Non-Confidential

TTX-333-Evitar™

“Sentinel Moment in Surgery”-Unrivaled Efficacy Data
Opportunity Summary

Temple Therapeutics BV ("Temple") is a clinical stage development company focused on patented drugs for proven and reimbursable high unmet medical needs in a hospital setting. The team focuses on translating top researchers’ and clinicians’ novel targets and differentiated approaches into drugs that establish gold quality standard of care. The core asset of the patent family was secured by an irrevocable worldwide license by Temple from AdeTherapeutics, Inc.

Successful completion will be executed in tandem with pharma licensing and royalty deals for the leading global markets. Significant market development completed over last 15 years by existing strategics. Global sales reaching $200M. Market potential pegged at $3B US.

Temple plans to file US-FDA IND and EMA-IMPD application for its lead indication and presented key data. TTX-333-Evitar™, by finishing Phase II and completing Pivotal Trials, as well as non-clinical GLP studies, and CMC development and validation in support of an NDA.
Lead Indication: TTX-333-Evitar™

First-Mover Drug to Set New Operating Practices

LARGE MARKET OPPORTUNITY
Ageing population, more surgeries Currently no effective preventative standard

COMPPELLING HUMAN CLINICAL DATA
5x improvement over placebo (p=0.0456)

COMPANY PROFILE
Privately held, significant value creation, capital efficient clinical program

BOARD & MANAGEMENT TEAM
Seven decades of experience in developing, marketing drugs and creating value

DEEP PIPELINE & STRONG KOL SUPPORT
Reference leadership possible in multiple indications in hospital & acute care. Top KOL’s on team

STRONG INTELLECTUAL PROPERTY PIPELINE
Extensive patent life, LCM opportunities, collaborations with top academic institutions
Platform for High Medical Need Currently Unmet

First-In-Class Solution → Accelerated Approval → Standard of Care

Lead Abdomino-Pelvic (TTX-333-Evitar™)

Spine

Provisional Patent Filing 2018

Ortho Sx

Provisional Patent Filing 2018

General Sx

ASBO/Anastomosis

Post Operative Fibrosis

Transplant Delayed Graft Function

Orphan & Fast Track Provisional patent filing

Oncology/Fibrosis Novel Target Efficacy in Various Cancers

Orphan & Fast Track Provisional patent filing 2017

NOVEL BIOLOGY APPROACH MODULATING HYPOXIA

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## Pipeline in Acute Care/Hospital

### Indication Status

<table>
<thead>
<tr>
<th>Drug Indication</th>
<th>POC (Animal)</th>
<th>POC (Humans)</th>
<th>Registration Trials</th>
<th>NDA Filing</th>
<th>Market Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TTX-333-Evitar™</strong></td>
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<tr>
<td><em>(Abdomino-Pelvic)</em></td>
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<tr>
<td>Evitar™</td>
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<tr>
<td><em>Subcellular Modulation to Prevent Adhesions</em></td>
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<tr>
<td><strong>TTX-330-Evitar™</strong></td>
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<tr>
<td><em>(Spinal Surgery Fibrosis Prevention)</em></td>
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<tr>
<td><strong>TTX-331-Evitar™</strong></td>
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<tr>
<td><em>(General Surgery Fibrosis Prevention Anastomosis)</em></td>
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<tr>
<td><strong>TTX-332-Transplant</strong></td>
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<tr>
<td><em>(Delayed Graft Function)</em></td>
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<tr>
<td><strong>TTX-334-Oncology</strong></td>
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<tr>
<td><em>(Chemo-Resistant Epithelial Ovarian)</em></td>
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</tbody>
</table>
Reducing Post-Operative Adhesion Formation with Intraperitoneal Glutamine

EP 1940439 – Issued October 27, 2010
  Validated in Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Great Britain

US 9,011,883 – Issued April 21, 2015;
  US Serial No. 14/660,382 – Abandoned; continuation of US 9,011,883.

