Investor Relations - SWK Holdings

Eton Pharmaceuticals Announces Third Quarter Financial Results and Highlights Business Progress

Biorphen® Expected to Launch by End of November
Company to Host Conference Call and Webcast Today at 4:30 p.m. ET (3:30 p.m. CT)

DEER PARK, Ill., Nov. 14, 2019 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today reported financial results for the third quarter ended September 30, 2019 and provided an update on business progress.

“Our first product approval was a major milestone for Eton and a great accomplishment by our team,” said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. “Initial interest in Biorphen from hospitals has been strong, and we expect to have the product available for customers before the end of this month. We also continued to make progress advancing our pipeline this quarter, as we work towards additional product launches in 2020.”

Recent Business Milestones and Updates:

- FDA approval of Biorphen. On October 21st, the FDA approved Biorphen, the first and only FDA-approved ready-to-use formulation of phenylephrine for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

- Executed debt transaction with SWK Holdings. This week, Eton announced it has secured a $10 million debt facility from SWK Holdings. The facility will give the company additional flexibility to pursue accretive business development activities while it invests in the commercial launch of Biorphen and the planned launch of ET-105 in early 2020.

- Licensed U.S marketing rights to ET-105. During the quarter, Eton closed the acquisition of U.S marketing rights to ET-105, which was executed upon the product’s NDA being accepted for review by the FDA. ET-105 is an innovative formulation of lamotrigine that will be administered to patients as an oral liquid, and its NDA has been assigned a PDUFA date of March 17, 2020.

Biorphen Commercial Launch

Eton currently has a team of five hospital-focused sales representatives actively promoting Biorphen and expects to expand the team to more than ten representatives by the first quarter of 2020. Since approval, Eton’s team has promoted Biorphen and met with key opinion leaders at conferences including the American College of Emergency Physicians (ACEP) and the American Society of Anesthesia (ASA), and has already engaged in discussions with pharmacy directors or physicians from more than 200 different institutions.

Eton estimates that the current phenylephrine injectable market is greater than 20 million Biorphen equivalent units per year. Over time, Eton expects to convert a significant share of the market to ready-to-use Biorphen, and in addition, expects to grow the market for phenylephrine as Biorphen’s three-year shelf life allows it to be stocked in additional locations throughout emergency rooms, crash carts, and in surgical centers where it previously was not feasible to stock ready-to-use phenylephrine due to the short expiry dating of compounded products.

Currently, ready-to-use phenylephrine injection is only available from 503B compounding pharmacies. Eton believes there is no longer a clinical need for 503B facilities to compound phenylephrine into ready-to-use formulations, and based on FDA guidelines, also believes 503B facilities would be in breach of FDA policy if they continue to sell ready-to-use phenylephrine injection after the availability of Biorphen.

Pipeline Update

Eton currently has eight product candidates in its late-stage pipeline, which the company defines as products that are expected to be submitted to the FDA within twelve months.

Product (Molecule)	Dosage Form	Category	Expected Submission Timing	Reference Product Market Size
EM-100 (Ketotifen)	Ophthalmic	OTC**	Submitted	$50 million +
ET-105 (Lamotrigine)	Oral Liquid	Neurology	Submitted	$700 million +
DS-300	Injectable	Hospital	2019	$75 million* +
ET-203	Injectable	Hospital	2019 - 2020	$90 million +
ET-103 (Levothyroxine)	Oral Liquid	Endocrinology	2020	$2.5 billion +
ET-104	Oral Liquid	Neurology	2020	$75 million +
DS-100	Injectable	Hospital	2020	$100 million* +
ET-101	Oral Liquid	Neurology	2020	$800 million +

Reference product market sizes based on IQVIA data unless noted.

*Based on management estimates

**Product will be marketed by Bausch Health

EM-100. Eton’s partner is finalizing an amendment to respond to the items addressed in the FDA’s Complete Response Letter, and the amendment is scheduled to be submitted before the end of November. Eton expects the amendment to be classified as a minor amendment, which would be assigned a three-month target action goal date by the FDA, allowing for a potential approval as early as the first quarter of 2020.

ET-105. The FDA review of ET-105 is ongoing and has been assigned a PDUFA date of March 17, 2020. Eton has proactively initiated a human factors study to support the filing and mitigate the potential for a delay in the approval timing. The human factors study is expected to be completed in January and will be added to the submission under review.

DS-300. Eton expects to submit the ANDA for DS-300 before the end of this year.

ET-203. Eton's partner has an FDA meeting scheduled to discuss options to address the concerns raised by the FDA regarding the original NDA submission. Eton believes the NDA will be resubmitted in the coming months.

ET-103. Eton has submitted the ET-103 clinical protocol to the FDA for review prior to the submission of its NDA. The company expects to receive FDA feedback in December 2019. If the protocol is acceptable, Eton would expect to file the NDA in the first quarter of 2020.

ET-104. Eton is in active discussions with the FDA regarding the product's pediatric requirements and expects to submit the NDA in the first half of 2020.

DS-100. Eton held a meeting with the FDA in August 2019. Based on the positive meeting outcome, the company expects the product's NDA to be submitted in 2020.

ET-101. Eton anticipates initiating ET-101's bioequivalence study in the first quarter of 2020. If successful, Eton would anticipate submitting the product's NDA in 2020.

