**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D. C. 20549**

# FORM 8-K

## CURRENT REPORT

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

Date of Report (Date of earliest event reported): July 17, 2017

**GT Biopharma, Inc.**
(Exact name of Registrant as specified in its charter)

| **Delaware** | **000-08092** | **94-1620407** |
|---|---|---|
| (State or other Jurisdiction of Incorporation or organization) | (Commission File Number) | (IRS Employer I.D. No.) |

**100 South Ashley Drive**
**Suite 600**
**Tampa, FL 33602**
**Phone: (800) 304-9888**
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Oxis International, Inc.**
(Former name, former address and former fiscal year, 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 l 4a- l 2 under the Exchange Act ( 17 CFR 240. l 4a- l 2)

☐ Pre-commencement communications pursuant to Rule l 4d-2(b) under the Exchange Act (17 CFR 240. l 4d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240. l 3e-4(c))

**ITEM 5.03 Amendment to Certificate of Incorporation.**

On July 17, 2017, the Registrant amended its Certificate of Incorporation for the purpose of changing the name of the Registrant from Oxis International, Inc. to GT Biopharma, Inc. The amendment also made other changes to the Certificate of Incorporation as described in the definitive information statement filed by the Registrant with the Securities and Exchange Commission on May 12, 2017.

**ITEM 8.01 Other Events.**

On July 25, 2017, the Registrant issued a press release giving additional details about its plans to acquire Georgetown Translational Pharmaceuticals, Inc. which was originally announced on June 26, 2017. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. A slide deck giving additional details about the acquisition and how it will add value to the Registrant is attached hereto as Exhibit 99.2 and is also incorporated herein by reference.

**SIGNATURE PAGE**

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

**GT Biopharma, Inc.**

Dated: July 25, 2017

By: /s/ Steven Weldon
Steven Weldon
Chief Financial Officer

# Oxis Releases Additional Details About Acquisition of Georgetown Translational Pharmaceuticals, Oxis to change name to "GT Biopharma, Inc".

LOS ANGELES, CA / ACCESSWIRE / July 25, 2017 / Oxis International Inc. (OTCQB: OXIS and Euronext Paris: OXI.PA) disclosed in an 8-K filing today that it published a slide deck on its website www.oxis.com that provides additional detail about its agreement to acquire Georgetown Translational Pharmaceuticals Inc. (GTP) and how the deal will add value to Oxis. Further, Oxis International Inc. has initiated a name change to GT Biopharma Inc. as part of its acquisition and 14C filing.

On June 26, Oxis announced that it had executed a binding LOI agreement to acquire GTP, a move that will deliver new management and a class of close-to-market Central Nervous Systems (CNS) products to Oxis.

Oxis agreed to pay 33 percent of its outstanding shares to GTP to complete the transaction, which is expected to close before Sept. 30.

The slide deck highlights several benefits of the acquisition for Oxis and its shareholders, including:

-- The acquisition of GTP's leading candidate, Pain Brake, a pain-relief drug expected to be submitted to the FDA as a New Drug Application in 15 to 18 months.

-- The acquisition of drug candidate GTP-004 for the treatment of myasthenia gravis, a rare muscular disease. The only approved drug for this disease carries significant GI side effects, limiting the tolerable dose. GTP-004 combines the existing drug with an approved treatment of GI disease, reducing side effects and allowing patients to tolerate a more effective dose.

-- The acquisition of GTP-011, a treatment for motion sickness. This is a repurposed version of an existing drug. It was designed to reduce or eliminate side effects in some elderly patients, allowing them to treat motion sickness without side effects that resembled symptoms of Alzheimer's Disease.

-- A new management team at Oxis (soon to be GT Biopharma). GTP co-founder Dr. Kathleen Clarence-Smith, a respected and experienced leader in the pharmaceutical industry, will become CEO of the combined companies. Additionally, a Chief Medical Officer, who formerly served as CMO with Pfizer, will join Oxis under the deal.

Prior to founding GTP, Dr. Clarence-Smith co-founded Chase Pharmaceuticals Corporation in Washington D.C. and served as Chairman of the company's Board from 2008 to 2014. Chase Pharmaceuticals was acquired by Allergan, PLC (AGN) in 2016 in a deal that, with milestones, could reach $1 billion.

Dr. Clarence-Smith also held executive management positions with Sanofi, Roche, Otsuka Pharmaceutical and Prestwick Scientific Capital. She is co-founder and a managing member of KM Pharmaceutical Consulting in Washington, D. C.

Dr. Clarence-Smith's vast experience will be extremely beneficial to Oxis' development of drugs in its pipeline, including OXS-1550, which is in an FDA Phase 2 clinical trial, and its
highly valued TriKE platform oncology assets, which are set to go into FDA clinical trials soon.

