Awaken the body’s power™
to protect, restore & regenerate
What are post operative adhesions?
Bands of scar tissue that form after most surgeries and stick to organs causing complications. Now, surgery’s single largest complication, cause of morbidities that lead to repeat surgeries, readmissions & longer length of stays. *(Practical Guide to the prevention of Surgical Adhesions, CME/CE)*

Risk of Adhesions v. Infection, Hemorrhage
1:17 v. 1:500

*Adhesion Awareness: A National Survey of Surgeons, World J. of Surgery, 2010*
Executive Summary
First-in-Class Drug Ready to capture $2.5B untapped market

• Clinical: Lead preparing for pivotal studies- *first-in-class* drug (Evitar™);
  • 48 Patient double blind RCT placebo controlled study & FDA PIND completed
  • Final Study report available March 2017 for adhesion prevention
  • **Secured Top KOL’s in the space to design and run pivotal program**

• IP: Irrevocable exclusive world-wide license for Evitar™, patent expiry extended to 2038 with recent filing; provisional filed on 2nd indication; filing provisional on third indication in transplant in 2017—orphan and fast track possibilities

• CMC: API cGMP in place, DMF’s filed in major markets, stability data available over 24 months; two clinical batches completed

• Pipeline: Promising products positioned for reference leadership in other surgery adhesion prevention indications (spinal, ortho, etc.), and transplant (orphan and fast track possibilities)

• Commercial: adhesion prevention-significant growth potential- **90% of the 2.5 billion USD** market is **untapped**

*Evitar™ prevents adhesion formation & delivers clinically relevant outcomes*

*Key to surgeon adoption, reimbursement & commands premium pricing*
Milestones for 2017

- **Nov’16**
  - FDA PIND

- **Dec’16**
  - Independent Medical Review of Data
  - Completed

- **Feb’17**
  - File Orphan Drug Application
  - EMA & FDA Q2’17

- **Mar’17**
  - QA Data Available
  - Engage in co-development discussions

- **Q2’17**
  - Complete Dose Ranging, GLP Tox & PK Studies

- **Q4’17-Q1’18**
  - Close Financing
  - $25M by end of Q3’17

Near term inflection points creates value and mitigate risks
Hospital/Acute Care/Out-Patient Markets
Reference leadership in product pipeline

First-in Class
- Provisional patent filing 2017

Accelerated Approval
- Spine
- Abdomino-Pelvic
- Ortho
- General

Standard of Care

Transplant
- Delayed Graft Function

Orphan & Fast Track Provisional patent filing 2017

Post Operative Fibrosis

2017-Filing for ODD & Breakthrough

Dermal Scar Revision

DAMAGE OR INJURY
- HYPOXIA

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“There is a significant unmet need in fibrosis, and this novel pharmaceutical approach has potential,” stated Dr. James Greenberg, Chief of Gynecology at the Faulkner Hospital and a Vice Chairman of Obstetrics & Gynecology at Brigham & Women's Hospital, Harvard Medical School, Boston, MA. “I believe the approach and efficacy shown sets a new standard of care in gynecology pelvic surgeries. For me it is important that it is not a barrier or medical devices which are not that effective.”
Post-operative complications
Most sensitive surrogate marker for quality* ratings for hospitals

"DOUBLE-EDGE" SCALPEL
Adhesion Drivers: Aging & More Repeat Surgeries

**Annals of Surgery, 2011, 254 (6), 907-913**

Large Untapped Adhesion Prevention Market

Limited or no options for laparoscopic abdominal and pelvic procedures; the fastest growing surgical segment. "First-in-Class Drug from Novel Biology could be ideal product" – Dr. Greenberg, Harvard Surgeon

Adhesion related Adoption Drivers

- Surgical complications slash profit margins from 5.8% to 0.1% (Jama Surgical May 11, 2016)
- 30 day re-admission rates wither away hospital quality rating
- Related medico-legal issues spike risk for hospitals and surgeons (Medico Legal Consequences, Int’l J. of Surgery, 2009)
- 7 procedures accounted for 80% of surgeries, 80% of patient fatalities, 79% of complications and 80% of national inpatient costs (JAMA Surg. 2016;151(6))

Global Market ($2.5B)

