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EyeGate Pharmaceuticals

Pharma & biotech

15 March 2018

Price	$0.63
Market cap	$11m

Ocular Bandage Gel awaiting return to clinic

Following positive data from its first Ocular Bandage Gel (OBG) pilot study, EyeGate has filed an amended Investigational Device Exemption (IDE) application with the FDA for a second trial. If accepted, the OBG may return to human trials in Q218. Data readouts from the trials in H218 in addition to the ongoing Phase III study for EGP-437 could prompt key value inflection drivers.

Ocular Bandage Gel supports corneal health

EyeGate's Ocular Bandage Gel is a topical eye drop based on its proprietary crosslinked thiolated carboxymethyl-hyaluronic acid (CMHA-S), a modified form of the natural polymer, hyaluronic acid (HA). HA has hydrating and healing properties when applied to the ocular surface, but it degrades rapidly. Through crosslinking, CMHA-S may adhere longer to the ocular surface and resist degradation. In Q117, EyeGate completed a pilot trial (n=39) of patients undergoing bilateral photorefractive keratectomy (PRK) surgery and found that at day 3, 83% of those receiving OBG had complete wound closure vs 54% in the standard-of-care arm.

Amended filing could lead to OBG studies in Q218

Prior to permitting the next OBG study to proceed, the FDA requested the filing of an IDE amendment detailing processes used in OBG's manufacturing to eliminate sources that could lead to contamination or raise microbial burden risk. EyeGate anticipates it could start its next PRK study (in upto 45 subjects) in H118 and it also plans another pilot OBG study in punctuate epitheliopathies (in upto 30 patients), a common sign of moderate dry eye. Each study could report data in H218 potentially leading to pivotal studies that could drive a 510(k) de novo regulatory filing in 2019.

Ocular Iontophoresis delivery system (OIDS)

EyeGate's OIDS applies a low electrical current to improve drug delivery into the eye (via electrorepulsion). EGP-437 incorporates a reformulation of corticosteroid dexamethasone with the OIDS. It is in a c 250-pt Phase III study to treat anterior uveitis, a condition that can still lead to vision loss despite treatment with the current standard-of-care (topical corticosteroids). If data is positive, the firm could submit a new drug application (NDA) under the 505(b)(2) pathway in early 2019.

Valuation: EV of $2.2m; funding needs imminent

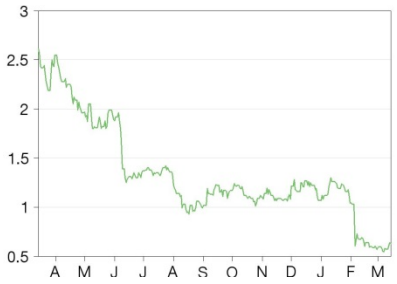
EyeGate had $7.8m cash at YE17. Its 2017 net burn rate was $6.5m, but this could increase in 2018 given the plans to start OBG studies in two indications. The firm may need to raise funds by Q318 to be on track with its planned timelines.

Historical financials

Year end	Revenue ($m)	PBT ($m)	EPS ($)	DPS ($)	P/E (x)	Yield (%)
12/16	0.67	(13.34)	(1.51)	0.00	N/A	N/A
12/17	0.41	(13.22)	(0.93)	0.00	N/A	N/A

Source: Company accounts

Share price graph



Share details

Code	EYEG
Listing	NASDAQ
Shares in issue	17.26m

Business description

EyeGate Pharmaceuticals is a specialty pharma firm developing two clinical-stage proprietary technologies for treating ocular diseases. EyeGate's OBG is being advanced for moderate dry eye and corneal wound healing. EGP-437 applies a reformulated dexamethasone to various inflammatory conditions.

Bull

- Large market opportunity in moderate dry eye
- Potential for iontophoresis platform to be extended to enable a patient-administered system to treat chronic conditions (possibly retinal edema)
- Over 3,000 treatments across multiple clinical trials suggest that EGP-437 does not significantly raise intraocular pressure, a side effect associated with prolonged corticosteroid usage

Bear

- The need to raise financing by YE18 to fulfil clinical development strategy could dilute equity holders
- High level of competition in dry eye market
- EGP-437 missed its primary endpoint in Phase IIb study (n=106) of post-cataract surgery inflammation, which raises uncertainty of its applicability for this specific indication

Analysts

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