Oxis' lead drug candidate, OXS-1550 (DT2219ARL), is a novel drug that binds to targets and destroys cancer cells, due to the action of the drug's cytotoxic payload. OXS-1550 has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia. It is currently in a FDA-approved Phase 2 trial at the University of Minnesota.

Anthony J. Cataldo, who is Oxis' Chief Executive Officer, will become Executive Chairman of the combined companies after the deal closes. He said Dr. Clarence-Smith's leadership will be extremely valuable to Oxis. There are not many Biotech executives that have successfully sold their company to big pharma and have navigated several drugs through FDA approval like Dr. Clarence-Smith, he said.

"I am excited by the prospect of joining Tony's (Anthony J Cataldo) team following his highly successful creation of Lion Biotechnologies, Inc. (now Iovance Biotherapeutics, Inc: Trading – IOVA). As founder of Oxis Biotech, it appears he has delivered again with oncology assets that are well positioned to be in the forefront of the next generation of targeted immunotherapies," said Dr. Clarence-Smith.

"Our existing oncology products (FDA Phase 2 OXS 1550 clinical trial and upcoming FDA TriKE phase 1 clinical trial) have now reached the point where Dr. Clarence-Smith's experience in taking drugs through FDA approvals and into the market, will bring significant value to our shareholders," Mr. Cataldo said.

The agreement to acquire GTP marks another major value-added inflection point for the shareholders of Oxis. The company continues to progress with recently announced partnership and milestone accomplishments.

**About Oxis Biotech, Inc.:**

Oxis Biotech is an immuno-oncology focused company developing innovative drugs focused on the treatment of cancer and other unmet medical needs. Oxis' lead drug candidate, OXS-1550 (DT2219ARL) is a novel bispecific scFv recombinant fusion protein-drug conjugate composed of the variable regions of the heavy and light chains of anti-CD19 and anti-CD22 antibodies and a modified form of diphtheria toxin as its cytotoxic drug payload. OXS-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When OXS-1550 binds to cancer cells, the cancer cells internalize the drug and are killed due to the action of drug's cytotoxic payload. OXS-1550 has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia. OXS-3550 TriKE technology was developed by researchers at the University of Minnesota Masonic Cancer Center. As demonstrated in non-clinical models, this targeted immunotherapy directs immune cells to kill cancer cells while diminishing drug-related toxicity.

**About GTP Inc.:**

GTP is a privately-owned biotechnology company focused on acquiring or discovering and patenting late-stage, de-risked, and close-to-market improved treatments for CNS disease (Neurology and Pain) and shepherding the products through the FDA approval process to the NDA. GTP products currently include treatment for neuropathic pain, refractory epilepsies, the symptoms of myasthenia gravis, and motion sickness.

**Forward-Looking Statements:**

Except for historical information contained herein, the statements in this release are forward-looking and made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently unreliable and actual results may differ materially. Examples of forward-looking statements in this news release include statements regarding the payment of dividends, marketing and distribution plans, development activities and anticipated operating results. Factors which could cause actual results to differ materially from these forward-looking statements include such factors as the Company's ability to accomplish its business initiatives, significant fluctuations in marketing expenses and ability to achieve and expand significant levels of revenues, or recognize net income, from the sale of its products and services, as well as the introduction of competing products, or management's ability to attract and maintain qualified personnel necessary for the development and commercialization of its planned products, and other information that may be detailed from time to time in the Company's filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

Media Contact:
Stuart Pfeifer
(310) 788-2850

SOURCE: Oxis International Inc.

GT

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# Forward Looking Statements

This presentation and the information contained herein does not constitute or form part of, and should not be construed as, an offer or invitation to sell or subscribe for, or a solicitation of any offer or invitation to acquire, dispose of or subscribe for, securities of Oxis International, Inc., GT Biopharma, Inc., or Georgetown Translational Pharmaceuticals, Inc. (the “Company") in any country where such offer, invitation or subscription would be prohibited by law. The publication of this presentation in certain countries may violate applicable regulations.

This presentation contains forward-looking statements that can be identified by such terminology such as “expects”, “potential”, “suggests”, “may”, or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management’s expectations regarding future research and development results could be affected by, among other things, uncertainties relating to clinical trials and product development; unexpected regulatory delays or government regulation generally; the Company’s ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general. Forward-looking statements speak only as to the date they are made. The Company does not undertake to update forward-looking statements to reflect circumstances or events that occur after the date the forward looking statements are made.