US Serial No. 15/480,148 – Pending; Continuation of US Serial No. 14/660,382
  Filed April 5, 2017; Awaiting first office action

JP 5194207 – Issued February 15, 2013

HK 1120223 – Issued August 12, 2011

CA 2618600 – Issued May 2, 2017

AU 2006279218 – Issued October 29, 2013

AU 2013204912 – Issued March 16, 2017; Divisional of AU 2006279218

AU 2016266102 – Pending; Divisional of AU 2013204912
  Filed December 2, 2016; Awaiting first action

Methods and Compositions for Reducing Synovial Joint Adhesion


Methods and Compositions for Increasing Fertility


Methods and Compositions for Treating Solid Tumors

US 15/338,092 – Filed October 28, 2016: Pending
Large Untapped Opportunity

Prevention is the KEY

- Bleeding - 15th Century
- Pain - 1842
- Antiseptic - 1867 (Lister)
- Adhesion Prevention in 2017

SURGEONS’ DREAM

Prevent /pri’vent/ verb
Keep something from happening

vs.

Reduce /ri’djuːs/ verb
Make smaller or less in amount, degree, or size

The Agnew Clinic by Thomas Eakins (1889)
The Problem: Adhesions

Hospitals’ Burden, Surgeons’ Nemesis, and Patients’ Nightmare

Post operative adhesions
Bands of scar tissue that form after most surgeries and stick to organs causing complications and high morbidities. (H. Ellis, A. Crowe 2009)

Problem
Adhesions were reported in Annals of Surgery in 1927 as surgery’s single largest complication. In 2017, it still is with no effective solution that PREVENT the formation of adhesions or the REFORMATION after being cut. (Practical Guide to the prevention of Surgical Adhesions, CME/CE)

Solution
Temple Therapeutics has discovered a novel and safe drug which when administered during surgery can restore homeostasis and promote normal tissue resolution, thus PREVENTING adhesions and potential REFORMATION after cutting.

Adhesion Literature Suggests:
Re-Alignment of Cellular Metabolism

Anti-inflammatory & Steroids
Aspirin to methylprednisolone

1975 1990 2009
Barrier Devices

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Temple’s Breakthrough Solution: Evitar™
First Drug Exploits Cellular Metabolism to PREVENT Adhesions

Temple Approach
Exploits the possibility of restoring balance at cellular level within hours of surgery. Prolonged hypoxia and oxidative stress during surgery can shift gene signalling pathways to promote adhesions.* Rapidly restoring tissue homeostasis at the time of surgery restores signalling pathways that eventuate normal resolution.

Milky Spots, TGF-β1, HIF 1a & Adhesion Formation
Milky spots dubbed for their milky appearance by anatomist Ranvier contain inflammatory and immune cells and are known to secrete TFG-β1, well studied fibrotic mediator (Gomez-Gil et al. 2014). The proliferation of number and size of omental milky spots after surgery increases elaboration of TGF-β1, HIF 1a and tips the balance in favor of fibrosis/adhesion.

Evitar™ (Alanyl-Glutamine)
Quickly administered intraperitoneal at the end of the surgical procedure, Evitar™ (including its active, glutamine), is taken up by peritoneal cells and restores aerobic metabolism through the Krebs Cycle. Restoration of normal metabolism activates cellular processes that support normal tissue resolution, as opposed to adhesion formation.

Evitar™ Controls Milky Spot Secretions of Cytokines

Evitar™ Controls Milky Spot Secretions of Cytokines

Restore the Balance for Normal Resolution vs. Adhesion Formation

Peritoneal Injury

Fibrosis Formation

Milky Spots

Milky Spots

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

Expand to cover 40-60% of omentum surface area

TGF-β3, tPA, fibrinolysis

Anti-fibrotic

Pro-fibrotic

HIF1a, TGF-β1, TGF-β2, VEGF, PAI

fibrin deposition

Pro-fibrotic, ↑ fibrin deposition

TGF-β3, tPA, fibrinolysis

Anti-fibrotic

HIF1a, TGF-β1, TGF-β2, VEGF, PAI

Pro-fibrotic

Normal Resolution

(Peritoneal Repair)

Adhesion or Fibrosis Formation

Evitar™

Milky Spots dubbed for its milky appearance by anatomist Ranvier contain inflammatory and immune cells and are known to secrete TFG-B, well studied fibrotic mediator (Gomez-Gil et al. 2014; Hall, Heel & Platell, 1998; Vanvugt et al. 1996; Shimotsuma et al. 1993; Shimotsuma, Kawate et al. 1989; Wijffels. Beelen et al. 1992; Platell, Cooper et al. 2000; Shimotsuma M,1989; Shimotsuma, Simpson-Morgan et al., 1994)
**Problem**  
Current products ineffective at **preventing** incidence of adhesions in laparoscopic surgeries.

