

# ***Littany Lane Investments***

## ***Second Quarter 2015 Synopsis - Four Biotechnology Companies***

Four biotechnology companies reported earnings last week. These companies include **Synta Pharmaceuticals (SNTA)**, **TransEnterix, Inc. (TRXC)**, **Xoma Corp (XOMA)**, and **Enzon Pharmaceuticals, Inc. (ENZN)**. Two of these companies have no revenues, but products in pipeline phases (SNTA and TRXC) and two companies have reduced earnings when compared to previous quarterly reports and organizational issues to overcome if they will continue as entities (XOMA and ENZN).

Small capitalization biotechnology companies have many risks associated with them, including: weak balance sheets, no revenues, growing operating expenses (both variable and fixed), high burn rates of cash, ongoing testing (research and development), reliance on and timing of FDA approval of product development, etc...

This report summarizes four companies that filed quarterly earnings with the SEC on Form 10-Q and other relevant information pertinent to each organization.

### **Synta Pharmaceuticals Corp (SNTA)**

#### **Summary**

**Synta Pharmaceuticals** is an innovative, agile biopharmaceutical company focused on research, development and commercialization of novel oncology medicines that have the potential to change the lives of cancer patients.<sup>i</sup> Its lead oncology drug candidate includes ganetespib, an Hsp90 inhibitor, which is in Phase III clinical trial for the treatment of non-small cell lung cancer; in Phase II clinical trial for patients with hormone receptor positive metastatic breast cancer; in Phase I clinical trial for the treatment of HER2 positive patients with metastatic breast cancer; in Phase II/III clinical trial for the treatment of patients with acute myeloid leukemia and myelodysplastic syndrome; in Phase I/II trial of paclitaxel in combination with ganetespib in patients with platinum-resistant ovarian cancer; and in Phase I/II trial in combination with the mTOR inhibitor sirolimus in patients with refractory sarcoma. The company's product pipeline also comprises Hsp90-inhibitor Drug Conjugate, a novel, proprietary small molecule cancer drug development program; Elesclomol, a mitochondria-targeting agent that is in Phase II clinical trial for ovarian cancer; and CRACM ion channel inhibitors and IL-12/23 inhibitors for the treatment of inflammatory diseases.<sup>ii</sup>

#### **Recent News and Analysis**

Financial results for the second quarter ended June 30, 2015 were released on August 6, 2015. Highlights on the financial end of the business were as follows:<sup>iii</sup>

- There were no revenues recognized in the second quarters of 2015 and 2014.
- Research and development expenses were \$16.4 million for the second quarter in 2015, compared to \$18.8 million for the same period in 2014. General and administrative

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expenses were \$3.1 million for the second quarter in 2015, compared to \$2.9 million for the same period in 2014.

- The Company reported a net loss of \$19.8 million, or \$0.15 per basic and diluted share, in the second quarter of 2015, compared to a net loss of \$22.3 million, or \$0.24 per basic and diluted share, for the same period in 2014.
- As of June 30, 2015, the Company had \$98.3 million in cash, cash equivalents and marketable securities, compared to \$97.7 million in cash, cash equivalents and marketable securities as of December 31, 2014.

### **Second quarter accomplishments and recent updates<sup>iv</sup>**

- **Pivotal, Phase 3 GALAXY-2 Clinical Trial Remains on Track for Interim Analysis of Overall Survival in 2015.** The Company's pivotal GALAXY-2 trial, a Phase 3 global, randomized, multi-center study comparing the combination of ganetespib and docetaxel to docetaxel alone for the second-line treatment of advanced non-small cell lung adenocarcinoma, remains on track to meet previously provided data readout timelines. Ganetespib, the Company's lead program, is a novel, potent small molecule inhibitor of heat shock protein 90 (Hsp90). Based on current projections and statistical assumptions, the Company expects that the first interim overall survival (OS) analysis of GALAXY-2 will be conducted by the end of 2015, and the second interim and final OS analysis will be conducted in 2016. Assuming positive interim results from the ongoing GALAXY-2 trial of ganetespib, and pending regulatory feedback, the Company plans to seek regulatory approval of ganetespib for NSCLC in 2016.
- **Results from the Phase 2 GALAXY-1 trial published in Annals of Oncology.** Results from the Company's Phase 2 GALAXY-1 trial were published in the May 21, online first issue of the journal Annals of Oncology. GALAXY-1 was a global, randomized, multi-center study designed to identify the patients with advanced NSCLC most likely to benefit from second-line treatment with ganetespib in combination with docetaxel versus docetaxel alone. The results from this trial demonstrated that patients diagnosed with advanced non-small cell lung adenocarcinoma more than six months prior to study entry derived the most benefit from combination treatment, leading to the selection of this population for the ongoing Phase 3 GALAXY-2 trial.
- **First patient enrolled in Phase 2 Portion of GANNET53 Study of ganetespib in ovarian cancer.** In June, Synta announced commencement of patient enrollment in the Phase 2 portion of the GANNET53 study, a randomized, pan-European study evaluating ganetespib in combination with paclitaxel vs. paclitaxel alone in over 200 patients with metastatic, predominantly p53 mutant, platinum-resistant ovarian cancer. Enrollment in the Phase 2 portion of GANNET53 follows the successful completion of the Phase 1 portion, the results of which were recently presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. The Phase 1 data