# Pending Merger Rationale

- Oxis International Inc. (OTCBB:OXIS)
  - Novel immuno-oncology platforms with lead product candidate currently in Phase 2 clinical trial
- Georgetown Translational Pharmaceuticals, Inc. (Private)
  - 505(b)(2)-focused CNS product candidate portfolio
  - More rapid development timelines anticipated to provide potential product approvals during more lengthy oncology timelines
  - Adds CEO with successful track record of developing drugs through FDA approval
- Combined company expected to provide multiple opportunities for value creation in both near and long-term time horizons

GT Biopharma, Inc.

# Investment Highlights

- Diversified drug development pipeline across two therapeutic categories – oncology and CNS
- Pipeline offers more balanced risk/reward profile with potential for steady news flow
- Lead immuno-oncology product candidate, OXS-1550, a novel bispecific antibody drug conjugate, currently in Phase 2
- Lead CNS product candidate, PainBrake, anticipated to be NDA-ready in ~15-18 months
- Experienced management team with track record of success in drug development and successful exits

# Management Team with Proven Track Record of Success

| Name / Title | Experience |
|---|---|
| **Anthony J. Cataldo**<br>Executive Chairman | ▪ Founder, Chairman and CEO of Lion Biotechnologies (LBIO) now know as: Iovance Biotherapeutics (IOVA) – current market cap of $400MM |
| **Kathleen Clarence-Smith, M.D., Ph.D.**<br>Chief Executive Officer | ▪ Founder and CMO, Chase Pharmaceuticals (acquired by Allergan for up to $1B in 2016)<br>▪ Founder and CEO, Prestwick Pharmaceuticals (acquired by Biovail for $100MM in 2008)<br>▪ Worldwide Head of CNS Development at Otsuka, Hoffmann-La Roche<br>▪ Worldwide Head of CNS at Sanofi |
| **Undisclosed**<br>Chief Medical Officer | ▪ Vice President and CMO and Medical Director, Oncology Clinical R&D of Pfizer |

# Oncology Scientific Advisory Board

| | |
|---|---|
| **Stephen Chang, Ph.D.** | ▪ Vice President of Research & Development, New York Stem Cell Foundation |
| **Lisa Haile, Ph.D., Esq.** | ▪ Partner, Co-Chair, Global Life Sciences Sector, DLA Piper<br>▪ Focuses on intellectual property |
| **Jeffrey Miller, M.D.** | ▪ Professor of Medicine, Division of Hematology, Oncology and Transplantation University of Minnesota, Masonic Cancer Center |
| **Daniel Vallera, Ph.D.** | ▪ Professor of Therapeutic Radiology Radiation Oncology, Department of Radiation Oncology University of Minnesota, Masonic Cancer Center |
| **Sean Xie, M.D., Ph.D., MBA** | ▪ Professor, Associate Dean for Research Innovation, and Director of CCGS and CDAR Centers, University of Pittsburgh School of Pharmacy |
| **Cassian Yee, M.D** | ▪ Professor, Department of Immunology, Division of Cancer Medicine and Director, Solid Tumor Cell Therapy, Center for Cancer Immunology Research, MD Anderson Cancer Center. |

# CNS Scientific Advisory Board

| | |
|---|---|
| **Thomas N. Chase, M.D.** | ▪ Sloan Business – MIT; MD Yale; Neurology – Harvard/MGH; National Institutes of Health – NINDS Director; Founding CEO of Chase Pharmaceuticals |
| **John Davis, M.D.** | ▪ Professor of Psychiatry and Research Professor of Medicine, University of Illinois at Chicago |
| **Abe Lieberman, M.D.** | ▪ Lonnie and Muhammad Ali Professor of Parkinson Research<br>▪ Director, Bob and Rene Fall Prevention Center at Barrow Neurological Institute |
| **Maral Mouradian, M.D.** | ▪ William Dow Lovett Professor of Neurology and Director of the Center for Neurodegenerative and Neuroimmunologic Diseases, Rutgers Biomedical and Health Sciences - Robert Wood Johnson Medical School |
| **Roger Porter, M.D.** | ▪ Adjunct Professor of Neurology, University of Pennsylvania<br>▪ Adjunct Professor of Pharmacology, USUHS, Bethesda<br>▪ Former Deputy Head of Clinical Research and Development, Wyeth Pharmaceuticals<br>▪ Former Deputy Director, NINDS, NIH |
| **Pierre N. Tariot, M.D.** | ▪ Director, Banner Alzheimer's Institute<br>▪ Co-Director, Alzheimer's Prevention Initiative<br>▪ Research Professor of Psychiatry, University of Arizona College of Medicine |