**Study Design**  
- Double-blind, placebo controlled randomized trial  
- **PLUS** blinded independent medical reviewers  
- 25%-33% of patients undergoing laparoscopy myomectomies develop adhesions *(Hermann & Widle 2015)*

**Results**  
- **89.8% reduction** in risk of **developing ANY adhesions** compared to those who received placebo  
- At least a **5x improvement** over placebo;  
- **p=0.0456**  
- No safety signals or AE’s or SAE’s

**Opportunity**  
**Evitar™** is an effective and promising safe drug to **PREVENT** adhesion formation after laparoscopy surgery
Evitar™ Prevents Post-Surgical Adhesions

Results of PoC Trial in Humans (OUS)

<table>
<thead>
<tr>
<th>Group*</th>
<th>Results**</th>
<th>Relative Risk &amp; 95% CI†</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evitar™ N=15</td>
<td>Prevention: 15/15</td>
<td>Relative Risk = 0.102</td>
<td>Patients who received Evitar™ had a 89.8% reduction in risk of developing adhesions compared to those who received the placebo.</td>
</tr>
<tr>
<td></td>
<td>No Prevention: 0/15</td>
<td>(95% CI: 0.006-1.708)</td>
<td></td>
</tr>
<tr>
<td>Placebo N=17</td>
<td>Prevention: 12/17</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No Prevention: 5/17</td>
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</tr>
</tbody>
</table>

*Difference in sample size were due to refusal for second look laparoscopies and protocol failures

**Combined results from three independent blinded medical reviewers

†95% CI is wide because of small sample size

P = 0.0456
Problem
Current products ineffective at preventing incidence of adhesions in laparoscopic surgeries.

Raising the Standard
• No adhesions is the goal for surgeons, patients and hospitals.

Results
• 82.9% reduction in risk of developing ANY adhesions compared to those who received placebo
• At least a 4x improvement over placebo; p=0.1024
• No safety signals or AE’s or SAE’s

Potential New Standard
Evitar™ is an effective and promising safe drug to COMPLETELY PREVENT adhesion formation after laparoscopy surgery.
## Evitar™ Prevents Post-Surgical Adhesions

### Results: Adhesions Present or Not

<table>
<thead>
<tr>
<th>Group</th>
<th>Results**</th>
<th>Relative Risk &amp; 95% CI†</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evitar™</td>
<td>Absent: 14/15</td>
<td>Relative Risk = 0.171 (95% CI: 0.0175-1.782)</td>
<td>Patients who received Evitar™ had a 82.9% reduction in risk of developing adhesions compared to those who received the placebo. P = 0.1024</td>
</tr>
<tr>
<td>N=15</td>
<td>Present: 1/15</td>
<td></td>
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</tr>
<tr>
<td>Placebo</td>
<td>Absent: 12/17</td>
<td></td>
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<tr>
<td>N=17</td>
<td>Present: 5/17</td>
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</tbody>
</table>

*Difference in sample size were due to refusal for second look laparoscopies and protocol failures

**Combined results from three independent blinded medical reviewers

†95% CI is wide because of small sample size
A clear need for a product that is easy to use in all procedures, applies quickly and achieves broad coverage that PREVENTS not just reduces adhesions throughout.