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demonstrated that the combination of ganetespib 150 mg/m<sup>2</sup> with paclitaxel 80 mg/m<sup>2</sup> once weekly for 3 out of 4 weeks was generally well tolerated, with no dose limiting toxicities, and was therefore chosen for the randomized phase 2 trial. GANNET53 is sponsored by Innsbruck Medical University in Austria and funded by the European Commission.

- **Results from three investigator-sponsored trials of ganetespib and preclinical results of STA-12-8666 presented at ASCO.** Promising results from three studies evaluating ganetespib combination therapy in ALK-positive lung cancer, platinum-resistant ovarian cancer, and rectal cancer were presented at the 2015 ASCO Annual Meeting. In addition, preclinical results for the Company's lead HDC candidate, STA-12-8666, in pediatric sarcoma were also presented at this year's ASCO Annual Meeting. STA-12-8666 is a conjugate of an Hsp90 inhibitor and SN-38, the active metabolite of the widely used drug irinotecan. The Company remains on track for an IND submission by the first quarter of 2016 to begin clinical studies of STA-12-8666.

#### **Guidance**

The Company expects its cash, cash equivalents and marketable securities of approximately \$98.3 million as of June 30, 2015 will be sufficient to fund operations at least through the first half of 2016. This estimate assumes no additional funding from new partnership agreements, equity financings or further sales under its ATM facility.<sup>v</sup>

On a quarterly basis, the Company is burning through an average of \$20.8 million per quarter, calculated over the past four quarters.

Consensus estimates for the third and fourth quarter 2015 are projecting net losses of \$0.16 and \$0.18 per share, respectively, with the year ended December 31, 2015 consensus forecast at \$0.65 loss per share.<sup>vi</sup>

On August 8, 2015, the Company filed a "shelf" registration (filed with the SEC on Form S-3) for \$300 million. Under the shelf registration process, the Company may offer shares of their common stock and preferred stock, various series of debt securities and/or warrants, rights or purchase contracts to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to \$300,000,000.

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**TransEnterix, Inc. (TRXC)**

**Summary**

**TransEnterix**<sup>®</sup> is a medical device company that is pioneering the use of robotics and flexible instruments to improve minimally invasive surgery by addressing the economic and clinical challenges associated with current laparoscopic and robotic solutions. The company is focused on the development and commercialization of the SurgiBot<sup>™</sup> System, a minimally invasive surgical system that is designed to be operated through a single surgical incision.

The SurgiBot System is currently in development and has not yet been cleared by the FDA for sale in the United States or by other regulatory authorities for sale outside the United States.<sup>viii</sup>

**Recent News and Analysis**

Financial results for the second quarter ended June 30, 2015 were released on August 6, 2015. Highlights on the financial end of the business were as follows:<sup>ix</sup>

- The Company has had no revenues in either the first or second quarter of 2015. In comparison, the company did have \$0.4 million in total revenues for the year ended December 31, 2014.
- The Company reported a net loss of \$9.3 million, or \$0.14 net loss per share. In comparison, the company reported a net loss of \$10.1 million or \$0.16 net loss per share in the first quarter ended March 31, 2015 and a net loss of \$10.6 million or \$0.18 net loss per share in the second quarter ended June 30, 2014.
- Research and development expenses totaled \$6.6 million and selling, general and administrative expenses totaled \$2.4 million, this compares to the year earlier quarterly results of \$7.9 million and \$2.4 million.
- As of June 30, 2015, the Company's cash and cash equivalents totaled \$71.1 million.

**Second quarter accomplishments and operating highlights<sup>x</sup>**

- Completed Good Laboratory Practices (GLP) Studies using the SurgiBot<sup>™</sup> System in April 2015.
- SurgiBot System FDA 510(k) Application Submitted June 1, 2015.
- Completed underwritten equity offering raising \$52.2 million in net proceeds, including the underwriters exercise of additional shares in July 2015.

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### Guidance

On a quarterly basis, the Company is burning through an average of \$9.8 million per quarter, calculated over the past four quarters.