# Pipeline

| Oncology Product Candidate (Indication) | Pre-clin | Ph I | Ph II | Ph III | Pre-NDA | Next Anticipated Milestone | Anticipated Time to Next Milestone |
|---|---|---|---|---|---|---|---|
| OXS-1550 BiKE (ALL & NHL) | | | | | | End of Phase II | 14 months |
| OXS-3550 TriKE (Myeloid Malignancies) | | | | | | IND opening | 3 months |
| OXS-1615 (Carcinoma) | | | | | | Completion of IND-enabling studies | 21 months |
| OXS-4235 (Mult. Myeloma & Sec. Osteolytic Lesions) | | | | | | Completion of IND-enabling studies | 18 months |

| CNS Product Candidate (Indication) | Pre-IND | Ph I | Ph II | Ph III | Pre-NDA | Next Anticipated Milestone(s) | Potential Time to NDA Filing |
|---|---|---|---|---|---|---|---|
| PainBrake (Neuropathic Pain) | | Bioequivalence/ Food Effect Studies | | | | Develop manuf. process & file IND | 15-18 months |
| GTP-004 (Myasthenia Gravis) | | PoC Study | | | | File IND & Orphan Drug application | 20 months |
| GTP-011 (Motion Sickness) | | PoC Study | | | | File IND | 30 months |

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# Oncology Portfolio

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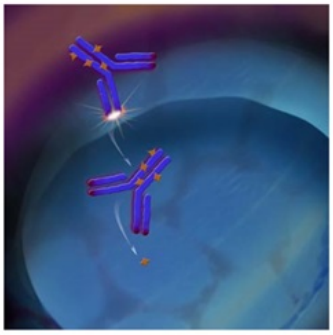
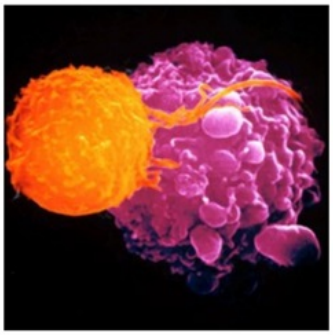
# Novel Immuno-Oncology Technology Platforms



- Antibody-Drug Conjugate (ADC) Therapeutic Platform
  - scFvs targeting CD19, CD22, CD33, CD133, TAG72
  - Full-length human MAbs targeting ICAM, FZD7, CD38
  - Payloads: Diphtheria Toxin, OXS-4235, Pseudomonas Exotoxin



- Antibody Directed Cell-Mediated Cytotoxic (ADCC) Therapeutic Platform
  - NK Cell Engagers (Core: CD16 scFv/IL15)
  - T-Cells Engagers (Core: CD3 scFv /TAG-72 w/wo cytokines or immune checkpoint inhibitors)

# Currently Approved ADC and ADCC Therapies

ADCETRIS® (brentuximab vedotin) from Seattle Genetics is a first-in-class FDA approved antibody-drug conjugate (ADC) targeting CD30+ cancer cells. Adcetris is approved for the treatment of certain lymphomas.

BLINCYTO® (blinatumomab) from Amgen is a first-in-class FDA approved bispecific CD19-directed CD3 T-cell engager antibody directed cell-mediated cytotoxic therapeutic (ADCC). Blinctyo is approved for the treatment of childhood acute lymphoblastic leukemia.

# OXS-1550 BiKE

## *Dual targeting delivering diphtheria toxin payload*

- Bispecific killer engager (BiKE) ADC targeting CD19+ and CD22+ cancers with de-immunized diphtheria toxin payload
- Indication: CD19+ and CD22+ B-cell malignancies:
  - Acute lymphoblastic leukemia (ALL) and non-Hodgkin's lymphoma (NHL)
- Broader therapeutic activity than competitive products resulting from bispecific scFv ADC design able to target cancer cells expressing CD19 or CD22 or both receptors
- Potent de-immunized diphtheria toxin payload disrupts cancer cell protein synthesis via inhibition of elongation factor-2 (EF-2)
- Phase I dose-escalation completed - DLT between 40 and 60 µg/kg - Durable response in 2 patients
- First patient enrolled in Phase II clinical trial in April 2017
- Licensed from University of Minnesota

