Ocular Therapeutix Announces Second Quarter 2014 Financial Results

August 28, 2014

BEDFORD, Mass.--(BUSINESS WIRE)--Aug. 28, 2014-- Ocular Therapeutix (Nasdaq: OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the second quarter ended June 30, 2014.

“The past several months have been transformational for Ocular Therapeutix,” said Amar Sawhney, Ph.D., President and Chief Executive Officer. “With the closing of our IPO in July, our solid balance sheet should enable the Company to progress with its robust clinical development programs in pain and inflammation, glaucoma and ocular hypertension, and chronic allergic conjunctivitis.” Dr. Sawhney continued, “We look forward to advancing our pipeline further in the second half of 2014 with the anticipated initiation of a Phase 2b clinical trial of our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension. We are also continuing to advance our Phase 3 clinical trials of our OTX-DP product candidate for the treatment of post-surgical ocular inflammation and pain.”

Second Quarter 2014 Financial Results

Ocular reported a net loss attributable to common stockholders of approximately $6.4 million, or $2.10 per share, for the quarter ended June 30, 2014, compared to $3.1 million, or $1.19 per share, for the quarter ended June 30, 2013. The second quarter 2014 results include $3.4 million in non-cash charges for stock-based compensation and licensing and consultant fees paid in common stock compared to $0.2 million in such non-cash charges in the second quarter of 2013.

Total operating expenses for the quarter ended June 30, 2014 were $6.0 million as compared to $3.0 million for the quarter ended June 30, 2013. Research and development (R&D) expenses for the quarter ended June 30, 2014 were $4.3 million, compared to $2.4 million for the second quarter of 2013. This increase is primarily related to the clinical development of the Company’s product pipeline, including the Phase 3 clinical trials of its OTX-DP product candidate for the treatment of post-surgical ocular inflammation and pain, the Phase 2 clinical trials of its OTX-DP product candidate for the treatment of chronic allergic conjunctivitis and a Phase 2a clinical trial of its OTX-TP product candidate for the treatment of glaucoma and ocular hypertension.

Ocular generated $0.1 million of revenue during the three months ended June 30, 2014 from initial sales of ReSure® Sealant. Sales of ReSure® Sealant commenced in the first quarter of 2014 and limited sales are anticipated during 2014 as the company seeks to build awareness of this product through a network of independent medical device distributors across the United States.

As of June 30, 2014, cash, cash equivalents, and short-term investments totaled $19.9 million. Subsequent to the end of the second quarter, Ocular completed an initial public offering (IPO) of its common stock and received $66.5 million in net proceeds.

Summary of Year-to-Date 2014 Accomplishments

- Ocular received net proceeds of approximately $66.5 million from the issuance and sale of 5,750,000 shares of its common stock in its IPO, including shares issued upon the exercise in full of the underwriters' over-allotment option.
- On July 25, 2014, Ocular’s shares began trading on the NASDAQ Global Market under the symbol "OCUL".
- Ocular strengthened its leadership team with the appointment of Bruce Peacock, a seasoned executive with significant experience in the biopharmaceutical industry, to the Board of Directors, and with the appointment of Brad Smith, an executive with experience with both public and private life sciences companies, as Chief Financial Officer.
- The American Medical Association (AMA) CPT Editorial Panel granted Ocular a Category III CPT code 0356T for the insertion of a drug-eluting implant in the punctum, a natural opening in the eyelid near the tear ducts. The new Category III CPT code, designated for emerging technologies, services, and procedures, became effective July 1, 2014.
- In January 2014, Ocular received approval from the U.S. Food and Drug Administration (FDA) to commercialize the ReSure® Sealant in the United States, indicated for prevention of postoperative fluid egress from corneal incisions with a demonstrated wound leak following cataract surgery. The ReSure® Sealant is the first and only surgical sealant that is FDA-approved for ophthalmic use.

Recent Clinical Highlights

- Ocular completed a 41-patient Phase 2a clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension. One of the two OTX-TP dosing arms of the study appeared to show reduction of intraocular pressure similar to comparator Timolol eye drops, although the trial was not powered to measure any endpoints with statistical significance. The results of this clinical trial provided valuable information for the design of a Phase 2b clinical trial of this product.
- In March, Ocular initiated a Phase 3 clinical program to evaluate the safety and efficacy of its OTX-DP product candidate, which incorporates the FDA approved corticosteroid dexamethasone as an active pharmaceutical ingredient, for the treatment of post-operative ocular inflammation and pain. Ocular has designed OTX-DP to provide a sustained, tapered release of dexamethasone over a period of approximately 30 days.
- Ocular presented six posters at the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in

Orlando, Florida, from May 4-8, 2014.

- Ocular presented eleven podium and posters, including clinical data on its ReSure® Sealant and sustained release dexamethasone, at the American Society of Cataract and Refractive Surgery (ASCRS) Annual Symposium in Boston, Massachusetts, from April 25-29, 2014.