**Seprafilm® or Interceed® Barriers Method**

- 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**

- 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

**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

*NOTE: Seprafilm, Interceed and Adept are registered trademarks for Sanofi, Johnson & Johnson and Baxter respectively*
# Competitive Analysis: Evitar™ In The Lead

*Easy to Use, Quick To Apply, and Laparoscope-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>Sepra Film (Sanofi-Genzyme)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Laparoscopic use</strong></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><strong>Type</strong></td>
<td>Drug Synthetic fabric</td>
<td>Device Liquid instillation</td>
<td>Device Bioreosorable Film</td>
<td></td>
</tr>
<tr>
<td><strong>Ease of use</strong></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><strong>Safety Issues</strong></td>
<td>No difference in safety compared to placebo 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>
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</table>
# Support of Key Knowledge Leaders (KOLs)

## Network That Enhances Clinical Trial Design & Implementation

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Affiliations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. James Greenberg</td>
<td>Chief of Gynecology at the Faulkner Hospital and Vice Chairman of Obstetrics &amp; Gynecology at <strong>Brigham &amp; Woman’s Hospital, Harvard Medical School</strong></td>
</tr>
<tr>
<td>Dr. Michael P. Diamond</td>
<td>Professor and Chair, Department of Obstetrics and Gynecology, William H. Brooks, MD, Distinguished Chair of Obstetrics and Gynecology, Associate Dean for Research, <strong>Medical College of Georgia</strong>; Senior Vice President for Research, <strong>Augusta University</strong></td>
</tr>
<tr>
<td>Ghassan M. Saed, PhD</td>
<td>Associate Professor in the Department of Obstetrics and Gynecology at <strong>Wayne State University School of Medicine</strong></td>
</tr>
<tr>
<td>Dr. Rudy deWilde</td>
<td>Medical Director, Clinic for Obstetrics and Gynecology at <strong>Pius-Clinic Oldenburg, University of Göttingen</strong> and Professor, Obstetrics and Gynecology at <strong>University of Bochum</strong></td>
</tr>
<tr>
<td>Dr. Richard ten Broek, PhD</td>
<td>General Surgery &amp; Research at <strong>Radboud University Nijmegen Medical Centre</strong></td>
</tr>
<tr>
<td>Dr. Togas Tulandi</td>
<td>Professor and Chair, Department of Obstetrics and Gynecology; Obstetrician &amp; Gynecologist-in-Chief; and Milton Leong Chair in Reproductive Medicine at <strong>McGill University</strong></td>
</tr>
<tr>
<td>Dr. Antonio Gargiulo</td>
<td>Medical Director, Center for Robotic Surgery; Reproductive Surgeon, <strong>Boston Center for Endometriosis</strong>; and Assistant Professor of Obstetrics &amp; Gynecology, <strong>Harvard Medical School</strong>; and Medical Director, Center for Reproductive Care at <strong>Exeter Hospital</strong></td>
</tr>
<tr>
<td>Dr. Karen Wang</td>
<td>Fellowship Director, AAGL; Fellowship in Minimally Invasive Gynecologic Surgery and Assistant Professor of Gynecology and Obstetrics at <strong>Johns Hopkins</strong></td>
</tr>
</tbody>
</table>
“Evitar™ offers a potential therapeutic option for preventing adhesion formation based on sound scientific principles with the exciting triad of Efficacy, Safety and Ease of Use.”

Dr. James Greenberg, MD, FACOG, Boston, MA.
**Evitar™: Poised To Improve Surgical Outcomes**

*The Benefits & Beneficiaries*

**TTX-333-Evitar™**

*A Surgeon’s Dream*

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**Problem**

Today as many as 66% of abdominal operations are in fact a reoperation with adhesions already present after previous surgeries.

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**Patients**

- Reduced Adhesion-Related Complications
- Reduces Adhesion-Related Readmissions
- Remote Chance of Negative Side Effects
- Abdominal-Procedure-Agnostic Use Case
- Evitar™ Applied ‘prior to closure’
- Extremely Inexpensive Cost per Unit

---

**Surgeons***

- Evitar™ Application < 1 Minute
- Zero New Medical Equipment
- Zero Additional Practice/Training
- Reduces Adhesion-Related Case Load
- Extremely Safe Product (Glutamine)
- Abdominal-Procedure-Agnostic Use Case

---

**Hospitals (Clinical Pharmacy)***

- Reduction In Readmissions, Revenue Increases
- Improved Operating Margins & Efficiency
- Abdominal-Procedure-Agnostic Use Case
- Extremely Inexpensive Cost per Unit
- Zero Additional Surgeon Training

---

**Solution**

Evitar™ has demonstrated in human clinical study to **PREVENT ADHESIONS**.

