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COMPANY NOTE | EQUITY RESEARCH | December 04, 2023

Healthcare: Biotechnology Company Update

Oryzon Genomics SA | ORY.SM - €2.06 - MADRID | Buy

| €1.86 - €2.93 |
|---------------|
| 58.98 |
| €121.20 |
| 58,487 |
| €15.00 |
| \$8.8 |
| €20.1 |
| |

| Tot. Debt | | €20.1 | | | | | | | | |
|-----------|---------|---------|---------|--|--|--|--|--|--|--|
| Rev (\$M) | | | | | | | | | | |
| Yr Dec | —2022— | —2023E— | —2024E— | | | | | | | |
| | | Curr | Curr | | | | | | | |
| 1Q | 0.0A | 0.0A | 0.0E | | | | | | | |
| 2Q | 0.0A | 0.0A | 0.0E | | | | | | | |
| 3Q | 0.0A | 0.0A | 0.0E | | | | | | | |
| 4Q | 0.0A | 0.0E | 0.0E | | | | | | | |
| YEAR | 0.0A | 0.0E | 0.0E | | | | | | | |
| EPS\$ | | | | | | | | | | |
| Yr Dec | —2022— | —2023E— | —2024E— | | | | | | | |
| | | Curr | Curr | | | | | | | |
| 1Q | (0.03)A | (0.03)A | (0.02)E | | | | | | | |
| 2Q | 0.01A | 0.02A | (0.02)E | | | | | | | |
| 3Q | (0.01)A | (0.02)A | (0.02)E | | | | | | | |
| 4Q | (0.05)A | (0.04)E | (0.02)E | | | | | | | |
| YEAR | (0.08)A | (0.07)E | (0.09)E | | | | | | | |
| P/E | NM | NM | NM | | | | | | | |



ORY: ALS Association Awards ORY a ~\$500k Grant to Evaluate ORY-4001 in ALS

To help fund preclinical evaluation of PRY-4001 in ALS, the ALS Association has awarded ORY a \$498.7k grant through its Lawrence and Isabel Barnett Drug Development Program. ORY-4001 is ORY's currently preclinical, highly selective HDAC6 inhibitor that is being developed in ALS.

- HDAC6 inhibition or depletion has been previously described as a potentially effective treatment for ALS, protecting against neurodegeneration in various ALS mouse and human iPSC models. ORY-4001 has also been shown to improve neuromuscular and neuromotor function, axonopathy, and demyelination in a mouse model of Charcot-Marie Tooth (CMT) type 1. Due to the key role altered axonal transport and proteostasis play in both CMT and ALS, ORY will evaluate ORY-4001 in ALS mouse models. ORY-4001 is currently advancing in its characterization in IND-enabling toxicology studies.
- Recall that in 1Q23, ORY announced that it selected ORY-4001, a selective HDAC-6 inhibitor, as its drug candidate to bring into the clinic for neurological diseases such as CMT and ALS, among others. HDAC-6 inhibitors are believed to be potentially effective treatments for CMT, ALS, and other neurological disorders lacking effective treatments. Last year, ORY and the CMT Research Foundation agreed to explore ORY's HDAC-6 inhibitors, and ORY-4001 was selected due to the positive preclinical results generated under this collaboration. ORY-4001 is highly selective against other HDAC classes, resulting in a favorable safety profile that avoids hematoxicity, as well as being strongly anti-inflammatory in vivo. ORY-4001 has shown multiple positive responses in a validated CMT1A peripheral neuropathy in vivo model which reliably recapitulates many of the symptoms of CMT in humans, and it will now enter into IND enabling studies. CMT is a progressive, degenerative peripheral nerve disease affecting 150k U.S. patients and over 3M globally. CMT is caused by a variety of genetic mutations, with CMT1A mutation causing the disease in about half of the patients.
- In late 2Q23, ORY orally presented encouraging preclinical results for ORY-4001 at the 2023 Peripheral Nerve Society annual meeting, showing the drug to reverse disease progression symptoms in a murine model of CMT. The current results have inclined ORY to start IND enabling studies for ORY-4001. In September, animal model data in CMT was presented at the Third Annual Global CMT Research Convention. ORY-4001 reversed disease progression symptoms in a CMT mouse model that reliably recapitulates many human symptoms, improving myelination and restoring axon integrity in the sciatic nerve, and improving compound muscle action potential and nerve conduction by contrast to untreated animals.

