

XTENT INC  
Form 8-K  
December 07, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

---

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

**December 3, 2007**

Date of Report (date of earliest event reported)

**XTENT, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-33282**  
(Commission File Number)

**41-2047573**  
(I.R.S. Employer  
Identification Number)

**125 Constitution Drive  
Menlo Park, California 94025-1118**  
(Address of principal executive offices)

**(650) 475-9400**  
(Registrant's telephone number, including area code)

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Edgar Filing: XTENT INC - Form 8-K

- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

**Item 1.01. Entry into a Material Definitive Agreement.**

On December 3, 2007, XTENT, Inc. ( XTENT ), Biosensors International Group, Ltd., a Bermuda corporation ( BIG ), and Biosensors Europe S.A., a corporation organized under the laws of Switzerland ( BESA ) and a wholly owned subsidiary of BIG entered into an Amended and Restated License Agreement (the Amended Agreement ). BIG and BESA are referred to together as Biosensors in this report.

The Amended Agreement amends and restates the License Agreement dated May 4, 2004 between XTENT, Sun Biomedical Ltd. (former name of BIG) and Occam International, B.V. (predecessor in interest to BESA), as amended by the First Amendment to License Agreement dated February 9, 2005, pursuant to which XTENT licenses the drug coating and purchases drug coating services for its Custom NX drug eluting stent systems (the Original Agreement ). The Original Agreement was filed with the Securities and Exchange Commission as Exhibit 10.7 to XTENT's Registration Statement on Form S-1 (Registration No. 333-136371), which was declared effective on January 31, 2007.

As with the Original Agreement, the Amended Agreement grants XTENT a worldwide, non-exclusive, license with royalties payable to Biosensors based on net sales of XTENT's products. The field of use for this license is limited to coronary and peripheral delivery of a series of short stent segments on a catheter where the physician has the ability to select the number of segments to be deployed. In Japan, XTENT's field of use is further limited to treating long lesions, multiple vessels or small vessels in coronary and peripheral applications.

The Amended Agreement grants XTENT the right to purchase the drug and polymer components of the drug coating separately from Biosensors for the sole purpose of mixing the drug/polymer formulation and coating XTENT's stents with such formulation for the use and sale thereof in XTENT's licensed field of use. XTENT shall also have the right to use certain technology owned by Biosensors to mix the drug coating, to apply the drug coating to XTENT's stents, and to perform certain necessary testing of the drug coating, each within XTENT's licensed field of use.

Under the Amended Agreement, Biosensors is no longer required to perform coating or testing services on XTENT's stents nor to provide other support services except testing that is required by the relevant regulatory agencies to develop the drug master files submitted by Biosensors on XTENT's behalf for approvals in the U.S., Europe and Japan.

In addition to paying royalties to Biosensors for the license, XTENT also purchases the drug and polymer components exclusively from Biosensors. Under the Amended Agreement, XTENT has agreed to pay increased prices for the drug and polymer and any services performed by Biosensors. The Amended Agreement also provides more detailed provisions governing the acceptance and rejection of the drug and polymer supplied by Biosensors.

Under the Original Agreement, Biosensors held the exclusive right to distribute XTENT's products in certain Pacific Rim countries including Japan, China, India, Australia, and others. Those exclusive rights had expired under the Original Agreement and therefore were not included in the Amended Agreement.

The Original Agreement further prohibited XTENT from making, using, or selling a stent coated with rapamycin or a derivative of rapamycin other than Biolimus A9, unless the drug coating was not approvable by May 2007. Under the Amended Agreement, this restriction remains in effect, but if a stent coated with Biolimus A9 has not been granted CE Mark within a certain period after execution of the Amended Agreement, this restriction terminates.

The Original Agreement granted Biosensors the right to terminate the Original Agreement if XTENT failed to obtain a CE Mark for its stent systems before May of 2008; provided that if XTENT's failure to obtain CE Mark was caused by a delay on the part of Biosensors, such date would be extended for a period equal to the length of the delay. Under the Amended Agreement, Biosensors has the right to terminate if XTENT has not obtained CE Mark within one year following the later of (i) signing the Amended Agreement; or (ii) the date the regulatory packages for the drug and polymer submitted by Biosensors for XTENT are approved by the MEB.

## Edgar Filing: XTENT INC - Form 8-K

The Amended Agreement terminates on the date that is eight years from the date upon which XTENT first receives regulatory approval of its drug eluting stent systems. The Amended Agreement further provides that the Amended Agreement will be automatically extended for an additional three-year term unless either party provides notice of termination at least three years prior to the termination date. Either party may terminate the Amended Agreement at anytime if the other party breaches the Amended Agreement and fails to cure that breach within sixty days of notice. Either party may also terminate the Amended Agreement if the other party makes an assignment for the benefit of creditors, files a petition in bankruptcy, is adjudicated insolvent or bankrupt, or if a receiver or trustee is appointed with respect to a substantial part of the other party's assets.

The Amended Agreement also provides that if XTENT undergoes a change of control (which includes a third party acquisition of 50% of XTENT's stock, a merger or a sale of substantially all of XTENT's assets) the acquiring company must pay a fee to Biosensors if it wishes to assume the Amended Agreement and use Biosensors' Confidential Information thereunder.

Under the terms of the Amended Agreement, each party releases the other from any and all claims against the other party which arise out of circumstances that the releasing party knew of or should have known of prior to the date of the Amended Agreement.

---

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**XTENT, INC.**

Date: December 6, 2007

By:

/s/ Jeffrey J. Grainger  
Jeffrey J. Grainger  
Vice President of Corporate  
Affairs and General Counsel

---