Hospital Profit Margin With or Without Complications

Profit Margin

0.0% 5.0%

With Without
# ATTRACTIVE TARGET MARKETS

Underserved and limited or no options with room for growth

## Adhesions from Abdominal & Pelvic Surgeries

| Market Potential | 9 + million procedures in US  
30+ million globally |
|------------------|-----------------------------|
| Market Needs     | Limited or no viable solutions laparoscopic procedures  
An easy to use, effective and broad coverage would meet the need, accelerate adoption and realize the potential |

## Epidural Fibrosis following Spinal Surgery

| Market Potential | 54 million Americans over 65  
Spine industry grown from $300M (1997) to $13B (2012)  
1.5+ million procedures in US  
3+ million procedures globally |
|------------------|-----------------------------------------------------------------|
| Market Needs     | CMS MS-DRG codes increased reimbursement by 20%  
Fibrosis may account for 20-36% of FBSS* & makes reoperations more difficult  
Reducing fibrosis with a safe and effective product would meet the need |

## Other surgical procedures (US data)

| Market Potential | 6+ million digestive system  
1+ million respiratory system  
7+ million CV  
700K knee replacements  
1.2+ million urinary system |
|------------------|-----------------------------------------------------------------|
| Market Needs     | Fibrosis complications lead to hospitalizations, re-operations and medico-legal issues  
Customized product design with input from surgical team could dominate the space |
No Current Standard of Care

Creates unmet medical need

Seprafilm® or Interceed® Barriers Method

Significant Limitations
• Not FDA Approved for laparoscopic surgeries
• Seprafilm®: Hard to use & handle-sticky; leaks with anastomosis
• Near perfect hemostasis environment required for Interceed®
• Adhesions still form

Adept® Barrier Method using an instillation

Significant Limitations
• Infection & swelling reported in trial
• Approved: gynecological laparoscopic adhesiolysis, clean cases
• Efficacy is marginal (9.8%) difference from Lactated Ringers solution (FDA Panel Review)
• Contraindicated to general surgery
• Adhesions still form

A clear need for a product that is easy to use in all procedures, applies quickly and achieves broad coverage that prevents adhesions throughout
Evitar™ Moves Beyond “Barrier” Thinking

First-in-Class Patented Drug could be the ideal product

- Restoring balance at cellular level may be possible within hours of surgery*
- Rapidly restoring tissue homeostasis enhances normal resolution*
- Shifts the gene signalling pathways activated by prolonged hypoxia and oxidative stress away from adhesion formation*


Anti-inflammatory & Steroids
Aspirin to methylprednisolone

1975 1990 2009

Barrier Devices

Adhesion Literature Suggests:
Re-alignment of Cellular Metabolism
Omental Milky Spots appear and increase with adhesion formation

Milky spots are corpuscles found in the omental glomeruli measuring 0.1-2 mm in size, hardly visible to the naked eye, and under low magnification look like tufts of cotton wool. They were first observed as dense corpuscles resembling cotton wool in the omentum and pleura of rabbits in 1863 by Recklinghausen. In 1874, Ranvier confirmed this discovery and named these corpuscles milky spots.

Milky spots are characterized by a permanent glomus pattern of vascular structure, specific cellular population and a specialized mesothelial lining. In humans, milky spots comprise of macrophages (70%), B-lymphocytes (10%), T-lymphocytes (10%), mast cells, and stromal cells.

The activation of milky spot growth in size and number occurs within 6 hours of abdominal surgery. It plays a key role in adhesion formation, at least in part by release of fibrotic mediators such as HIF1α, TGF-β1, TGFB2, VEGF.

Novel Approach-Cellular Modulation
Evitar™ Controls Milky Spot Secretions of Cytokines

Evitar™

Normal Resolution

Peritoneal Injury

Fibrosis Formation

Milky Spots a

Normally cover 1-2% of omentum surface area remains constant

TGF-β3, tPA,
↑ fibrinolysis
Anti-fibrotic

↑ fibrin deposition
Pro-fibrotic

Normal Healing
(Peritoneal Repair)

