
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): September 12, 2018

EyePoint Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51122
(Commission
File Number)

26-2774444
(IRS Employer
Identification No.)

480 Pleasant Street
Watertown, MA
(Address of principal executive offices)

02472
(Zip Code)

Registrant's telephone number, including area code: (617) 926-5000

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On September 12, 2018, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its fiscal fourth quarter and fiscal year ended June 30, 2018 results and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto. In connection with the press release, the Company also hosted a conference call and webcast on September 12, 2018 to discuss its fiscal fourth quarter and fiscal year ended June 30, 2018 results and certain other information. A copy of the transcript of this conference call is furnished as Exhibit 99.2 hereto.

The information contained in this report, including Items 2.02 and 9.01 and Exhibits 99.1 and 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

The following Exhibits are furnished with this report on Form 8-K:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of EyePoint Pharmaceuticals, Inc. dated September 12, 2018.
99.2	Conference call transcript by EyePoint Pharmaceuticals, Inc. dated September 12, 2018.

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

-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-

September 12, 2018 WATERTOWN, Mass., (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. LUVIEN® (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
Total current assets	<u>39,909</u>	<u>17,740</u>
Intangible assets, net	31,358	364
Other assets	403	573
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
Total current liabilities	<u>21,663</u>	<u>5,290</u>
Long-term debt	17,309	—
Derivative liability	19,780	—
Other long-term liabilities	1,231	51
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
Total stockholders' equity	<u>11,687</u>	<u>13,336</u>
Total liabilities and stockholders' equity	<u>\$ 71,670</u>	<u>\$ 18,677</u>

Operator

Good morning, my name is Daniel, and I will be your conference operator today. At this time, I would like to welcome everyone to the EyePoint Pharma Fiscal 2018 Fourth Quarter and Full Year Financial Results Conference Call. (Operator Instructions) Please be advised that this call is being recorded at the company's request.

I would now like to turn the call over to Mr. David Price, EyePoint's Chief Financial Officer.

David J. Price — *EyePoint Pharmaceuticals, Inc.* — CFO

Thank you, Daniel, and thank you all for joining us on today's conference call to discuss EyePoint Pharma Fiscal 2018 Fourth Quarter and Full Year Financial Results. Joining today's call are Nancy Lurker, President and Chief Executive Officer; Leonard Ross, Vice President, Finance and Chief Accounting Officer, who will also be available during the question-and-answer session; and Dario Paggiarino, Vice President and Chief Medical Officer.

Nancy will provide an overview of the progress made to date regarding our commercial preparations ahead of 2 potential launches in the first half of 2019 and highlight upcoming milestones. I will provide an overview of 2018 fiscal fourth quarter and full year results. We will then open the call up for your questions.

Earlier this morning, we issued a press release detailing the 2018 fiscal fourth quarter and full year results. A copy of the release can be found in the Investor Relations tab on the corporate website, www.eyepointpharma.com.

Before we begin our formal comments, I'll remind you that various remarks we will make today constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. These include statements about our future expectations, clinical developments and regulatory matters and time lines, the potential success of our product candidates, financial projections and our plans and prospects. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the risk factors section of our most recent quarterly report on Form 10-Q, which is on file with the SEC, and in other filings that we may make with the SEC in the future.

Any forward-looking statements represent our views as of today only. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so even if our views change. Therefore, you should not rely on these forward-looking statements as representing our views as of any date subsequent to today.

I'll now turn the call over to Nancy Lurker, President and Chief Executive Officer of EyePoint.

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc.* — *President, CEO & Director*

Thank you, David, and good morning, everyone. Thank you for joining us on today's call to review our fiscal 2018 fourth quarter financial results, recent operating and clinical achievements and commercial preparations ahead of the launches of DEXYCU and, if approved, YUTIQ. The upcoming months will be a transformative and a very exciting time for EyePoint. We have a lot to cover on this call as we have many significant achievements.

