Oncoxx Biotech

Short Project Description: Oncoxx Biotech and Mediterranea Theranostic (Oncoxx) are Biotech Companies based in Italy, as partnership between academic institutions and private entrepreneurs. The idea stems from the know-how and research of Dr Saverio Alberti. Dr Alberti's patents form the basis of this business idea. Trop-2 induces tumor growth and metastasis, and is expressed by most cancer types, in up to 90% of individual cases. The mission of Oncoxx is to develop new anti-Trop-2 therapies and related diagnostic tests. These will determine if the tumor of each individual patient expresses the therapeutic target Trop-2. They will also allow to follow the progression of the disease and monitor therapeutic efficacy. The new anticancer therapies will be based on proprietary anti-tumor monoclonal antibodies, which only recognize the cancer form of Trop-2 and synergize in vivo.

Business Summary: Oncoxx Biotech was founded on sep. 13th 2012, as a partnership between University of Chieti researchers and private entrepreneurs. The company is now based at the CESI Institute, Laboratory of Cancer Pathology University of Chieti, in L' Aquila, and at the Unit of Medical Genetics, University of Messina, Italy. Preclinical experimentation has been completed, with proof of efficacy in preclinical settings in vivo and lack of toxicity in primates. Immediate focus (first two years of planning) is to bring these humanized anti-Trop-2 antibodies to clinical experimentation.

Customer Problem: (1) Monoclonal antibodies are successful anticancer agents. New ones targeting novel cancer molecules are urgently needed. We have generated antibodies anti-Trop-2, a pan-tumor cancer target, which work efficiently in animal models. (2) Key to any anti-tumor therapy is its therapeutic index, i.e. ratio between efficacy (tumor growth inhibition) and toxicity (side effects). We have developed an anti-Trop-2 antibody that only recognizes the cancer form of Trop-2. This maximizes the therapeutic index, and provides a key competitive advantage versus competitors.

Company Profile

Legal Entity Name: Oncoxx Biotech srl
Address: VIA Garibaldi 15
ZIP Code: 66034
City: Lanciano
Province: Chieti
Country: ITALY
ID: VAT, 02415750690; US EIN 98-1135202; REA, CH-177258; National Research Registry, 60967FWF
URL: www.oncoxx.com
Industry: Healthcare
Sector: Biopharmaceuticals
Subsector: Drug Discovery
Partnering status: Available for out-licensing, merger or acquisition
Marketing rights: Europe, USA China, Japan, Australia, Canada.
Operational sites: Chieti, L'Aquila, Messina

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Products: Oncoxx products are anti Trop-2 antibodies for therapy of the big killers, i.e. Breast, Pancreas, Lung, Stomach, Colon, Ovary, Prostate cancers, Lung metastases, Liver metastases. Tailored diagnostics maximize their effectiveness.

Target Market: In the US, Colorectal, Pancreas, Lung, Breast, Ovary, Endometrium, Prostate cancer new cases per year: ≈1,000,000. Trop-2 expressing tumors: 650,000 per year.

Market size: Up to 20 b$ per year.

Business Model: The focus of the company is on the development of anti-Trop-2 antibodies for cancer therapy. The business evolution is based on licensing the PCTs that protect Oncoxx technology and findings. The aim is to close a strategic deal with a major pharmaceutical company in order to go on clinical validation and then to the market.

Competitors: Immunomedics, Daiichi Sankyo.

Competitive Advantage: Key assets of Oncoxx are leadership in Trop-2 research, unique know-how on Trop-2, proprietary anti-Trop-2 antibodies, efficacy in vivo, the highest therapeutic index on the market, granted PCT in European community, US and China, major network of collaborators.

Advisory Board: J. Tso (PDL founder), William Kerr (SUNY), Hiromitsu Nakauchi (Stanford). De Simone & partners (Rome) for intellectual property protection.

Past Significant Milestones:
a: identification of the Trop-2 target and demonstration of fundamental function in cancer growth
b: generation of two series of anti-Trop-2 monoclonal antibodies. Targeting of a cancer-specific epitope
c: engineering of two humanized antibodies with unvaried binding efficacy on target
d: efficacy of anti-Trop-2 monoclonals against human tumors in immunosuppressed mice
e: anti-tumor synergy of the two monoclonals in vivo
f: generation of highly-producing cells (transfected CHO)
g: generation of multiple ADCs, with distinct technologies and payloads. Proof of high efficacy in vivo

Exit Strategy: Release of both the research and associated patents on the market through a strategic deal with a major pharmaceutical company or through licensing of key PCTs.