ORY Intraday Price: €2.08 at 10:57AM ET

VALUATION

Our 12-month price target of €15, is based on a DCF analysis using a 40% discount rate that is applied to all cash flows and the terminal value, which is based on a 4x multiple of our projected 2030 operating income of \$869 million. We arrive at this valuation by projecting future revenue from vafidemstat in borderline personality disorder and Kabuki syndrome, as well as iadademstat in AML and SCLC.

Factors that could impede shares of ORY.SM from achieving our price target include vafidemstat and iadademstat failing to generate statistically significant clinical results. Also, regulatory agencies could fail to approve these drugs even if pivotal clinical trials are statistical successes, due to the agency viewing the results as not clinically meaningful. Loss of key management personnel could also impede achieving our price target, as could smaller than projected commercial opportunity due to changes in market size, competitive landscape, and drug pricing and reimbursement.

RISKS

- Clinical risk. ORY.SM's clinical staged products could fail to deliver statistically significant results in latestage clinical trials, substantially reducing the value of ORY.SM's product candidates and therefore our target price.
- Regulatory risk. Even if successful in the clinic, ORY.SM's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce ORY.SM's value and therefore our target price.
- **Financing risk.** ORY.SM will need additional capital to fund its operations, and such financing may not occur, or it could be substantially dilutive to existing investors.
- Competitive risk. For any future approved ORY.SM products, they may not be well adopted in a competitive marketplace, which would adversely affect ORY.SM's value and therefore our target price.
- High stock price volatility. This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

Founded in 2000 in Barcelona, Spain, Oryzon (ISIN Code: ES0167733015) is a clinical stage biopharmaceutical company and the European leader in epigenetics, with a strong focus on personalized medicine in CNS disorders and oncology. Oryzon's team is composed of highly qualified professionals from the pharma industry located in Barcelona, Boston and San Diego. Oryzon has an advanced clinical portfolio with two LSD1 inhibitors, vafidemstat in CNS and iadademstat in oncology, in several Phase II clinical trials. The company has other pipeline assets directed against other epigenetic targets. In addition, Oryzon has a strong platform for biomarker identification and target validation for a variety of malignant and neurological diseases. For more information, visit www.oryzon.com.