TGF-β1, TGF-β2
VEGF, PAI
Anti-fibrotic

TGF-β1, TGF-β1
VEGF, PAI
Pro-fibrotic,
↑ fibrin deposition

Milky Spots a

Expand to cover 40-60% of omentum surface area

TGF-β3, tPA
fibrinolysis
Anti-fibrotic

## EVITAR™ First-in-Class Drug

Easy to use, quick to apply & laparoscopic friendly

<table>
<thead>
<tr>
<th>Differentiation Parameters</th>
<th>Evitar™ (Temple Therapeutics)</th>
<th>Gynecare INTERCEED® (Johnson &amp; Johnson)</th>
<th>Adept® (Baxter)</th>
<th>SepraFilm® (Sanofi-Genzyme)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic use</td>
<td>Yes administered laparoscopically in current trial</td>
<td>Not FDA Approved</td>
<td>Yes FDA Approved with conditions</td>
<td>Not FDA Approved Fined by US DOJ for use</td>
</tr>
<tr>
<td>Type</td>
<td>Drug</td>
<td>Device</td>
<td>Device</td>
<td>Device</td>
</tr>
<tr>
<td></td>
<td>Sterile Aqueous form</td>
<td>Synthetic fabric</td>
<td>Liquid instillation</td>
<td>Bioresorable Film</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Easily applied in &lt;1 min through commonly found syringes</td>
<td>Education &amp; training required Known to extend procedure time</td>
<td>Easy Significant volume 1000ml in peritoneal cavity</td>
<td>Education &amp; training required Known to extend procedure time</td>
</tr>
<tr>
<td>Safety Issues</td>
<td>No AE’s reported in current trial</td>
<td>AE’s reported</td>
<td>AE’s reported</td>
<td>AE’s reported Currently under a Petition to FDA to remove off market</td>
</tr>
</tbody>
</table>

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“DROP IT IN EVERY PROCEDURE”

Value Propositions Balances customer needs & maintains strong margins

**Surgeon**
- <1 min. application time, no change in habits or training
- Easily works equally well in open or scope procedures
- Reduces operation time, potential complications

**Hospital**
- Priced right as a % of total procedure, no capital investment required
- One product for many procedures, economies of scale
- Saves OR time, reduces complications and readmissions

Margins 90%+
### ACCELERATED CLINICAL PATHWAY

**Elective surgeries, clear endpoints & small trials**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Regulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>N=48</td>
<td>N=300+</td>
<td></td>
</tr>
<tr>
<td><strong>Evitar™</strong></td>
<td></td>
<td></td>
<td>patients</td>
<td>patients</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>100% enrolled</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td><strong>File ODD Application in US &amp; EU</strong></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>505(b)1 Pathway Potential</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Orphan and Breakthrough Possibility with Expedited</td>
</tr>
</tbody>
</table>

- Current trial is a **double blind placebo controlled randomized** study with both a laparoscopic arm (N=38) and laparotomy (N=10), both randomized 1 to 1 in myomectomies (removal of fibroids) with 6-8 week post-op laparoscopy second look follow-up which is the gold standard for assessing adhesions

- Blinded Independent Reviewers (in Progress):
  - Togas Tulandi MD, MHCM, Professor & Interim Chair of Obstetrics and Gynecology, and Milton Leong Chair in Reproductive Medicine, McGill University, Interim Chief of Department of Obstetrics and Gynecology, McGill University Health Center
  - Antonio Rosario Garguilio, MD, Assistant Professor, Harvard Medical School, Infertility and Reproductive Surgery Obstetrics/Gynecology
  - Dr. Donna Chizen, MD, Reproductive Endocrinologist, Obstetrics and Gynecology, University of Saskatchewan
# CLINICAL TRIAL SUMMARY