Comparable Exits: Several similar transaction already closed: Arius (Anti-cancer antibodies)-Roche: 191 millions CAD (July /August 2008). Xenon (Metabolic diseases)-Novartis: 157 millions USD (September 2004). Plexxikon (Metabolic diseases)-Wyeth: 372 millions USD (October 2004). Nastech (Metabolic diseases)- Merck: 346 millions USD (September 2004). U3 Pharma AG (Anti-cancer antibodies)-Daiichi Sankyo Co Ltd: 150 millions € (May 2008). EOS (Anti-cancer small molecules)-Clovis: 450 millions € (2013).

Startup.teaser.valueProposition: The mission of Oncoxx Biotech is the development of new anticancer therapies and related diagnostic tests (laboratory and radiology analyses). The aim of these diagnostic tests will be to determine if the tumor of each individual patient expresses the molecules that constitute the therapeutic targets and to follow the progression of the disease to monitor therapeutic efficacy.

Key publications:

1. Alberti S, Herzenberg LA: DNA methylation prevents transfection of genes for specific surface antigens. Proc Natl Acad Sci USA 1988, 85:8391-8394
2. Alberti S et al: Biochemical characterization of Trop-2, a cell surface molecule expressed by human carcinomas: formal proof that the monoclonal antibodies T16 and MOv-16 recognize Trop- 2. Hybridoma 1992, 11:539-535
3. Alberti S et al: DNA methylation prevents the amplification of TROP1, a tumor associated cell surface antigen gene. Proc Natl Acad Sci USA 1994, 91:5833-5837
4. Fornaro M et al: Cloning of the gene encoding TROP-2, a cell- surface glycoprotein expressed by human carcinomas. Int J Cancer 1995, 62:610-618
5. El Sewedy T et al: Cloning of the murine Trop2 gene: conservation of a PIP2-binding sequence in the cytoplasmic domain of Trop-2. Int J Cancer 1998, 75(2):324-330
6. Ripani E et al: The human Trop-2 is a tumor-associated calcium signal transducer. Int J Cancer 1998, 76:671-676.
7. Calabrese G et al: Assignment of TACSTD1 (alias TROP1, M4S1) to human chromosome 2p21 and refinement of mapping of TACSTD2 (alias TROP2, M1S1) to human chromosome 1p32 by in situ hybridization. Cytogenet Cell Genet 2001, 92(1-2):164-165
8. Mangino G et al: Presentation of native Trop-2 tumor antigens to human cytotoxic T lymphocytes by engineered antigen-presenting cells. Int J Cancer 2002, 101(4):353-359
9. Guerra E et al: A bi-cistronic CYCLIN D1-TROP2 mRNA chimera demonstrates a novel oncogenic mechanism in human cancer. Cancer Res 2008, 68(19):8113-8121
10. Trerotola M et al: CD133, Trop-2 and alpha2beta1 integrin surface receptors as markers of putative human prostate cancer stem cells. Am J Transl Res 2010, 2(2):135- 144
11. Trerotola M et al: Trop-2 inhibits prostate cancer cell adhesion to fibronectin through the β1 integrin-RACK1 axis. J Cell Physiol 2012, 227(11):3670-3677
12. Guerra E et al: The Trop-2 signalling network in cancer growth. Oncogene 2013, 32:1594-1600
13. Trerotola M et al: Up-regulation of Trop-2 quantitatively stimulates human cancer growth. Oncogene 2013, 32 222-233.
14. Ambrogi F. et al.Trop-2 is a determinant of breast cancer survival. PLoS One 9 (10): 1-11 e96993 (2014)
15. Antolini L et al. Lymph nodes micrometastases do influence breast cancer outcome. J. Clin. Oncol. 33 (33): 3977-8 (2015).
16. Guerra E. et al. Trop-2 induces tumor growth through Akt and determines sensitivity to Akt inhibitors. Clin. Cancer Res. 22 (16) 4197-4205 (2016)
17. Avellini C. et al.The trophoblast cell surface antigen 2 and miR-125b axis in urothelial bladder cancer. Oncotarget 8(35): 58642-58653 (2017)
18. Relli V. et al. Distinct lung cancer subtypes associate to distinct drivers of tumor progression. Oncotarget 9(85): 35528-35540 (2018)
19. Relli V. et al. Abandoning the Notion of Non-Small Cell Lung Cancer. Trends Mol. Medicine 25, No. 7:585-594 (2019)