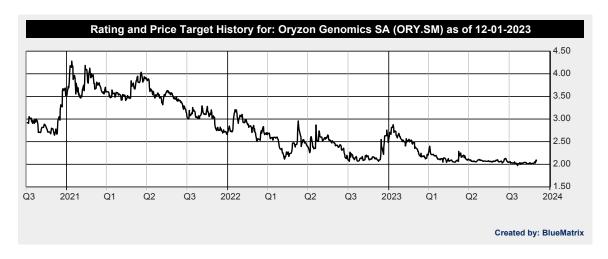
ORYZON GENOMICS SA

| Oryzon Genomics SA | | | | | | | | | | | | | | | | | | | Jonatha | n Aschoff, I | Ph.D. (646) | 616-2795 |
|----------------------------------|----------|----------|----------|----------|----------|----------|---------|---------|---------|---------|----------|---------|---------|---------|---------|----------|---------|---------|---------|--------------|-------------|-----------|
| Income Statement | | | | | | | | | | | | | | | | | | | | | jaschoff@ | @roth.com |
| Fiscal Year ends December | | | | | | | | | | | | | | | | | | | | | | |
| (in 000, except per share items) | | | | | | | | | | | | | | | | | | | | | | |
| | 2017A | 2018A | 2019A | 2020A | 2021A | 2022A | 1Q23A | 2Q23A | 3Q23A | 4Q23E | 2023E | 1Q24E | 2Q24E | 3Q24E | 4Q24E | 2024E | 2025E | 2026E | 2027E | 2028E | 2029E | 2030E |
| Global iadademstat revenue | | | | | | | | | | | | | | | | | 7,653 | 61,183 | 122,988 | 181,436 | 214,468 | 224,938 |
| Global vafidemstat revenue | | | | | | | | | | | | | | | | | 98,463 | 342,237 | 520,351 | 615,106 | 684,577 | 721,921 |
| Collaboration revenue | 20 | | | | | | | | | | | | | | | | | | | | | |
| Total revenue | 20 | | | | | | | | | | | | | | | | 106,116 | 403,421 | 643,339 | 796,542 | 899,045 | 946,858 |
| Cost of revenue | | | | | | | | | | | | | | | | | 2,701 | 11,709 | 22,833 | 31,765 | 39,065 | 43,178 |
| R&D | 6,363 | 8,489 | 12,647 | 13,591 | 15,118 | 17,701 | 4,372 | 4,264 | 3,821 | 3,859 | 16,316 | 3,898 | 3,937 | 3,976 | 4,016 | 15,827 | 18,992 | 20,891 | 21,936 | 22,155 | 22,377 | 22,600 |
| G&A | 4,502 | 2,993 | 3,176 | 3,484 | 5,529 | 4,771 | 1,223 | 1,096 | 674 | 809 | 3,802 | 817 | 825 | 833 | 842 | 3,317 | 5,970 | 8,956 | 9,851 | 10,836 | 11,378 | 11,947 |
| Total operating expenses | 10,865 | 11,482 | 15,823 | 17,075 | 20,647 | 22,472 | 5,595 | 5,360 | 4,495 | 4,668 | 20,118 | 4,715 | 4,762 | 4,809 | 4,858 | 19,144 | 27,664 | 41,555 | 54,620 | 64,757 | 72,820 | 77,725 |
| Operating income | (10,845) | (11,482) | (15,823) | (17,075) | (20,647) | (22,472) | (5,595) | (5,360) | (4,495) | (4,668) | (20,118) | (4,715) | (4,762) | (4,809) | (4,858) | (19,144) | 78,452 | 361,865 | 588,719 | 731,786 | 826,224 | 869,133 |
| Other income (net) | 5,659 | 8,143 | 11,522 | 11,805 | 12,510 | 16,661 | 4,215 | 4,054 | 3,669 | 2,000 | 13,938 | 3,000 | 3,000 | 3,000 | 3,000 | 12,000 | | | | | | |
| Net income (pretax) | (5,186) | (3,339) | (4,301) | (5,269) | (8,137) | (5,811) | (1,380) | (1,306) | (826) | (2,668) | (6,180) | (1,715) | (1,762) | (1,809) | (1,858) | (7,144) | 78,452 | 361,865 | 588,719 | 731,786 | 826,224 | 869,133 |
| Net financial & tax | 1,047 | (1,991) | (187) | (1,098) | (2,760) | (1,276) | 392 | (2,459) | 300 | (250) | (2,017) | (250) | (250) | (250) | (250) | (1,000) | - | 90,466 | 147,180 | 182,946 | 206,556 | 217,283 |
| Net income | (6,233) | (1,348) | (4,114) | (4,171) | (5,377) | (4,535) | (1,772) | 1,153 | (1,126) | (2,418) | (4,163) | (1,465) | (1,512) | (1,559) | (1,608) | (6,144) | 78,452 | 271,399 | 441,539 | 548,839 | 619,668 | 651,850 |
| EPS basic | (0.20) | (0.04) | (0.10) | (0.08) | (0.10) | (80.0) | (0.03) | 0.02 | (0.02) | (0.04) | (0.07) | (0.02) | (0.02) | (0.02) | (0.02) | (0.09) | 1.10 | 3.63 | 5.63 | 6.66 | 7.17 | 7.18 |
| EPS diluted | (0.20) | (0.04) | (0.10) | (0.08) | (0.10) | (80.0) | (0.03) | 0.02 | (0.02) | (0.04) | (0.07) | (0.02) | (0.02) | (0.02) | (0.02) | (0.09) | 0.92 | 3.06 | 4.78 | 5.69 | 6.17 | 6.22 |
| Basic shares outstanding | 31,711 | 34,638 | 41,589 | 49,235 | 52,762 | 53,354 | 56,190 | 57,339 | 58,154 | 58,212 | 57,474 | 66,944 | 67,614 | 67,681 | 67,749 | 67,497 | 71,137 | 74,693 | 78,428 | 82,349 | 86,467 | 90,790 |
| Diluted shares outstanding | 31,711 | 34,638 | 41,565 | 49,235 | 52,762 | 53,354 | 56,190 | 57,339 | 58,154 | 58,212 | 57,474 | 66,944 | 67,614 | 67,681 | 67,749 | 67,497 | 85,174 | 88,731 | 92,465 | 96,387 | 100,504 | 104,827 |

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Shares of Oryzon Genomics SA may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.



Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

IB Serv./Past 12 Mos. as of 12/04/23

| Rating | Count | Percent | Count | Percent |
|-------------------|-------|---------|-------|---------|
| Buy [B] | 358 | 75.37 | 214 | 59.78 |
| Neutral [N] | 81 | 17.05 | 29 | 35.80 |
| Sell [S] | 3 | 0.63 | 2 | 66.67 |
| Under Review [UR] | 31 | 6.53 | 3 | 9.68 |

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Ratings System Definitions - ROTH MKM employs a rating system based on the following:

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Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH MKM does not publish research or have an opinion about this security.

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