# OXS-1550: Phase I Results

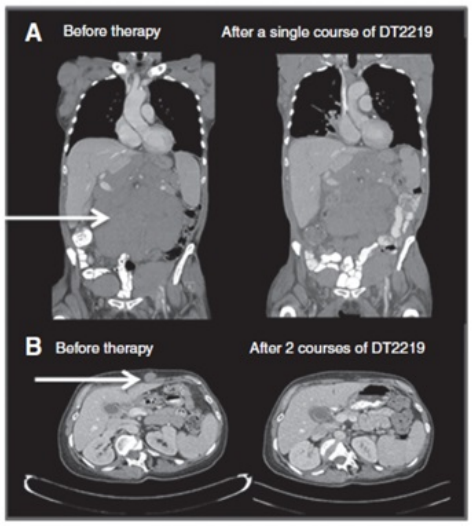



**Figure 2.**
Imaging studies in patients attaining objective response on phase I study. A, abdominal CT imaging of 77-year-old patient with rituximab and chemotherapy-refractory CLL treated with DT2219 at dose level 40 μg/kg every other day × 4 doses before and at day 28 after therapy is shown. The 40% reduction in the abdominal tumor mass was observed after a single course of therapy. B, CT images of a 53-year-old female with $CD22^{+}CD19^{+}$ relapsed chemotherapy refractory marginal zone lymphoma. The patient was treated at dose level 60 μg/kg/day QOD×4 and experienced a DLT of capillary leak syndrome and neutropenia. After regulatory approval, the patient received a second treatment course 8 weeks later at a reduced dose of 40 μg/kg/day QOD×4, which resulted in complete resolution of the tumor mass. CT images were taken before therapy and after the second course of DT2219. Arrows indicate a tumor mass.

- **Panel A:** Partial Response in 77 yr old patient with refractory chronic lymphocytic leukemia
- **Panel B:** Complete Response in 53 yr old patient with refractory marginal zone lymphoma which is ongoing at 27 months post therapy

*Vallera, D., Miller, J., et. al., Clin Cancer Res: 21(6) 2015*

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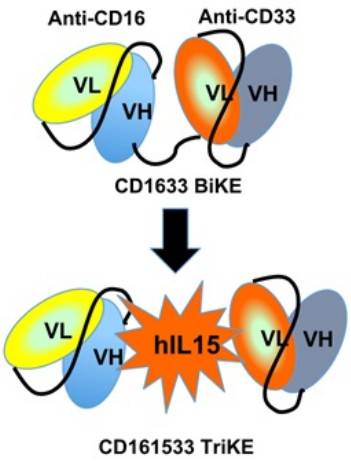
# OXS-1550: Phase II Trial Design

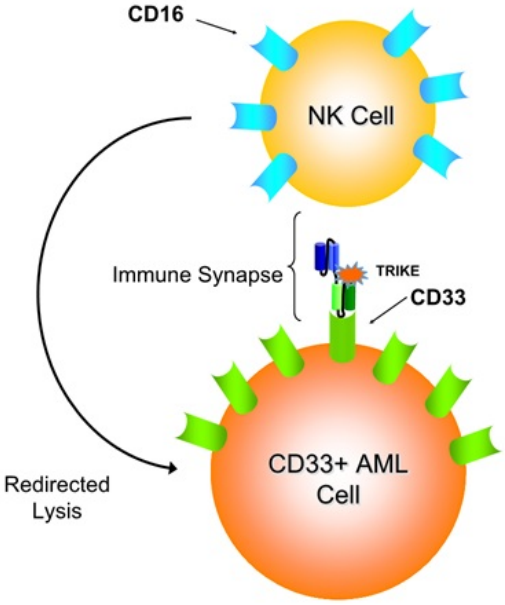
| | |
|---|---|
| **Study Design** | ▪ Continuation Phase I dose/schedule finding component using MTD identified during previous Phase I study, but with a higher number of doses<br>▪ Two-stage Phase II extension component to confirm safety and make a preliminary determination of activity level by disease using the dose identified in Phase I |
| **Dosing / Disease Assessment** | ▪ Minimum of 1 cycle of OXS-1550<br>– I.V. infusion on days 1, 3, 5, 8 and days 15, 17,19, 22 of a 28-day treatment cycle<br>– Disease reassessment on day 29<br>– If patient has clinical benefit and no unacceptable side effects, they may receive up to 2 additional cycles until disease progression and/or unacceptable toxicity<br>▪ Dose cohorts: 40, 60, 80 µg/kg/dose |
| **Enrollment Criteria** | ▪ Patients ≥12 years with relapsed or refractory CD19+ and/or CD22+ B-lineage leukemia/lymphoma<br>▪ Phase I: Standard 3+3 design requiring 6 to 12 patients<br>▪ Phase II: Two stage design by disease – assigned to Arm 1(NHL) or Arm 2 (Leukemia) stage 1: enroll a total of 9 patients (including all treated at the MTD in Phase I and evaluable after 1st cycle of treatment) if 1 or more responds within the Arm, activate stage 2 enrolling an additional 8 patients to that Arm |
| **Clinical Site** | ▪ Masonic Cancer Center, University of Minnesota |
| **Principal Investigator** | ▪ Veronika Bachanova, M.D., Ph.D. |
| **Co-Principal Investigators** | ▪ Jeffery S. Miller, M.D.<br>▪ Michael Verneris, M.D.<br>▪ Aleksandr Lazaryan, M.D., M.P.H., Ph.D. |
| **IND Sponsor** | ▪ Daniel Vallera, Ph.D. |