For those new to the EyePoint story, the company is a result of pSivida Corporation's acquisition of Icon Bioscience, which closed on March 28, 2018, at which time the company was rebranded to EyePoint Pharmaceuticals. Since then, we've made tremendous progress in evolving the company from an R&D-driven clinical-stage company into an emerging commercial-stage specialty pharmaceuticals company focused on ophthalmology, using products derived from 2 technology platforms from the pSivida and Icon portfolios. The strategic acquisition of Icon added DEXYCU to our pipeline, which uses the Verisome drug delivery technology, allowing for a single injection that releases over time.

DEXYCU, or dexamethasone intraocular suspension, was approved by the U.S. Food and Drug Administration on February 9, 2018, for the treatment of inflammation following ocular, otherwise, known as eye surgery. It's administered as a single intraocular injection in the posterior chamber at the end of cataract surgery and is the first long-acting intraocular steroid approved by the FDA for the treatment of postoperative inflammation.

Last week, we announced that the Centers for Medicare and Medicaid Services, or CMS, has approved transitional pass-through status and reimbursement through a C-Code. The code C9034 will become effective on October 1, 2018.

DEXYCU complements our ophthalmology pipeline, especially our late-stage candidate YUTIQ, which is a 3-year treatment for posterior segment uveitis, which is currently under regulatory review by the FDA and has a PDUFA action date of November 5, 2018.

The potential launch of DEXYCU, plus the potential approval of YUTIQ later this year will position us to launch 2 products in the first half of 2019, subject to the successful commercial scale-up of DEXYCU and FDA approval of YUTIQ. We will be able to significantly utilize the commercial organization that we are currently building by leveraging our entire corporate and commercial infrastructure other than the field reps, all of which are dedicated to ophthalmology.

Before I highlight our preparations on the commercial front, I would like to highlight the distinct opportunities for each of these therapies.

Let's begin with DEXYCU. In the United States, there are approximately 4 million cataract surgeries each year and growing with the aging population. It's the #1 surgical procedure performed in the U.S. There is a high unmet medical need among patients who undergo cataract surgery as the current standard of care, steroid drops to treat inflammation post eye surgery is extremely challenging, requiring a burdensome schedule of up to 70 drops over a period of 30 days. Many of these patients are elderly and may have health conditions such as cognitive impairment or osteoarthritis in their hands that make administering a lengthy steroid eye-drop regimen difficult and confusing.

DEXYCU represents a major advance compared to the standard of care for these patients since it will potentially eliminate the need for steroid eye drops after surgery, which is the most complicated dosing regimen of the 3 types of eye drops typically given after cataract surgery.

DEXYCU requires the administration of a single injection of 5 microliters of dexamethasone encapsulated in the fully bioerodible Verisome technology at the conclusion of surgery, which provides a steady release of drug over a number of days and weeks. DEXYCU can eliminate the need for daily steroid drops that are currently administered on a titrating regimen for up to 1 month.

In our pivotal Phase III clinical trial for DEXYCU, 60% of patients had 0 anterior chamber cells by day 8 post cataract surgery. Anterior chamber cells are a marker for inflammation, and measuring the number of cells post surgery on day 8 is the gold standard for clinical trials. This is a very good efficacy result.

Further, as steroids are known to increase intraocular eye pressure, physicians want to know if DEXYCU will raise eye pressure. In the same Phase III pivotal clinical trial, the main intraocular eye pressure increase in patients on DEXYCU versus placebo was 1.6 millimeters of mercury by day 3, a very modest increase. IOP, intraocular pressure, increased by less than 1 millimeters of mercury by day 8 and remained stable at around 14 millimeters of pressure through day 90, the last time point of the study.

Our market research supports our confidence in the potential of DEXYCU. Physicians consistently stated a very high intent to use DEXYCU over existing steroid drop treatments, particularly after becoming familiar with its efficacy and safety data. We are in the process of continuing the scale up of commercial supplies of DEXYCU to support our planned launch in the first half of 2019.