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*A hospital landscape analysis and TPP assessment was conducted by Dr. Ira Studin of Stellar Managed Care where Directors of Clinical Pharmacy and Surgeons were interviewed from high volume centers and large hospital health systems in the following states: CA, CO, TX, MI, OH, MA, NY, KY & NC.*

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One of Evitar™’s Target Markets

Evitar™ In The United States

U.S. Segment

Total Addressable Market (TAM)

Serviceable Addressable Market (SAM)

Serviceable Obtainable Market (SOM)
SOM: Est. Total Number of OBGYN Procedures Performed in the U.S. Using Evitar™ ‘Pre Closure’ Annually Assuming 50% Market Penetration

Example of U.S. Market Economics:
2.47 Million Procedures
x $700 USD per Unit
= $1.73 Billion

Other Geographies of Interest:
- Japan
- European Union
- Brazil & Mexico
- China
- India
- South Korea

Annual Assumptions, U.S. Market:
4.49 Million OBGYN Surgical Procedures ÷ 36,593 U.S. OBGYN Surgeons in 2010
= 135.24 Average Surgeries/Surgeon/Year

69,192 Abdominal Surgeons in 2010
* 135.24 Average Surgeries/Surgeon/Year
= 9.36 Million Abdominal Procedures (TAM)

36,593 U.S. OBGYN Surgeons in 2010
* 135.24 Average Surgeries/Surgeon/Year
= 4.95 Million OBGYN Procedures (SAM)

4.95 Million OBGYN Procedures
* Base Case Market Penetration of 50%
= 2.47 Million Procedures Using Evitar™ (SOM)
Proven Management Team

History of Exceptional products, regulatory, legal, finance & clinical

Sanj Singh, MBA
CEO

Over 20 years of industry experience in leadership positions; building top teams & strong strategic relationships, business development and raising capital
Board of Directors, BioteCanada
Previously: Co-founder, President & CEO of AdeTherapeutics Inc.

Lynne Robertson, MS, PhD
Chief Operating Officer

Over 33 years experience in strategic and tactical drug, device, biologics development from concept to commercial launch in the US and EU, including drug discovery, formulation and process development and scale up, analytical chemistry, regulatory affairs, clinical development, cGMP & cGCP regulatory compliance, IP and due diligence, commercial planning and launch.
Formerly of Gwen Ryan Solutions (Co-founder and Principal, Quintiles Transnational, Nostrum Pharmaceuticals (CSO), KOS, Schering Plough, Mylan, Wyeth-Ayerst

Len Smith, MSc., JD
Strategic Counsel

Over 20 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

Board of Directors

Zahir Lavji, Chairman
Previous, President-Abbott Japan
EVP-Int’l Marketing, Abbott

Bill Densel, CEO CheckCap
Previous, CEO-Beacon Medical;
Director-Marketing & Sales for Biosurgery, Genzyme

Steven Damon
Current, CEO-4P Therapeutics
Previous, VP-Altea, Durect, and Kimberly Clark

James Hattersley
Current, Sr. VP BD-Adherium
Previous
Nektar, Sun Pharma, Antares, & Abbott

Guy-Jean Savoir
Current, Director-Carnot Laboratories
Founder, Investor, Diversified Corporate Holdings

Jason Ding, CPA, CBV
National Life Science Practice Leader-Deloitte Canada

Saad Gilani
Financier, MD & Head of Healthcare Investments, Yorkville Advisors

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Steady progression to clinical development:
✓ Secured Top KOL’s
✓ Completed FDA PIND Meeting
✓ POC trial completed with 5x improvement over placebo
✓ MOU for long term supply of API from cGMP manufacturer
✓ Data presented at 52nd Congress of European Society of Surgical Research Meeting (June 15th 2017, Amsterdam)
✓ Series B $25 million financing begins along with Regional Licensing Discussions
✓ Final Clinical Study Report on POC available (November 2017)
✓ Prioritize objective: approval of an indication in myomectomy
✓ Endpoints for pivotal clinical studies & rationale completed
✓ US FDA IND in Progress
✓ Europe & Canada CTA in progress
**TTX-333-Evitar™ Development Plan**  
*(US, Europe, Canada, APAC)*