Third Quarter Financial Results

Research and Development (R&D) Expenses: R&D expenses were $3.4 million for the third quarter of 2019 versus $1.5 million for the same period in 2018. The increase was primarily due to a $2.0 million licensing payment to acquire marketing rights to ET-105 and increased costs associated with headcount and the operation of the company's R&D laboratory facility that was established in late 2018, partially offset by reduced product-specific development costs in the period.

General and Administrative (G&A) Expenses: G&A expenses were $1.6 million for the third quarter of 2019 versus $0.8 million for the same period in 2018. The increase was primarily driven by higher employee-related costs from increased headcount, public company expenses, and marketing expenses associated with product launch preparation activities.

Net Loss: Eton reported a net loss for the third quarter of 2019 of $5.0 million versus $2.9 million for the same period of 2018.

Cash Position: As of September 30, Eton reported cash and cash equivalents of $11.8 million compared to $26.7 million as of December 31, 2018.

Conference Call and Webcast Information:

Eton Pharmaceuticals will host a conference call and webcast today at 4:30 p.m. ET (3:30 p.m. CT). To access the conference call, please dial 1-866-795-8473 (domestic) or 1-470-495-9161 (international) and refer to conference ID 1416459. The webcast can be accessed under "Events & Presentations" in the Investors section of the Company's website at https://ir.etonpharma.com. The webcast will be archived and made available for replay on the company's website approximately two hours after the call and will be available for 30 days.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently pending regulatory approval with the FDA.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with the expected ability of Eton to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding Eton's business strategy, Eton's plans to develop and commercialize its product candidates, the safety and efficacy of Eton's product candidates, Eton's plans and expected timing with respect to regulatory filings and approvals, and the size and growth potential of the markets for Eton's product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Eton's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Eton's development programs and financial position are described in additional detail in Eton's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eton undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Eton Pharmaceuticals, Inc.
Condensed Statements of Operations
(In thousands, except per share amounts)
(Unaudited)

	For the three months ended		For the nine months ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Revenue	$ —	$ —	$ 500	$ —
Operating expenses:				
Research and development	3,418	1,544	11,322	4,525
General and administrative	1,624	830	5,123	3,510
Total operating expenses	5,042	2,374	16,445	8,035
Loss from operations	(5,042)	(2,374)	(15,945)	(8,035)
Other income (expense):				
Interest and other income, net	77	25	321	82
Change in fair value of warrant liability	—	(561)	—	(1,057)
Loss before income tax expense	(4,965)	(2,910)	(15,624)	(9,010)
Income tax expense	—	—	—	—
Net loss	(4,965)	(2,910)	(15,624)	(9,010)
Accrued dividends on redeemable convertible preferred stock	—	(300)	—	(900)
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	—	(429)	—	(1,257)
Net loss attributable to common stockholders	$ (4,965)	$ (3,639)	$ (15,624)	$ (11,167)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.28)	$ (0.65)	$ (0.88)	$ (2.40)
Weighted average number of common shares outstanding, basic and diluted	17,878	5,615	17,706	4,658

Eton Pharmaceuticals, Inc.
Condensed Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 11,777	$ 26,735
Prepaid expenses and other current assets	330	767
Total current assets	12,107	27,502
Property and equipment, net	1,169	773
Operating lease right-of-use assets, net	191	—
Other long-term assets, net	40	52
Total assets	$ 13,507	$ 28,327
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	$ 549	$ 1,421
Accrued liabilities	558	603
Total current liabilities	1,107	2,024
Operating lease liabilities, net of current portion	52	—
Total liabilities	1,159	2,024
Commitments and contingencies (Note 13)		
Stockholders’ equity		

Common stock, $0.001 par value; 50,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 17,807,167 and 17,607,928 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	18	18
Additional paid-in capital	73,822	72,153
Accumulated deficit	(61,492)	(45,868)
Total stockholders' equity	12,348	26,303
Total liabilities and stockholders' equity	$ 13,507	$ 28,327

Eton Pharmaceuticals, Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30, 2019	Nine months ended September 30, 2018
Cash flows from operating activities		
Net loss	$ (15,624)	$ (9,010)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,387	1,631
Depreciation and amortization	299	40
Change in fair value of warrant liability	—	1,057
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	426	(493)
Accounts payable	(403)	254
Accrued liabilities	(263)	150
Net cash used in operating activities	(14,178)	(6,371)
Cash used in investing activities		
Purchases of property and equipment	(1,062)	(182)
Cash flows from financing activities		
Proceeds from employee stock purchase plan and stock option exercises	282	—
Net cash provided by financing activities	282	—
Change in cash and cash equivalents	(14,958)	(6,553)
Cash and cash equivalents at beginning of period	26,735	13,156
Cash and cash equivalents at end of period	$ 11,777	$ 6,603
Supplemental disclosures of cash flow information		
Cash paid for interest	$ —	$ —
Cash paid for income taxes	$ —	$ —
Supplemental disclosures of non-cash investing and financing activities:		
Accrued dividends on redeemable convertible preferred stock	$ —	$ 900
Deemed dividends for accretion of redeemable convertible preferred stock issuance costs	$ —	$ 1,257

Company Contact:
David Krempa
dkrempa@etonpharma.com
847-805-1077

Source: Eton Pharmaceuticals