Now let's turn to YUTIQ, which contains a steroid, 0.18 milligrams of fluocinolone acetonide, in a tiny micro-insert implant that lasts for 3 years, and should we get FDA approval, will be indicated for noninfectious posterior segment uveitis, which represents the third leading cause of blindness in the U.S.

Currently, patients with posterior segment uveitis have limited treatment options and the most common treatment is frequent injections or systemic use of generic steroids or an implant that lasts only 2 or 3 months with a list price of \$1,400 per device. And over a 3-year period, this therapy can cost approximately \$17,000. If approved, YUTIQ could address this area of high unmet need and provide patients with a treatment option that has the advantage of delivering consistent micro dosing for up to 3-year time period without drug peaks and valleys. Consistent drug delivery over an extended period of time is an important element of treatment, as the overall regimen aims to prevent flares, which can lead to blindness.

The scientific data continue to support YUTIQ's safety and efficacy. At the 36th Annual Scientific Meeting of the American Society of Retinal Specialists, known as ASRS, that took place from July 20 to 25, 2018 in Vancouver, 3 presentations highlighted 12-month efficacy and safety data supporting YUTIQ.

In summary, efficacy results from a confirmatory 3-year prospective Phase III study demonstrated a durable decrease in uveitic recurrence in injectable fluocinolone acetonide intravitreal insert, otherwise known as YUTIQ in eyes versus sham eyes.

Data from the first year of a 3-year study also showed that the recurrence rate in fluocinolone acetonide randomized eyes were significantly lower than sham eyes, 37.9% versus 97.6%, respectively; p value of less than 0.001.

Lastly, in an analysis of a full intent-to-treat cohort at 1 year, a single intravitreal injection of fluocinolone acetonide not only provided effective anti-inflammatory treatment for 1 year but also significantly reduced the need for adjunctive therapies, 6.9% of fluocinolone acetonide eyes versus 61.9% of sham eyes.

Based on these data, we continue to receive a very high degree of interest in YUTIQ from retina and uveitis specialists. In Q4 2018, we plan to report data for YUTIQ from the 24-month and in the first half of 2019, the 36-month follow-up period from the first Phase III clinical trial.

On the commercial front, we've been making tremendous progress building our infrastructure across multiple [functions] at the company in preparation for the U.S. launch of DEXYCU and, pending regulatory approval, YUTIQ.

We strengthened our team with several key appointments, including David Price, who you heard from at the beginning of our call as CFO. David brings over 25 years of experience in the health care, investment banking and accounting industries and most recently served as Chief Financial Officer of Concordia International Corporation, a publicly traded generic pharmaceutical company.

On the regulatory front, Dr. John Weet, our new Senior Vice President, Regulatory Affairs and Quality brings over 40 years of experience in regulatory affairs to EyePoint. He has extensive experience in the oversight of U.S. FDA relations and negotiations across multiple therapeutic areas, including ocular disease.

We also continue to add very strong commercial talent, and all of these individuals are industry veterans with a strong track record of success demonstrated during their careers. We're delighted to welcome them to the EyePoint team as we continue building our foundation for the future.

We have also strengthened our Board of Directors with the appointment of Dr. Göran Ando, who was appointed in June 2018. Dr. Ando is the former Chairman of the Board of Novo Nordisk A/S and has a distinguished career in the global pharmaceutical industry that has spanned nearly 4 decades.

Last week, we announced that Dr. Ando was elected as Chairman of the Board. As part of this transition, Dr. David Mazzo will step down as Nonexecutive Chairman but will remain on the board and will continue to serve as Chair of the Compensation Committee. We thank David Mazzo for his many years of service to EyePoint Pharmaceuticals as Chairman of the Board.

Turning to our commercial preparations. We've completed several initiatives ahead of our commercial launch that support our 4-pillar commercialization plan, which consists of hiring a top-tier sales team, a robust medical education rollout, gain payer access and launch a superior marketing strategy.

We've made significant progress towards our goal, including we finalized an agreement with a premier contract sales organization. Our sales leadership team will lead the efforts and work closely with the contract sales organization to build a dedicated EyePoint sales team. We have deployed and are currently moving forward with executing a robust medical education program in the U.S.