Consensus estimates for the third and fourth quarter 2015 are projecting \$0.13 net loss per share, respectively, with the year ended December 31, 2015 consensus forecast at \$0.56 loss per share.<sup>xi</sup>



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### **Xoma Corp (XOMA)**

#### **Summary**

**XOMA Corporation** is a leader in the discovery and development of therapeutic antibodies. The Company's innovative product candidates are the result of its expertise in developing ground-breaking monoclonal antibodies, which have created new opportunities to potentially treat a wide range of human diseases. **XOMA** is developing gevokizumab (IL-1 beta modulating antibody) in a Phase 3 clinical study of pyoderma gangrenosum, a rare ulcerative skin disease. Additionally, **XOMA**'s scientific research has produced the XMet platform, which consists of separate classes of Selective Insulin Receptor Modulators (SIRMs) antibodies. **XOMA** 358, the lead antibody in the XMetD program, is a monoclonal antibody that reduces both the binding of insulin to its receptor and down-regulates insulin signaling and could have a major effect on the treatment of abnormal metabolic states. **XOMA** 358 recently completed Phase 1 testing and Phase 2 clinical trials in two hyperinsulinemic hypoglycemic indications are expected to launch in 2015. **XOMA** also has a library of compounds to advance in clinical development or license to a pharmaceutical partner, including **XOMA** 089, a novel anti-TGF $\beta$  monoclonal antibody that could be a significant advancement in immuno-oncology, and XMetA, which could replace long-acting insulin.<sup>xiii</sup>

#### **Recent News and Analysis**

Financial results for the second quarter ended June 30, 2015 were released on August 6, 2015. Highlights on the financial end of the business were as follows:<sup>xiv</sup>

- **XOMA** reported total revenues of \$2.5 million in the second quarter ended June 30, 2015, compared with \$6.0 million in the corresponding period of 2014. The reduction in 2015 revenues reflects lower activity under the Company's existing contracts with National Institute of Allergy and Infectious Diseases (NIAID) for the development of anti-botulism agents.
- Research and development (R&D) expenses for the second quarter of 2015 were \$19.7 million, compared with \$19.6 million in the corresponding period of 2014.
- Selling, general and administrative (SG&A) expenses were \$5.1 million in the second quarter of 2015, as compared to \$5.2 million in the corresponding quarter of 2014.
- For the second quarter of 2015, **XOMA** had a net loss of \$23.8 million, or \$0.20 net loss per share, compared with a net loss of \$11.9 million, or \$0.11 net loss per share for the second quarter of 2014. Excluding non-cash charges related to the revaluation of warrant liabilities, net loss in the quarters ended June 30, 2015 and 2014, was \$23.6 million and \$19.9 million, respectively.

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- On June 30, 2015, **XOMA** had cash, cash equivalents, and short-term investments of \$51.0 million. The Company ended December 31, 2014, with cash, cash equivalents, and short-term investments of \$78.4 million.
- Thomson Reuters consensus estimates for the Company for the second quarter was a net loss of \$0.18 per share (an earnings miss of \$0.02 per share), with analyst expectations for revenues to come in at \$4.38 million (a revenue target miss of \$1.84 million).

#### **Additional second quarter news and operating highlights**

- The Company announced disappointing results from its Phase 3 EYEGUARD(TM)-B study on July 22, 2015. "Although the study did not achieve its main objective, we did see signals of drug activity such as preserved visual acuity, less severe ocular exacerbations and a reduced incidence of reported macular edema in patients treated with gevokizumab," said Paul Rubin MD, Senior Vice President Research and Development and Chief Medical Officer. "We will continue to work closely with our partner, Servier, and uveitis experts to conduct a thorough analysis of the data to fully understand gevokizumab's impact on several clinically relevant endpoints."<sup>xv</sup>

#### **Guidance**

On a quarterly basis, the Company is burning through an average of \$24.8 million per quarter, calculated over the past four quarters. This average number includes only the total operating expenses, and does not take into account any revenues the Company may generate over the quarter.

Consensus estimates for the third and fourth quarter 2015 are projecting \$0.16 net loss and \$0.10 net loss per share, respectively, with the year ended December 31, 2015 consensus forecast at \$0.64 net loss per share.<sup>xvi</sup>

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**Enzon Pharmaceuticals, Inc. (ENZN)**

**Summary**

**Enzon Pharmaceuticals, Inc.** receives royalty revenues from existing licensing arrangements with other companies primarily related to sales of four marketed drug products, namely, PegIntron®, Sylatron®, Macugen® and CIMZIA®.

The primary source of the Company's royalty revenues is sales of PegIntron, which is marketed by Merck & Co., Inc.