# OXS-3550

## *Trispecific Killer Engager (TriKE) Fusion Protein Mechanism of Action*




**TriKE-Mediated Killing**




**TriKE-Mediated ADCC**

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# OXS-3550

## *TriKE for Myeloid Malignancies*

- Trispecific ADCC NK Cell engager targeting CD16 receptor on NK cells and CD33 receptor on cancer cells Contains IL-15 as an NK cell activator
- Indication CD33+ myeloid malignancies:
  - Acute Myelogenous Leukemia (AML)
  - Myelodysplastic syndrome
- Unique incorporation of IL-15 into design yielding a trispecific scFv ADCC construct
  - Targets CD33+ myeloid malignancies
  - Binds to the CD16 receptors on NK cells with IL-15 activating the NK cell regardless of the presence of killer cell immunoglobulin-like receptor (KIR) ligands which inhibit NK cell activity
- Pre-IND meeting held on April 4, 2017- IND filed June 8, 2017
- Phase I clinical trial expected to begin Q3 2017
  - 4 days continuous infusion x 3 weeks cycle course
  - Dose finding and extended Phase II component
- Partnership agreement with Altor BioScience Corp.
  - Dr. Patrick Song-Shiong serves as Chairman of Altor
- Licensed from the University of Minnesota

# OXS-1615

## *TetraKE for Carcinoma*

- Tetraspecific ADC targeting CD16/IL-15/EpCAM/CD133
- Targets EpCAM+ present on the majority of solid tumors and CD133+, an establishe cancer stem cell marker
- Potential indications: carcinomas including breast, prostate, pancreatic, head and neck, colon, kidney, liver, and lung
- Licensed from University of Minnesota

# OXS-4235

## *Starting development: Small molecule for multiple myeloma*

- Small molecule P62-ZZ inhibitor targeting the treatment of multiple myeloma and associated osteolytic lesions
- In *in vitro* and *in vivo* models of multiple myeloma and osteoporosis, OXS-4235 demonstrated the ability to kill multiple myeloma cells, and decrease osteolytic lesions in bone
- Pre-IND meeting anticipated for Q1 of 2018
- Licensed from Dr. Sean Xie of University Of Pittsburgh

# CNS Portfolio

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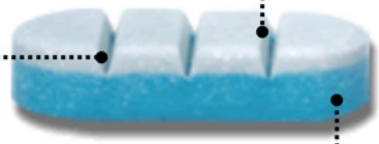
# AccuBreak Technology Platform

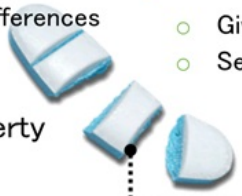
## *Innovative Design for Maximum Dose Flexibility and Accurate Breakability*

- Precise adjustment of dose timing and amount:
  - Alleviates disabling peak-dose side effects
  - Maximizes efficacy
  - Minimizes side effects
- Formulation is particularly adapted to drugs for which:
  - No marketed dosage form allows precise and easy dose fractionation
  - Narrow therapeutic window
  - Dose-limiting side effects prevent full efficacy
  - Considerable inter-individual differences in dosage
- Formulation intellectual property

- Top layer contains drug formulation
  - Predivided during manufacturing into exact doses



- Deep score penetrates nearly to bottom layer, making splitting the tablet easy
- Bottom layer formulation contains no drug
  - Gives tablet mechanical stability
  - Serves as a break region when splitting the tablet



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# AccuBreak Tablets Have Relatively Straightforward Path to NDA Approval

- For the NDA to be a 505(b)(2)
  - Total tablet strength must remain the same as initial tablet
  - Package insert must remain the same (except for new tablet description)
- Only 2 Phase I studies in healthy volunteers (N=24 to 48) are expected to be needed for NDA filing + 3 commercial tablet batches
- Special and expensive equipment is required for tablet manufacturing - Contracted with a US manufacturer who has the equipment