We've also begun our payer and reimbursement assessments. As we announced on September 5, we're also very pleased that DEXYCU has received from CMS its pass-through transitional C-Code, which allows for Medicare Part B reimbursement. Further, if approved, YUTIQ will likely be covered by Medicare and other payers.

Our marketing plans are in full swing. We are in the process of implementing new systems and processes to ensure that the company operates with robust data and metrics as we transition to commercialization.

We have made tremendous progress and are confident in our commercial build-out and in preparing for these important launches. In addition, we continue to work on our pipeline products, our shorter-acting 9-month YUTIQ, which remains on track to file in 2019 upon NDA approval for our 3-year YUTIQ. We continue to progress our other preclinical products, specifically a tyrosine kinase inhibitor program and our collaboration for glaucoma with our pharma partner.

With that, I will turn the call over to David to review our 2018 financial results for the fourth quarter and full year. David?

David J. Price — *EyePoint Pharmaceuticals, Inc.* — CFO

Thank you, Nancy. I first want to take this opportunity to say that I'm extremely honored and excited to have joined EyePoint during such an important time of its development. I was immediately impressed by the company's innovative ophthalmology pipeline and accomplished management team with deep experience in launching pharmaceutical products. I look forward to being a member of this team through the next stage of growth and transition into a commercial entity.

I will now turn to the financial results, which are outlined in our press release that was issued this morning.

As of June 30, 2018, cash and cash equivalents totaled \$38.8 million compared to \$16.9 million as of June 30, 2017. The total number of common shares outstanding at June 30, 2018, were 74.5 million.

Net cash used from operations for fiscal 2018 totaled approximately \$21.9 million compared to \$20.5 million in fiscal 2017.

In June 2018, we received shareholder approval for a second tranche of growth capital under our agreement with EW Healthcare Partners, an established health care-focused investment firm, Rosalind Advisors and another accredited investor.

Under the agreement, EyePoint sold approximately \$25.5 million of units. Each unit consisted of 1 share of common stock and 1 warrant to purchase a share of common stock.

In addition, the transaction enabled the company to draw down an additional \$5 million under our SWK loan facility.

Now turning to the income statement. For the fourth quarter ended June 30, 2018, EyePoint recognized \$0.7 million in revenue, the same amount as recognized for the 3 months ended June 30, 2017.

For the full year 2018, revenues were \$3 million compared to \$7.5 million in 2017. The 2017 revenue figure included the recognition of deferred collaborative research and development revenue, totaling \$5.6 million resulting from the termination of the Pfizer collaboration agreement.

Operating expenses for the 3 months 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's intangible assets, professional services and stock-based compensation.

Nonoperating expense in the current quarter totaled \$24.6 million, which included a \$24 million noncash charge for the change in fair value of a derivative liability associated with the reevaluation of the second tranche transaction immediately prior to the June 25, 2018, closing.

Net loss for the fourth 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 corresponding fiscal 2017 period. Net loss for the 12 months ended June 30, 2018, was \$53.2 million or \$1.15 per share compared to a net loss of \$18.5 million or \$0.58 (sic) [\$0.52] per share for fiscal 2017.

As we advance the company's commercial readiness for the launch of DEXYCU and YUTIQ, if approved by the FDA, combined with the working capital required to launch these 2 products, we anticipate that we will continue to be cash flow negative through the next 12 months.

I'll now turn the call back to Nancy for closing remarks. Nancy?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Thank you, David. Before we take your questions, let me highlight our anticipated near-term milestones.

First, we've been successful in securing C-Code pass-through reimbursement for DEXYCU. I will note that C-Codes are granted quarterly based on application submitted that must meet the pass-through status criteria. Second, we will continue to work collaboratively with the FDA to gain regulatory approval for YUTIQ on our set PDUFA date of November 5, 2018. Lastly, we plan to launch DEXYCU, subject to a successful commercial supply scale-up and YUTIQ, subject to favorable regulatory approval in the first half of calendar year 2019.