Anticipated Clinical Milestones and Development Plans

- During the fourth quarter of 2014, Ocular intends to initiate a Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension.
- During the fourth quarter of 2014, Ocular expects to release Phase 2 clinical trial data of OTX-DP for the treatment of chronic allergic conjunctivitis. A total of 60 patients have been randomized 1:1 to receive either OTX-DP or a proprietary placebo punctum plug, using a Modified Conjunctival Allergen Challenge Model (CAC™). OTX-DP is administered as a one-time sustained release corticosteroid with a four-week release. Primary endpoints of the Phase 2 trial include ocular itching and conjunctival redness.

About Ocular Therapeutix

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix's lead product candidates are in Phase 3 clinical development for post-surgical ocular inflammation and pain, and Phase 2 clinical development for glaucoma, ocular hypertension and chronic allergic conjunctivitis. The Company is also evaluating sustained-release injectable anti-VEGF drug depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved to seal corneal incisions following cataract surgery.

Forward-looking Statements

"Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the development of the Company's product candidates, such as the timing and conduct of the Company's Phase 3 clinical trial of OTX-DP for the treatment of post-operative inflammation and pain following cataract surgery and the Company's Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension, the expected timing to release data relating to the Company's Phase 2 clinical trial of OTX-DP for the treatment of chronic allergic conjunctivitis, pre-commercial activities, the advancement of the company's earlier stage pipeline, future sales of ReSure Sealant and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including statements about the clinical trials of our product candidates. Such forward-looking statements involve substantial risks and uncertainties that could cause Ocular Therapeutix' clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to the timing and costs involved in commercializing ReSure® Sealant, the initiation and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the sufficiency of cash resources and need for additional financing or other actions and other factors discussed in the "Risk Factors" section of the final prospectus for the Company's IPO, which is on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release."

Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	**2013**	**2014**	**2013**
Revenue	$ 97	$ —	$ 124	$ —
Operating expenses:				
Cost of revenue	20	—	29	—
Research and development	4,292	2,404	9,250	4,891
Selling and marketing	535	143	845	280
General and administrative	1,196	442	2,771	878
Total operating expenses	6,043	2,989	12,895	6,049

Loss from operations	(5,946)	(2,989)	(12,771)	(6,049)
Other income (expense):				
Interest income	1	3	2	8
Interest expense	(257)	(107)	(300)	(256)
Other income (expense), net	(190)	3	(331)	7
Total other income (expense), net	(446)	(101)	(629)	(241)
Net loss and comprehensive loss	(6,392)	(3,090)	(13,400)	(6,290)
Accretion of redeemable convertible preferred stock to redemption value	(5)	(9)	(11)	(17)
Net loss attributable to common stockholders	$ (6,397)	$ (3,099)	$ (13,411)	$ (6,307)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.10)	$ (1.19)	$ (4.54)	$ (2.45)
Weighted average common shares outstanding, basic and diluted	3,044,605	2,595,771	2,952,689	2,575,612

Ocular Therapeutix, Inc.

Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	June 30, 2014	**December 31, 2013**
Assets		
Current assets:		
Cash and cash equivalents	$ 19,944	$ 17,505
Accounts receivable from related party	1	19
Accounts receivable	60	250
Inventory	109	—
Deferred offering costs	2,197	—
Prepaid expenses and other current assets	283	240
Total current assets	22,594	18,014
Property and equipment, net	1,152	904
Restricted cash	228	228
Total assets	$ 23,974	$ 19,146
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$1,525	$545
Accrued expenses	1,629	741
Deferred revenue	250	250
Notes payable, net of discount, current	1,085	1,806
Total current liabilities	4,489	3,342
Preferred stock warrants	852	254
Deferred rent, long-term	119	27
Notes payable, net of discount, long-term	13,594	651
Total liabilities	19,054	4,274

Commitments and contingencies (Note 11)		
Redeemable convertible preferred stock (Series A, B, C, D and D-1), $0.001 par value; 34,229,025 and 33,979,025 shares authorized at June 30, 2014 and December 31, 2013, respectively; 32,842,187 shares issued and outstanding at June 30, 2014 and December 31, 2013; aggregate liquidation preference of $74,436 at June 30, 2014 and December 31, 2013	74,355	74,344
Stockholders' deficit:		
Common stock, $0.0001 par value; 47,500,000 and 45,000,000 shares authorized at June 30, 2014 and December 31, 2013, respectively; 3,129,285 and 2,676,648 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	—	—
Additional paid-in capital	4,745	1,308
Accumulated deficit	(74,180)	(60,780)
Total stockholders' deficit	(69,435)	(59,472)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 23,974	$ 19,146

Source: Ocular Therapeutix, Inc.

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