# Chronic Neuropathic Pain

## *Urgent Need for Better Drugs - Prevalence Increasing with Aging Population*

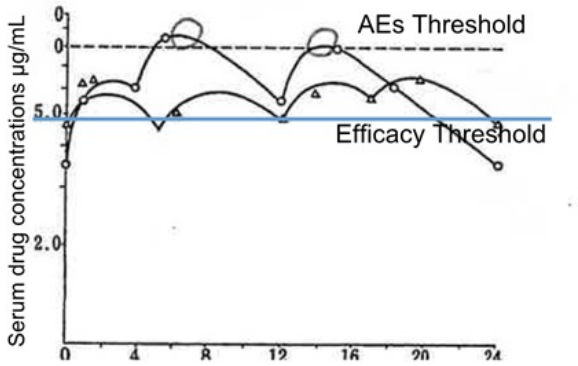
- Neuropathic pain reflects a chronic dysfunction of the nervous system
  - Causes include diabetic neuropathy, postherpetic neuralgia, certain forms of chemotherapy, trauma, and multiple sclerosis
- ~16 MM Americans suffer from chronic neuropathic pain and the prevalence is increasing due to aging population(1)
- Current drugs provide a useful degree of pain relief in only about half the patients
  - Only 1 in 4 patients experiences >50% pain relief
  - Very few patients achieve complete relief of pain;
  - ~30% of patients have no or very little relief
- Peak dose-limiting side effects (mainly sedation) cause patients to be under-dosed, thereby contributing to inadequate pain relief

*Yawn et. al., 2009*

# PainBrake for Chronic Neuropathic Pain

- PainBrake can achieve nearly complete pain relief but without peak dose side effects
  - Frequent small accurate doses of analgesic to avoid peak dose side effects and maintain constant pain control
  - Active component of PainBrake does not give rise to tolerance or dependence, and does not have abuse potential
  - Intend to file Orphan Drug application for a specific disease that responds particularly well to the product

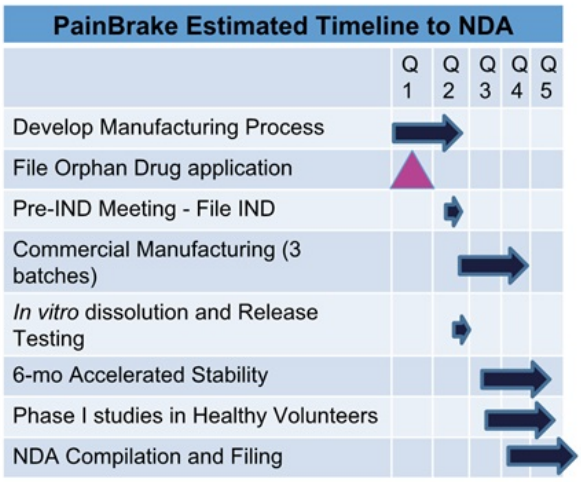
**Dose Fractionation Provides Greater Efficacy**




GT Biopharma, Inc.

# PainBrake: Potential Timeline to NDA Filing

- Anticipate that 2 Phase I trials needed for 505(b)(2) NDA, provided that total tablet strength is within FDA-approved range
  - NDA filing potentially in 15-18 months from funding
- Estimated total budget to NDA filing of ~$2.6 MM




GT Biopharma, Inc.

# GTP-004 for Myasthenia Gravis

## *Addresses Medical Need for Safer and Better Tolerated Treatment*

- Only one drug, Pyridostigmine, currently approved for this rare muscular disease
  - Approved drug restores muscle strength to pre-disease state, but GI side effects (nausea, vomiting, diarrhea) are dose limiting
  - Disease causes patients to be wheelchair bound
  - ~60,000 patients in the US[1]
- GI adverse effects are an important source of discomfort, may lead to non-compliance or decrease the dose of efficacious treatment
- GTP-004 combines Pyridostigmine with an approved antagonist of the GI side effects
  - Fixed dose combination of the two approved drugs
  - Orphan Drug application filed
  - Patents filed in early 2017

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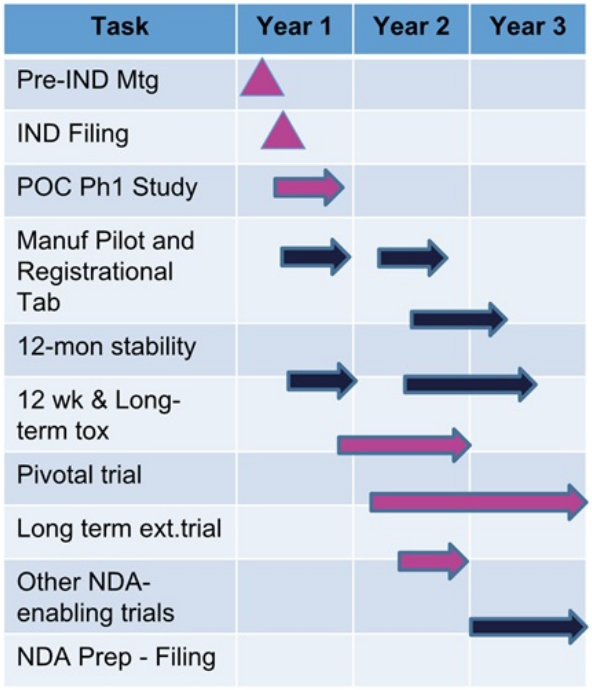
*Source: [1]Howard JF. Clinical Overview of MG. Myastenia Gravis Foundation of America Accessed at http://www.myasthenia.org/HealthProfessionals/ClinicalOverviewofMG.aspx on May 22, 2017*