The Company currently has no clinical operations and limited corporate operations. The Company was previously dedicated to the research and development of innovative therapeutics for patients with high unmet medical needs. The Company wound down its remaining research and development activities during 2013 and has no intention of resuming any clinical development activities or acquiring new sources of royalty revenues.<sup>xviii</sup>

**Recent News and Analysis**

Financial results for the second quarter ended June 30, 2015 were released on August 7, 2015. Highlights on the financial end of the business were as follows:<sup>xix</sup>

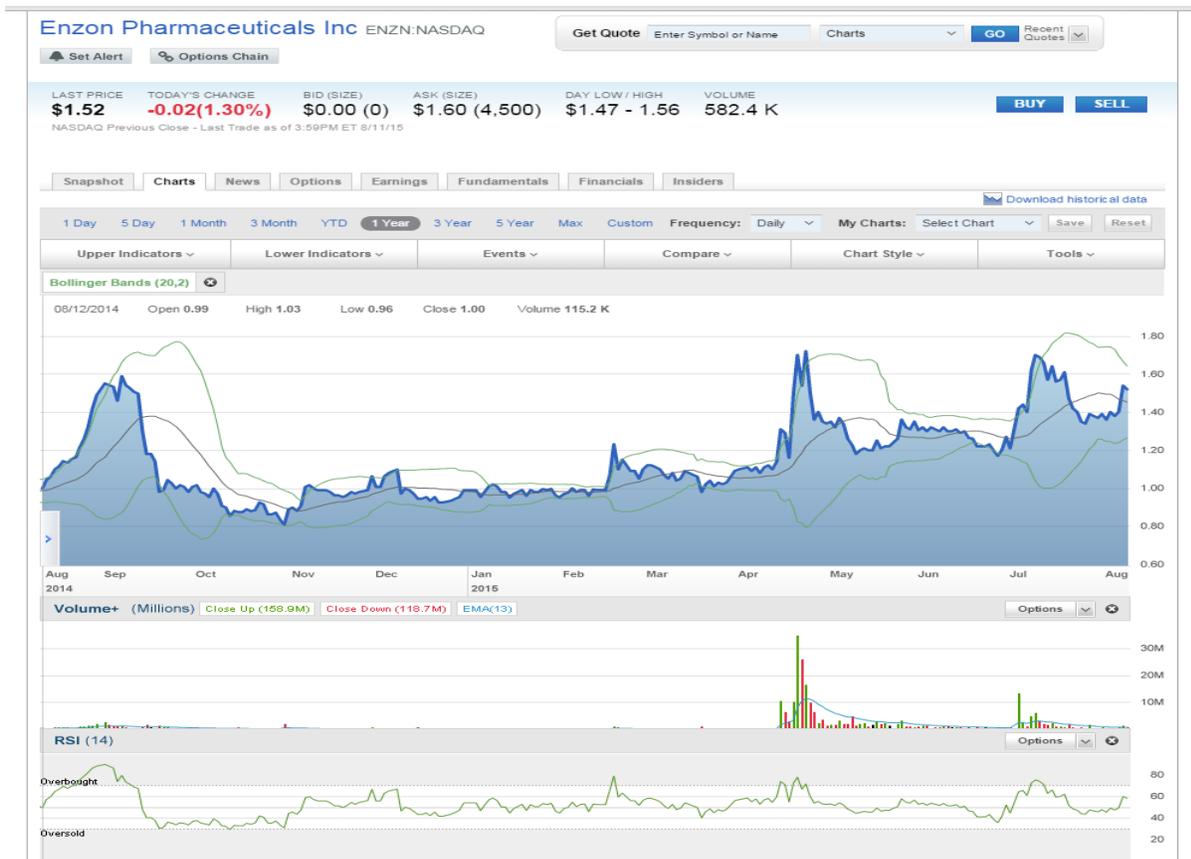
- ENZN reported total revenues of \$5.2 million in the second quarter ended June 30, 2015, compared with \$7.7 million in the corresponding period of 2014.
- Operating expenses (general and administrative) were \$0.5 million in the second quarter of 2015, as compared to \$0.8 million in the corresponding quarter of 2014.
- For the second quarter of 2015, ENZN had net income of \$3.8 million, or \$0.09 net per share, compared with net income of \$6.9 million, or \$0.16 per share for the second quarter of 2014.
- On June 30, 2015, ENZN had cash, cash equivalents, and short-term investments of \$39.6 million. The Company ended December 31, 2014, with cash, cash equivalents, and short-term investments of \$35.0 million.

**Additional second quarter news and operating highlights**

- On June 30, 2015, **Enzon Pharmaceuticals, Inc.** Board of Directors declared a special cash dividend of \$0.50 per share of the Company's common stock, payable on August 12, 2015 to stockholders of record as of July 21, 2015.<sup>xx</sup>

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### Sources

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### **Littany Lane Consulting and Jeffrey S. Grossman, CFA August 12, 2015**

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