<table>
<thead>
<tr>
<th>Proposed Indication</th>
<th>As an adjunct to good to surgical technique, Evitar reduces adhesion formation following abdominal pelvic surgeries.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Design</td>
<td>Double blind, placebo controlled randomized trial</td>
</tr>
<tr>
<td>Sample size</td>
<td>N= 48, with 24 subjects receiving the treatment (Evitar™); 24 subjects receiving the placebo laparoscopically; with 10 subjects undergoing a myomectomy by laparotomy.</td>
</tr>
<tr>
<td>Primary Endpoint</td>
<td>Statistically significant reduction in adhesions observed in the Evitar™ treated group compared to placebo at 6-8 weeks post-myomectomy. Based on the analysis approach the primary endpoint will be met if the Treatment group has a statistically significant fewer patients in the “Adhesions” category (and therefore, 30% more in the “Non-Adhesions” category) compared to the Placebo group.</td>
</tr>
<tr>
<td>Secondary Endpoint</td>
<td>Establish safety and tolerability of formulation and fixed dosage of Evitar into the peritoneal cavity</td>
</tr>
<tr>
<td>Efficacy</td>
<td>The ability of Evitar™ to reduce post surgical adhesions will be determined during the 8-week post-operation follow up laparoscopic examination. Both the incidence and the severity of adhesions will be assessed. The incidence of adhesions will be determined visually. Digital recording of all surgeries and sites where the uterine surface was opened/incised/cauterized/sutured will be compared between first and second surgeries. Severity of the adhesions will be assessed using the AFS (American Fertility Society) scoring system, which evaluates the extent and aspect of adhesions at four anatomical sites, right ovary, right tube, left ovary, left tube. All findings will be recorded in the subject’s case report form (CRF).</td>
</tr>
</tbody>
</table>
### Inclusion criteria

- Subjects are female
- Subjects are 18 years of age or older at the time of consent
- Subjects have a BMI between 17-40
- Subjects must have signed informed consent form
- Subjects have a preoperative diagnosis of uterine fibroids and plan to have a myomectomy completed surgically as part of their standard care
- Subjects must have a physical examination and compliance assessment

### Main exclusion criteria are:

- Subjects whose BMI is outside the range of 17-40
- Subjects participating in another clinical trial with a drug or device
- Subjects who have participated in a clinical trial with a drug or device within 30 days prior to this study
- Subjects with suspected or diagnosed pregnancy
- Subjects with undiagnosed vaginal bleeding
- Subjects with suspected intraabdominal infection
- Subjects who are immunocompromised
- Subjects diagnosed with cancer
- Subjects treated with hemostatic agents (e.g. fibrin sealant, collagen, oxidized cellulose)
- Subjects treated with adhesion prevention agents other than the Anti-Adhesion product (APP) (e.g. Intergrel® Adhesion Prevention Solution, Seprafilm® Membrane)
- Subjects taking anti-epileptic medications
- Subjects who have been treated with Methotrexate or other chemotherapeutics agents
- Subjects with an American Fertility Society score of Stage D at the time of myomectomy as determined by the surgeon
Pivotal Clinical Strategy with Orphan Designation

mPOC
- in vitro-markers
- tracer study on glutamine to uncover metabolism

Safety
- GLP Tox
- Dose Response

Regulatory Interactions

Evitar

Phase 2B/3 Registration Trial

First Approval in Orphan Indication 2021

mPOC = mechanistic proof of concept

cPOC = clinical proof of concept

Additional Registration Trials
**Evitar™ Pivotal Clinical Program Synopsis**

<table>
<thead>
<tr>
<th>Proposed Indication</th>
<th>First in class drug to improve fertility in patients undergoing myomectomies, laparoscopic or laparotomic) by reducing and/or preventing adhesion formation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Endpoint</td>
<td>Improvement in fertility rate of 50% from baseline (literature suggests that anywhere from 33% to 50% of women undergoing myomectomies without any adhesion prevention products do conceive). Confirmed pregnancy by ultrasound fetal heart rate at 6 weeks</td>
</tr>
<tr>
<td>Secondary Endpoint</td>
<td>Presence of adhesions in abdominal wall by imaging at 6 to 8 weeks</td>
</tr>
<tr>
<td>Inclusion criteria</td>
<td>Females, age 18-37, male partner is ok, tubes are ok, unexplained infertility (trying for one year without success), presence of one myoma &lt;3cm in the uterus determined by transvaginal ultrasound</td>
</tr>
<tr>
<td>Follow up Period</td>
<td>One year from last patient in; 24 months to 36 months</td>
</tr>
<tr>
<td>Proposed Sample Size</td>
<td>300</td>
</tr>
<tr>
<td>Proposed Trial Centers</td>
<td>7 (4 in Europe; 2 US &amp; 1 in Canada) primary centers Other centers in Latin America, CES, Japan, AU, S. Korea and India possible</td>
</tr>
</tbody>
</table>
# PROVEN TEAM