**Gynecological Indication (unless otherwise noted)**

<table>
<thead>
<tr>
<th>Value Drivers:</th>
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<tbody>
<tr>
<td>➢ Confirmation of POC results on larger sample</td>
<td></td>
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<tr>
<td>➢ FDA &amp; others: acceptance of well-designed feasible RCT with high likelihood of success</td>
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**IND & IMPD Filing in Progress**

**Q1 2018**
- File IND in ‘18 - US
- File CTA in CAN

**Q2 2018**
- Close on Series B funding
- Start Phase II PK/Dose Ranging & GLP Tox Studies
- File Fast Track Application
- Complete & submit draft Pivotal Trial protocols to FDA for review
- File in CTA/IMPD in The Netherlands as MS for National procedure
- Clinical Mfg, for Phase II / Registration Trials / Animal POC General Surgery
- Start stability testing clinical lots (registration batches)

**Q3 2018**
- Finalize Pivotal Trial protocols (comparator Ringers Lactate)
- Contract CRO
- Conduct Animal POC for general surgery ABSO

**Q4 2018**
- Finish Tox Study
- Finish Phase II PK-Dose Ranging Study
- File CTAs in EU Big 5
- File INDs in APAC (Korea)
- File for Breakthrough Designation in US

**Q1 2019**
- Conduct End of Phase II meeting in US
- Prepare sites worldwide for registration

**Q2 2019**
- Start registration trials in US CAN & EU FPFV
- File for Breakthrough Designation in US

**Q3 2019**
- Enroll last patient in US, EU & CAN

**Q4 2019**
- Draft Clinical Study Reports: US, EU & CAN

**Q1 2020**
- LPLV – last patient follow-up in US & CAN
- Data Base Lock
- Unblinding & Preliminary Results of registration trials US & CAN

**Q2 2020**
- Submit US NDA, CAN NDS, Netherlands MAA, leveraging US Phase II & Tox data, & US or CAN registration trial data

**Q2 2022**
- Pre NDA meeting US
- Pre filing/advisory meetings - other HAs

**Q3 2022**
- Expected approval of Gyne Indication: US, CAN & NL

**Q4 2022**
- Final CSRs for Gyne Indication: US, EU & CAN

**Q3 2023**
- Market Launch in US, CAN & NL with Licensing Partner(s)
- Begin MR procedures for approvals in EU Big 5

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**Positioning For Pharma**

*Evitar™ - Subcellular Modulation To Prevent Adhesions*

**Exit for investment via license agreements & royalties**

**Key success factors:**

- Temple continues its effort to initiate and maintain visibility to Pharma by market area
- Clinical plan for pivotal trial will address FDA & health authorities (HA) requirements for clinically relevant outcomes, which corresponds with endpoints desired by gynecological surgeons
- Concurrent filing with Canada, EU, & other HAs to ensure progress on multiple market approvals
- Existing clinical and mechanistic data plus proposed approach ensures successful completion of a randomized controlled trial to support drug approval

**Japan, Mexico/Latin American, South Korea, China, Russia, India** and other regional markets may see an exit prior to completion of Pivotal Trials in the US and EU, through licensing agreements:

- Opportunity to access non-dilutive capital

**US and EU** markets licenses will be executed after completion of Pivotal Trials, to maximize value inflection on the IP and the asset base

For markets where foreign data from clinical trials are acceptable for registration, i.e. **Canada, Brazil and Australia:**

- Temple will explore co-marketing/distribution agreements with local distributors, in order to capture optimal economics versus a licensing deal

Temple has an MOU in place with global manufacturer for cGMP manufacture of the active pharmaceutical ingredient of Evitar™ (10 year supply contract)
Contact Information

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New York, NY 10022
646 780 8449 Main
646 780 8422 Fax

www.dominickanddickerman.com

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Investment Banking
Phone: 646 780 7826
sspence@dominickanddickerman.com

Clark F. MacKenzie, Jr.
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References