It's been nearly 2 years since I joined EyePoint and I'm so proud of the progress that the team has made in a short period of time. As we all work together as a team to build a commercial-stage specialty pharma company focused on ophthalmology, my level of excitement and enthusiasm about our prospects are even greater. Our team is united in our passion and urgency to foster innovation in ophthalmology and lay the important groundwork to ensure our future growth and commercial success. I thank everyone for your time today, and we look forward to keeping you updated on our continued progress.

Operator, we're now ready to take your questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from François Brisebois with Laidlaw.

François Daniel Brisebois — *Laidlaw & Company (UK) Ltd., Research Division — Healthcare Equity Analyst*

Sorry, I dropped off a little bit here. So sorry if you mentioned this, but I just wanted to hit a couple of things here. First of all, I was wondering in terms of the pass-through C-Code. Just I was wondering if you could give a little more color on why you're only approaching or, I guess, not only but you're approaching 40% of the population, which is Medicare Part B first and then attacking other patients and maybe a time line on that. And then, I guess, maybe an explanation as to why the C-Code could potentially be more than 3 years from experiences with other (technical difficulty)

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Thank you for the questions. What I'm going to do first is turn it over to David just for a quick update on one of our financial comments. So David, why don't you answer that question, then I will answer François'?

David J. Price — *EyePoint Pharmaceuticals, Inc. — CFO*

Great. Thank you, Nancy. I just want to correct I inadvertently mentioned that our loss per share for the year ended June 30, 2017, was \$0.58 per share. That should be \$0.52 per share. So I just want to correct the record for that. Thank you very much. Nancy?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Okay. So François, back to your question on the C-Code, which you asked about the various books of business. So just for our listeners, there are different segments of the patient population. There is your Medicare Part B. There is your commercial payers. There is a your Medicare Advantage, which operates usually like a commercial book of business and then obviously Medicaid B in Department of Defense and then cash. The majority of approximately 4 million surgeries are Medicare Part B, which is approximately about 40% of the 4 million patients and then cash pay — excuse me, commercial, and I'm going to wrap in Medicare Advantage because that operates similar to commercial, runs about another 30% to 40% and then you have the Medicaid DoD and cash pay business. Let me stress, we will be going after all pieces of the business; however, with commercial and Medicare Advantage, most of them — some of them may want rebates. The problem with rebates is that, that flows through to the average selling price, which affects the C-Code. So we will be going after all pieces of the business. We just want to be [cautious] for those payers that we believe, and there will be some, who will be more willing to pay the C-Code rate and a good reason why they should. We fully expect to go after that piece of business.

And François, I'm sorry, your follow-up question around that was — repeat that, please?

François Daniel Brisebois — *Laidlaw & Company (UK) Ltd., Research Division — Healthcare Equity Analyst*

It's just the C-Code will be good for 3 years. I'm just wondering if there is potential for it to last longer than that.

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Yes. So obviously, we can't predict the future. Right now, the C-Code will sunset after 3 years. Now you can still use and get payment in the commercial book of business and in the Medicare Advantage book of business, which isn't as — they can follow the C-Code, but they're not required to follow the C-Code. The Medicare Part B book of business will use the C-Code. Just for the audiences' reminder, the C-Code — the pass-through transitional payment expires after 3 years and then the product will get wrapped into the cataract bundled payment. So what we are working on now is to potentially work with CMS to change those regulations. There is an active working group to effect that change. And we believe that the current way it's written is not meant for drugs because that bundled payment was primarily intended originally, if you look at the way the law was — the regulations were promulgated for surgical supplies and for the facility fee. Drugs, because obviously, they generally cost substantially more than surgical supplies, it was never quite envisioned, at least that's our understanding. (inaudible) with part of the bundled payment. So we do believe

there is a good case to make drugs separate and be paid just like all other drugs under Medicare Part B, which is an ASP plus today, I believe it's around 3.4% as all other Medicare Part B drugs are paid. So let me reiterate that. So we do have a working group. We also are going to be working with Congress to potentially change the statutory regulations and there is a precedent for that. There was a bill that was passed for those drugs that have their C-Code expired effective December 31, 2017, they got an extra 2-year extension. So obviously, we can't predict the future, but we do believe there is a good case to be made that either the regulations will change and should change or the statutory law changes. And we are working rather aggressively to try to effect those changes.

