, 2018 closing date and \$720,000 of interest expense and amortization of debt discount in connection with our March 2018 term loan agreement. Net loss for the quarter ended June 30, 2018 was \$34.4 million, or \$0.62 per share, compared to a net loss of \$6.1 million, or \$0.16 per share, for the

prior year quarter.

Revenue for the year ended June 30, 2018 was \$3.0 million compared to \$7.5 million for the year ended June 30, 2017. The prior year period included the recognition of deferred collaborative research and development revenue totaling \$5.6 million resulting from the termination of the Pfizer collaboration agreement.

Royalty income increased to \$1.6 million for the year ended June 30, 2018 compared to \$970,000 for the prior year, related primarily to the consummation of an amended agreement with Alimera Sciences, Inc. in July 2017 that converted a profit share arrangement to a sales-based royalty. Operating expenses for the year ended June 30, 2018 were \$29.2 million compared to \$26.1 million for the prior year. For the year ended June 30, 2018, the Company recorded a non-cash charge to non-operating expense of \$26.3 million resulting from the change in fair value of derivative liability.

Net loss for the year ended June 30, 2018 was \$53.2 million, or \$1.15 per share, compared to a net loss of \$18.5 million, or \$0.52 per share for the year ended June 30, 2017. There are currently 74,512,048 shares of common stock outstanding.

Conference Call Information

EyePoint will host a conference call today, Wednesday, September 12, 2018, at 8:30 AM ET, to discuss the fourth quarter and fiscal year 2018 financial results, recent accomplishments, clinical developments and commercial launch plans. 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 5782568. A live webcast will be available on the Investor Relations section of the corporate website at <http://www.eyepointpharma.com>.

A replay of the call will be available beginning September 12, 2018, at approximately 11:30 AM ET and ending on September 19, 2018 at 11:30 AM ET. The replay may be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID Number: 5782568. A replay of the webcast will also be available on the corporate website during that time.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals, Inc. (formerly pSivida Corp.) (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. The Company has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. In addition, 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 capable 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., is currently sold directly in the U.S. and several EU countries. Retisert® (fluocinolone acetonide intravitreal implant), for posterior uveitis, is licensed to and sold by Bausch & Lomb, Inc. The New Drug Application for EyePoint's lead product candidate, YUTIQ™ three-year treatment of non-infectious posterior segment uveitis, has been accepted for filing by the FDA and is currently under standard review with a PDUFA date of November 5, 2018. 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, 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 or believe may occur in the future 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; the number of clinical trials, including clinical trials conducted outside the U.S., and data required for marketing approval for YUTIQ in the U.S.; our ability to use data in promotion for YUTIQ; our ability to successfully produce commercial supply of DEXYCU and commercialize 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, if approved, YUTIQ; our ability to successfully commercialize YUTIQ, if approved, in the U.S.; potential off-label sales of ILUVIEN® for non-infectious posterior segment uveitis ("NIPU"); consequences of fluocinolone 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; the development of our next-generation Durasert™ short-acting treatment for uveitis; 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		Year Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Revenues:				
Collaborative research and development	\$ 218	\$ 461	\$ 1,343	\$ 6,569
Royalty income	497	240	1,618	970
Total revenues	<u>715</u>	<u>701</u>	<u>2,961</u>	<u>7,539</u>
Operating expenses:				
Research and development	4,765	4,213	16,178	14,880
Sales and marketing	1,512	-	1,512	-
General and administrative	4,220	2,624	11,545	11,235
Total operating expenses	<u>10,497</u>	<u>6,837</u>	<u>29,235</u>	<u>26,115</u>
Loss from operations	(9,782)	(6,136)	(26,274)	(18,576)
Interest and other income	27	20	101	91
Interest expense	(720)	-	(720)	-
Change in fair value of derivative liability	(23,953)	-	(26,278)	-
Net loss	<u>\$ (34,428)</u>	<u>\$ (6,116)</u>	<u>\$ (53,171)</u>	<u>\$ (18,485)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.62)</u>	<u>\$ (0.16)</u>	<u>\$ (1.15)</u>	<u>\$ (0.52)</u>
Weighted average common shares outstanding:				
Basic and diluted	<u>55,387</u>	<u>38,673</u>	<u>46,226</u>	<u>35,344</u>

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

	<u>June 30,</u> <u>2018</u>	<u>June 30,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,776	\$ 16,898
Other current assets	1,133	842
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Total current assets	39,909	17,740
Intangible assets, net	31,358	364
Other assets	403	573
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Total assets	<u>\$ 71,670</u>	<u>\$ 18,677</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,663	\$ 5,240
Accrued development milestone	15,000	-
Deferred revenue	-	50
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Total current liabilities	21,663	5,290
Long-term debt	17,309	-
Derivative liability	19,780	-
Other long-term liabilities	1,231	51
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Total liabilities	<u>59,983</u>	<u>5,341</u>
Stockholders' equity:		
Capital	374,840	323,323
Accumulated deficit	(363,991)	(310,820)
Accumulated other comprehensive income	838	833
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Total stockholders' equity	<u>11,687</u>	<u>13,336</u>
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Total liabilities and stockholders' equity	<u>\$ 71,670</u>	<u>\$ 18,677</u>



Source: EyePoint Pharmaceuticals, Inc.