# Oxurion NV (OXUR.BR)

## Initiation Report

**Initiating Coverage**

**February 5, 2019**

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### LifeSci Investment Abstract

Oxurion NV (Euronext Brussels: OXUR) is a biopharmaceutical company focused on developing a broad pipeline of disease-modifying treatments for diabetic eye diseases, including diabetic retinopathy (DR) and diabetic macular edema (DME). Currently, anti-VEGF treatments comprise 97% of the market share in DME, despite 30-50% of DME patients experiencing suboptimal, or transient, responses using these treatments. Although the pathology for DME is not yet fully understood, evidence suggests that multiple factors associated with DME need to be addressed in order to elicit an optimal response. Oxurion intends to address this unmet need with its pipeline of 3 mechanistically novel drugs, that address targets either upstream of or independent to VEGF. Should Oxurion demonstrate a meaningful benefit in patients responding sub-optimally to anti-VEGF therapy, we believe the Company would be well-positioned to gain market share as physicians look to expand their armamentarium for treating DME in combination with existing therapies.

### Key Points of Discussion

- **Diabetic Retinopathy and Macular Edema are Becoming Increasingly Prevalent.** Diabetic Retinopathy (DR) is a neurovascular complication of both type 1 and type 2 diabetes (T1D/T2D) and is the leading cause of vision loss in adults between 25 and 74 years. DR affects approximately 154 million people worldwide, with 30.8 million of those also suffering from diabetic macular edema (DME), a common cause of vision loss. In the United States, 10.6 million people suffer from DR, with approximately 2.1 million also affected by DME. The prevalence of DR and DME is intimately tied to that of diabetes and is expected to grow in the United States to 17.5 million and 3.5 million, respectively, by 2035. As the prevalence of diabetes grows in the US and advancements in health and technology lead to diabetes patients having longer lifespans, the need for effective treatments for DR and DME will become increasingly important.

### Analysts

**David Sherman, Ph.D. (AC)**
(212) 915-2570
dsherman@lifescicapital.com

**Rahul Rakhit, M.S.**
(646) 876-5544
rrakhit@lifescicapital.com

### Market Data

| | |
|---|---|
| **Price** | **$4.88** |
| **Market Cap (M)** | **$187** |
| **EV (M)** | **$97** |
| **Shares Outstanding (M)** | **38.2** |
| **Avg Daily Vol** | **66,140** |
| **52-week Range:** | **$3.74 - $7.24** |
| **Cash (M)*** | **$89.6** |
| **Net Cash/Share** | **$2.35** |
| **Annualized Cash Burn (M)** | **$56.3** |
| **Years of Cash Left** | **1.6** |
| **Debt (M)** | **$0.0** |
| **Short Interest (M)** | **0.00** |
| **Short Interest (% of Float)** | **0.0%** |

**Estimated*

### Financials

| FY Dec | | 2016A | 2017A | 2018A |
|---|---|---|---|---|
| EPS | H1 | (0.47) | (0.49) | (0.46) |
| | H2 | NA | NA | NA |
| | FY | (1.85) | 0.70 | NA |

- **The Standard of Care Treatment for DME is Inadequate.** Every year, the US spends over $5 billion on existing pharmacologic treatments for DR and DME, with anti-VEGF treatments comprising 97% of the market share, yet 30%-50% of DME patients experience suboptimal responses to these therapies and continue to be at risk for vision loss. The pathology for DME is quite complicated and not yet fully understood, but it is more than likely that multiple factors associated with DME need to be addressed in therapy decisions to elicit an optimal response. Oxurion's pipeline contains three drug candidates (THR-317, THR-687, and THR-149) that have the potential to provide mechanistically novel treatments to address such complications. With these 3 shots on goal, Oxurion has the potential to drive long term growth as physicians look to expand their armamentarium for treating DME in combination with existing therapies.

- **Eylea's Success Highlights THR-317's Potential.** According to EvaluatePharma, Regeneron's (NasdaqGS: REGN) *Eylea* (aflibercept) earned over $1 billion in 2017 DME sales, whereas Roche's (SIX: ROG.VX) *Lucentis* (ranibizumab) earned approximately $300 million in DME sales. Although both drugs are categorized as anti-VEGF treatments, *Eylea* has held a larger portion of the DME market due to aflibercept's ability to inhibit both VEGF and PlGF, allowing the drug to elicit a stronger response. We believe *Eylea*'s success underscores the potential for a combination anti-VEGF/anti-PlGF treatment in DME, and with *Lucentis* losing patent protection in 2020, an influx of generic anti-VEGF drugs could drive treatment costs down, leaving room for payers to cover adjunctive therapies that demonstrate a defined benefit within this patient population.

- **Critical Readouts in H2 2019.** With 3 data readouts in DME and 1 in macular telangiectasia type 1 (MacTel 1) in 2019, Oxurion is flush with opportunities to demonstrate the value of its pipeline, as well as further elucidate the underlying mechanisms that drive the progression of DR and DME. The Company anticipates a data readout in Q3/Q4 2019 for its lead asset, THR-317, which is currently being assessed in a Phase II study (THR-317-002) comparing a combination therapy of THR-317/ranibizumab against ranibizumab monotherapy. Although *Eylea*'s mechanism of action touches upon the potential of inhibiting both VEGF and PlGF, this Phase II study is designed to quantify the added benefit of PlGF inhibition and to further validate PlGF's role in disease progression. Should Oxurion demonstrate superior efficacy in combination, we believe the Company can position itself as an adjunctive therapy to *Eylea* in the subset of DME patients experiencing suboptimal treatment results on the monotherapy alone. Bear in mind, if THR-317 is prescribed in 30% of cases in which anti-VEGF treatments are prescribed, the drug could amass over $390 million in annual revenue.

  In addition to a Phase II data read out for THR-317, Oxurion also anticipates Phase I data read outs for THR-687 and THR-149 in DME. Both programs were designed to inhibit targets either upstream of or independent to VEGF that are believed to play a role in a number of disease hallmarks. As a result, the safety and tolerability data expected from Phase I trials for THR-149 and THR-687 could be an important factor in mitigating both products' risk profiles.

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**Expected Upcoming Milestones**

- Q3/Q4 2019: Data expected for THR-687 Phase I study in DME
- Q3/Q4 2019: Data expected for THR-149 Phase I study in DME
- Q3/Q4 2019: Data expected for THR-317-002 Phase II study in DME
- Q3/Q4 2019: Data expected for THR-317-003 Phase II study in MacTel 1
- H2 2019: Oncurious Phase I/IIa top line data expected in Medulloblastoma
- YE 2019/early 2020: Oncurious expected to reach Go/No-Go milestone for preclinical immuno-oncology assets

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