François Daniel Brisebois — *Laidlaw & Company (UK) Ltd., Research Division — Healthcare Equity Analyst*

Okay, great. Now that's very helpful. And then just one last one for me. In terms of finances, I just wanted to touch on the noncash that was booked as the liability of \$24 million from the second tranche. If you guys could just give a little bit more color on to how that's just a onetime event and not basically an operating expense here.

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

So I'll turn that over to David. Sorry, Len. Sorry, I apologize.

Leonard S. Ross — *EyePoint Pharmaceuticals, Inc. — VP of Finance & CAO*

Thank you, François. As we previously disclosed in EyePoint's 10-Q for the March 2018 quarter, the company's right and obligation to sell the common stock and warrants in the form of units, to EW Healthcare and the other participating investors in the second tranche was recorded as a liability on March 28, the date of the first tranche closing. Such a liability is subject to mark-to-market valuation adjustments. And as a result of the significant increase in our share price during the fourth quarter, the derivative liability increased by \$24 million from March 31 through the settlement date of the shares that were issued in the tranche two closing on June 25. While this charge is recorded in the profit and loss account, it is a noncash, nonoperating charge and was a significant contributor to the increased net loss for the year compared to fiscal 2017.

Operator

And our next question comes from Andrew D'Silva with B. Riley FBR.

Andrew Jacob D'Silva — *B. Riley FBR, Inc., Research Division — Senior Analyst*

Couple of quick bookkeeping questions. First, what is the current outstanding share count? And then outside of changes in derivative liabilities, what were other noncash charges during the quarter or year, stock-based comp, depreciation and amortization and things of that nature? And while you're pulling that, can you give a little bit color on the second tranche warrants? If my understanding is correct, now that you've got the pass-through status, they do have to be exercised or they expire, correct?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Yes. So Andy, this is Nancy. Len will answer about the warrants. So go ahead, Len.

Leonard S. Ross — *EyePoint Pharmaceuticals, Inc. — VP of Finance & CAO*

Yes. So in terms of noncash charges, there was about \$2.7 million of stock-based compensation during the year. There was about \$1 million of amortization of intangibles. You may recall there were previous intangibles that became fully amortized at the end of calendar '17. And the intangible associated with the Icon acquisition is currently amortized at a rate of about \$2.4 million a year, of which obviously there is just 1 quarter or little over \$600,000 in the current fiscal year.

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

And share count?

Leonard S. Ross — *EyePoint Pharmaceuticals, Inc. — VP of Finance & CAO*

The share count is 74.5 million shares outstanding. That's the same as at June 30.

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Okay. And David on the warrant question?

David J. Price — *EyePoint Pharmaceuticals, Inc. — CFO*

Sure. Andy, the warrants are exercisable. As of now, we have formally notified EW and the other investors of the C-Code that provides them with 15 business days upon which to exercise the warrants, and we do anticipate that they will exercise those before or on the 28th of September, which is the last day.

Andrew Jacob D'Silva — *B. Riley FBR, Inc., Research Division — Senior Analyst*

Okay, perfect. And then with the past pass-through status coming through, did that happen earlier than anticipated? I had it in my notes that you would target the beginning of calendar year '19 to get that commenced because, I guess, once the clock starts, it's 36 months — would it be 36 months from October 1 or is it 36 months from the date you actually launched the product?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Yes. So let me clarify. I've never stated when we would file the C-Code. I have always said we would file the C-Code as we get close to the commercialization. As to the timing, the C-Code is effective October 1, 2018, but the 3-year time clock does not start until the quarter closest to the first commercial sale. So, in essence, the 3-year clock starts in the quarter that we would have the commercial sale or the quarter closest to the first commercial sale.