# GTP-004: Potential Timeline to NDA Filing

- Anticipate 505(b)(2) NDA expected to require 1 placebo-controlled trial
- Expect to be able to reference all preclinical (toxicology), pharmacokinetic and clinical safety data of each approved drug component
- Primary endpoint of placebo-controlled trial will be side effects
- Estimated total budget to NDA filing of ~$7.2 MM

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# GTP-011 for Motion Sickness

***Clear Medical Need for Better Treatments***

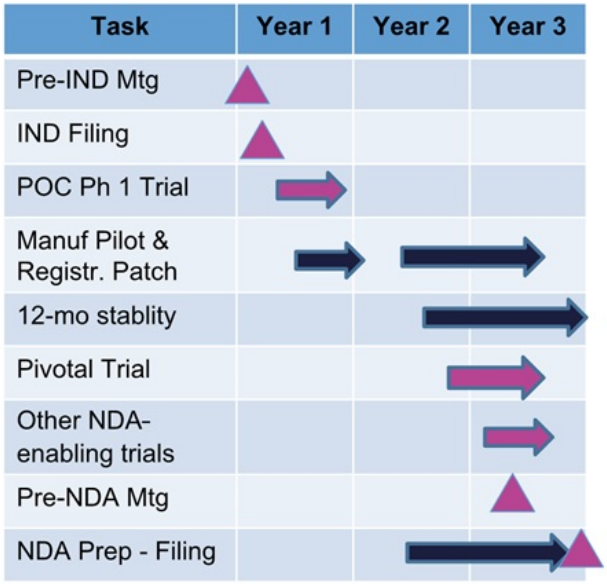
- Prevalence 9-38% of population[1] (depending on the study) Children 2 to 12 years old are most susceptible.
- Novartis' Transderm Scop (scopolamine transdermal patch) is first-line treatment
  - Deleterious side effects, especially in elderly, are a concern
  - Not indicated for children
- GTP-011 potentially avoids deleterious effects of scopolamine
  - Has been shown not to affect cognition and memory in healthy volunteers and it does not cause Alzheimer-like symptoms in the elderly
  - Repurposed drug with new formulation
- Patents filed in early 2017

GT Biopharma, Inc.

*Source: [1]Koslucher F, Haaland E, Malsch A, Webeler J, Stoffregen TA. "Sex Differences in the Incidence of Motion Sickness Induced by Linear Visual Oscillation". Aerosp Med Hum Perform 2015; Sep;86(9):787-93. doi: 10.3357/AMHP.4243.2015.*

# GTP-011: Potential Timeline to NDA Filing

- Anticipate 505(b)(2) NDA will require 1 placebo controlled trial
- Confirm in healthy volunteers in specialized center that GTP-011 prevents motion sickness ("go/no -go" study)
- If "go," manufacture 3 commercial batches for NDA
- Conduct multicenter study in specialized labs in healthy volunteers to demonstrate safety and efficacy
- Estimated total budget to NDA filing of ~$7.1 MM

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# Anticipated Upcoming Milestones

| | Q4 2017 – Q1 2018 |
|---|---|
| **GTP-004** | ▪ File IND<br>▪ Complete Phase I Proof-of-Concept |
| **GTP-011** | ▪ File IND<br>▪ Complete Phase I Proof-of-Concept |
| **OXS-1550** | ▪ Phase II ongoing |
| **OXS-3550** | ▪ IND Opening Start Phase I/II |
| **OXS-1615** | ▪ Solid Tumor TriKE Start Phase 1/11 Fall |
| **OXS-4235** | ▪ Start IND-enabling studies |

# Financials & Capitalization – Pro Forma

| | Current Structure | Post 1:300 Reverse Split |
|---|---|---|
| Stock Price | $0.02 | $6.00 |
| | | |
| Current Common Shares Outstanding (Pre-Merger) | 148,932,433 | 496,441 |
| | | |
| Common Shares Outstanding (Post-Merger) | 5.0B | 16.5M |
| | | |

- Closing price was $0.02 on July 5, 2017
- Assumed conversion price of all current debt is $0.007

GT Biopharma, Inc.

# Investment Highlights

- Diversified drug development pipeline across two therapeutic categories – oncology and CNS
- Pipeline offers more balanced risk/reward profile with potential for steady news flow
- Lead immuno-oncology product candidate, OXS-1550, a novel bispecific antibody drug conjugate, currently in Phase 2
- Lead CNS product candidate, PainBrake, anticipated to be NDA-ready in ~15-18 months
- Experienced management team with track record of success in drug development and successful exits