## Relevant experience: clinical, regulatory, legal, finance, marketing & sales

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Experience Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanj Singh, MBA</td>
<td>CEO</td>
<td>Over 20 years of industry experience in leadership positions; building top teams &amp; strong strategic relationships, business development and raising capital. Board of Directors, BioteCanada. Formerly of: Co-founder, President &amp; CEO of AdeTherapeutics Inc.</td>
</tr>
<tr>
<td>Lynne Robertson, MS</td>
<td>CEO</td>
<td>Over 29 years of experience in biomedical and pharmaceutical industries. Concept through commercial launch, including discovery, CMC and clinical development, regulatory and compliance, program management and executive leadership. Experience with medical devices, combos, Rx and OTC drugs in Europe and North America. Formerly of Quintiles, KOS, Schering Plough, Mylan, Wyeth Ayerst and cofounder of Gwen Ryan Solutions pharma consulting.</td>
</tr>
<tr>
<td>Len Smith, MSc., JD</td>
<td>Strategic Counsel</td>
<td>Over 20 years crafting and carrying out strategies for transactions and operations relating to innovative technologies and products leading to growth and profits. Structuring and negotiating technology, financing, and corporate deals (licenses, acquisitions, collaborations, joint ventures, mergers, etc.) and other contracts; board, regulatory compliance, IP strategy. Formerly of Valeant, Medicis &amp; Novo Nordisk</td>
</tr>
<tr>
<td>Zahir Lavji, Chairman</td>
<td>President of Abbott Japan</td>
<td>Previous EVP of Int’l Marketing, Abbott</td>
</tr>
<tr>
<td>Bill Densel, CEO CheckCap</td>
<td>CEO-Beacon Medical</td>
<td>Director Marketing &amp; Sales, Biosurgery, Genzyme</td>
</tr>
<tr>
<td>Steven Damon</td>
<td>CEO 4P Therapeutics</td>
<td>Previous VP of Altea, Durect, Kimberly Clark</td>
</tr>
<tr>
<td>Guy-Jean Savoir</td>
<td>Director Carnot Laboratories</td>
<td>Founder, Investor, Diversified Corporate Holdings</td>
</tr>
<tr>
<td>Jason Ding, CPA, CBV</td>
<td>Sr. Life science practice leader, Deloitte</td>
<td>Previous</td>
</tr>
<tr>
<td>Saad Gilani</td>
<td>Financier, Sr. Portfolio Advisor</td>
<td>Yorkville Advisors</td>
</tr>
</tbody>
</table>
## Pipeline in Acute Care/Hospital

Prepping for IND in 2018

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>POC In Vitro</th>
<th>POC Animal</th>
<th>Clinical Trials</th>
<th>NDA Filing</th>
<th>Market Launch</th>
<th>IP Expiry</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTX-330-Spinal</td>
<td></td>
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<tr>
<td>TTX-332-Transplant*</td>
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</tbody>
</table>

Animal data & IP data available along with Clinical & Regulatory development for both

*TTX-332 will be rolled into a Newco with a 24 month IND development program
ENGINEERED VALUE
Timeline, data & pipeline drive value creation

- **Q1-’17**
  - PIND FDA meeting & Complete Phase I/II Trial

- **Q2-3-’17**
  - Data Lock Jan 2017
  - Double blind data read out
  - File Orphan Designation

- **Begin Co Development License Discussions**

- **Prep for pivotal trial in lead indication in Western EU & USA**

- **Market entry for lead expected 2021**
  - Major market license through co-development in Q4-2017-Q1-2018
Market Driven Product Development Approach
We go for standard of care where none exists

Market & Product Insight from our scientific, medical advisory board of surgeons & payer

Mitigate Risk through validation

- Unmet medical need, clinical trial, reimbursement & product design vetted by SAB prior to acquiring IP and initiating development

- Breakthrough designation, orphan and/or 505(b)2 provides for rapid clinical development

Quality differentiated products for major unmet medical need

- Disease modifying based on clinicians’ & payers’ input

- Value proposition: Reduce repeat procedures, lower readmissions rates & length of stays

- Reducing complications increases hospital quality rating & improves operating margins

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References