Andrew Jacob D'Silva — *B. Riley FBR, Inc., Research Division — Senior Analyst*

Okay, great. That's good. And then when you were referencing previous caller's questions, changing the statutory laws, you were essentially referencing taking DEXYCU from Medicare Part B to Part D, is that correct? Is that essentially what the...

David J. Price — *EyePoint Pharmaceuticals, Inc. — CFO*

No. We're simply saying — and again, this is still somewhat influx, but we are looking at different ways that we could either get an extension on the C-Code, as the other drugs got an extension, but that requires a law — a statutory change, or make it a statutory law whereby after 3 years, it just reverts back to ASP plus, whatever the percent is. So there is a number of ways we could tackle this, but right now not to go back to Medicare Part D because we're not in Medicare Part D. We're in Medicare Part B, as you know. And Medicare Part B for our listeners is that part of the Medicare drug segment where drugs are administered either in a hospital or outpatient setting or a physician's office. Medicare Part D generally applies to drugs that are delivered directly to the patient through the pharmacy and the patient self administers.

Andrew Jacob D'Silva — *B. Riley FBR, Inc., Research Division — Senior Analyst*

Okay. So I misunderstood that. And then as far as YUTIQ, your discussions with the FDA, anything abnormal that would give you any pause on getting the green light in November? And does having Retisert and ILUVIEN in the market help you in the process or as you're going through discussions?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

So let me comment that right now generally, we don't comment on FDA discussions, but we are looking forward to a PDUFA date of November 5. I'll just leave it at that. And as for ILUVIEN and Retisert, the only comment I'll make on that is that we do have right of reference to the ILUVIEN's safety database, which was obviously part of our application process to the FDA. And since that's been on the market for a number of years, there is a large body of safety data, which is generally quite benign. Obviously, there is always some safety issues, but it's relatively benign.

Andrew Jacob D'Silva — *B. Riley FBR, Inc., Research Division — Senior Analyst*

Good. Fair enough. And then last thing, can you let us know outside of regulatory approval for YUTIQ, what are the biggest items that you need to tackle between now and when you launch the products? And then perhaps more importantly, what items are keeping up you at night? And what should we do to chart your progress with that and not coffee or caffeine?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

Good questions, Andy. Listen, like all launches, we have a significant ramp-up that's occurring. But we're quite pleased with our progress. In fact, we've made tremendous progress on the commercial ramp-up. So for example, we've signed a contract with our contract sales organization. We built out entirely our commercial organization except for actually hiring the sales representatives, which we won't do until we're closer to launch. So we are actively implementing particularly for DEXYCU, which is approved, our medical education plan and doing a significant amount of outreach, and we've got a robust publication plan. We've done a tremendous amount of work in that arena and our #1 goal is to just raise awareness about DEXYCU as well as the potential upcoming launch of fluocinolone. So in terms — I'm not going to answer in terms of what keeps me up at night. Obviously, there is a lot of work that still needs to be done. But as I said, we're making very, very good progress and we're very pleased.

Operator

(Operator Instructions) Our next question comes from Yi Chen with H.C. Wainwright.

Yi Chen — *H.C. Wainwright & Co, LLC, Research Division — MD of Equity Research & Senior Healthcare Analyst*

Could you please comment on what the operating expenses could look like once both products are launched?

Nancy S. Lurker — *EyePoint Pharmaceuticals, Inc. — President, CEO & Director*

And we'll have David answer that question.

David J. Price — *EyePoint Pharmaceuticals, Inc.* — CFO

Sure. It's David. We haven't put guidance out with regards to 2019 or post launch at this juncture. Suffice to say that we believe that — over time we will have positive operating margin for the business once we get — once we reach a level of sales that is at a more normal level post launch. But realistically, the level of expenses is something that we're not prepared to guide on at this juncture similar to the revenue.

Operator

And I'm not showing any further questions at this time. Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program, and you may all disconnect. Everyone, have a wonderful day.