Patents:
1. PCT: E. Guerra, M. Trerotola, S. Alberti “Use of circulating serum Trop-2 as new tumor biomarker” - PCT/EP2016/025148 - International filing date 17 Nov. 2016. Granted EU 16797460.9-1118 13 Jun. 2019; pending US.
2. PCT: E. Guerra, S. Alberti “Humanized anti-Trop-2 monoclonal antibodies and uses thereof” - WO2016087651 A1 - International filing date 4 Dec 2015; international publication date 9 June 2016. Granted EU 28 Nov. 2019.
3. Patent: E. Guerra, S. Alberti “Humanized Anti-Trop-2 Monoclonal Antibodies and Uses Thereof” - CH2014A000032 - Filing date 4 Dec 2014.
4. Patent: S. Alberti, M. Trerotola, E. Guerra “Use of Serum Circulating Trop-2 as New Tumor Biomarker” - 102015000074105 - Filing date 18 Nov 2015; Granted IT 26 Apr. 2018.
5. PCT: S. Alberti, E. Guerra “Use of Trop-2 as predictive marker of response to anti-tumor therapy based on inhibitors of CD9, Akt and molecules of the tetraspanin signalling network” - PCTIIT2013/WO201317177.7 - International filing date 6 May 2013. Granted EU EP2850433 15 Aug. 2018; pending US, CA, AU, JP.
6. Patent: S. Alberti "Oligonucleotide sequences that inhibit the expression of chimeric mRNA that control the growth of tumor cells and their use in the medical field" - CH2012A000016 - Filing date 12 Nov. 2012.
7. Patent: S. Alberti, E. Guerra “Use of Trop-2 as a predictive marker of response to anti-tumor therapy based on inhibitors of CD9 and Akt and molecules of the tetraspanin signalling network” - M12516Q3131/CH2012A000008 - Filing date 16 May 2012. Granted IT.
8. PCT: S. Alberti, E. Guerra “Oligonucleotide sequences able to silence the expression of the CYCLIN D1/TROP2 chimera and use thereof in the medical field” - WO2010035304 - International filing date 25 Set 2009. Granted US US 8,507,664; Granted EU EP2342342; Granted AU AU2009297961B; Granted IT 0001398773; pending JP, CA.
9. PCT: S. Alberti “Anti-Trop-2 monoclonal antibodies and uses thereof in the treatment and diagnosis of tumors” - WO2010089782 - International filing date 5 Feb 2009. Granted US US 8,715,662 6 May 2014; Granted EU 2009787638 26 Oct 2016; Granted China CN102448492A 9 May 2012; Granted AU AU2009339664B; Granted CA 2750038 4 Oct 2016; pending JP.
10. Patent: S. Alberti, E. Guerra "Use of a CYCLIN D1/TROP2 fusion mRNA for tumor diagnosis and therapy” - M08925Q2218 - Filing date 25 Sep. 2008.
11. PCT/EP: A. Anastasi, F. Petronzelli, S. Alberti, R. De Santis “Anti-EpCAM antibody and uses thereof” - 548/PCT/EPBS000R548 - Filing date 2 Apr. 2008. Granted IT 15 June 2011 #2142570; Granted US 28 Nov. 2012 US8318911B2.
12. Patent: S. Alberti “Anti-Trop-2 antibodies and related use” - CH07A000018 - Filing date 6 Aug. 2007.
13. Patent: S. Alberti “New technologies for the analysis of the proteome” - CH05A000007 - Filing date 14 Apr. 2005. Granted IT 10 jul. 2009 0001363767.
14. Patent: S. Alberti, A. Sese “Nucleic Acids Sensors” - CH02A000009 - Filing date 16 Sep. 2002. Granted IT 23 feb. 2006 0001332234.

Key Partners:
Main researchers at the Universities of Genoa, Naples, Turin, Milan, Ferrara, Bari, Ancona, Chieti; National Research Council Rome.
Collaborating institutions abroad include Rush University, Chicago, Universitè de Lille, France, York University, UK, University of Pittsburgh, Jefferson Cancer Center, Philadelphia, UCL, London, UK, University of Cambridge, UK, Stanford University, Tokyo University, Japan, MIT, Boston, SUNY, New York, UC Davis, University of Rotterdam, The Netherlands, University of Montreal, Canada & University of Beijing, China; Mayo clinic, Rochester
Supporting companies include Abnova, Taipei, Taiwan; Kinexus Systems Proteomics, Vancouver, Canada; AITEK, Genoa; BMR, Padova; NEXTAGE, Genoa; ENEA-Ylichron, Roma; VISION DEVICE, Chieti, NRGsys, L’ Aquila