The Path To A Regenerative Medicine Cure

Corporate Presentation
January 2021
Forward-Looking Statements

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Regenerative Medicine - The Future Now

Regenerative Medicine (RM) is a rapidly evolving field of science developing new therapeutic solutions to treat disease:

- with the repair or growth of new tissues & organs, i.e. organ regeneration
- repairing cells at the gene level to prevent disease, i.e. gene therapy
- with therapeutic cells (islets / stem cells) producing proteins or other factors, i.e. cell therapy

Why is RM important? .... Paradigm shift in chronic disease treatment & outcomes

- RM provides the potential of a functional cure vs. mask disease & long-term treatment of symptoms with prescription medicines

Sernova .... Well positioned for RM cell therapy success

- intentional stepwise strategic development approach has led to success & leadership
- RM companies assuming cell therapy technical barriers can be overcome with 'home run' approaches have experienced failures in the clinic to date
Sernova: Innovator & Leader

Publicly traded, clinical-stage RM therapeutics solution innovator & leader:

- Cell therapy therapeutics solution platform treating chronic diseases & enhancing daily QOL
- **Integrated RM therapeutic solution** (Cell Pouch™ + therapeutic cells or tissue + immune-protection)
- Broad platform application potential: **multiple large market indications**
- **Cell Pouch** overcomes current barriers associated with therapeutic cells survival & function by forming **organ-like environment** for the cells to **produce missing proteins, hormones**, etc.
- **Diabetes lead program** & 1st company with RM therapeutic product showing insulin production & early clinical efficacy indicators for type 1 diabetes (T1D). **Active US Phase I/II clinical trial.**
- **Pre-Clinical proof-of-concept** demonstrated for **hemophilia A & thyroid disease**
Sernova’s Platform Approach

Integrated RM Therapeutic Solution for Treatment of Chronic Diseases

Cell Pouch
- Implantable proprietary medical device that provides vascularized environment for therapeutic cells

Therapeutic Cells
- Human cells (donor / stem) & tissues that produce & release missing proteins or hormones into the bloodstream

Immune Protection
- Technologies to protect therapeutic cells from immune system attack
Cell Pouch™ Manufacturing

Manufacture of the Cell Pouch™ in multiple sized is conducted GMP by a US contract manufacturer in a Class VII Clean Room

Product and process development is conducted in accordance with manufacturer’s Quality System

- ISO 13485
- EU Medical Devices Regulation MDR 2017/745
- US FDA Quality System Regulations (QSR) 21 CFR 820
- Canadian Medical Device Regulation (CMDR)

Two-year real-time Cell Pouch™ product stability and package integrity
Worldwide IP / Patent Portfolio

*International patents & patent applications portfolio in multiple patent families with broad application & continued expansion:*

- Composition & use of medical devices for delivery & cell transplantation
- Glucose responsive insulin secreting stem cell technologies
- Local immune protection technologies

*Broad geographic coverage:*

- North America
- South America
- Europe
- Asia
Diabetes... Hope for a Functional Cure

**The Reality:** Diabetes is one of the most prevalent diseases & pervasive medical problems impacting society & everyday quality of life (QOL) today

- 463 million affected worldwide and nearly 10% of these individuals have T1D
- T1D represents a potential commercial opportunity of $30B+ for Sernova

**The Hope:** A functional cure for everyone suffering from diabetes

**The Problem:** Lack of integrated RM therapeutic solution

**The Future:** Blockbuster potential for Sernova’s platform which could establish a new standard of care for diabetes treatment & management. Potential to be the biggest therapeutic advancement in diabetes treatment since insulin discovery 100 years ago.

*(1) source: International Diabetes Federation*
## Sernova Pipeline

<table>
<thead>
<tr>
<th>CELL POUCH CANDIDATE</th>
<th>PRE-CLINICAL</th>
<th>PHASE I</th>
<th>PHASE II</th>
<th>PHASE III</th>
<th>DEVELOPMENT STAGE</th>
<th>INDICATION</th>
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<tbody>
<tr>
<td>HUMAN DONOR ISLETS, SYSTEMIC IMMUNE PROTECTION</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PHASE I/II INITIATED DEC 2018</td>
<td>HYPOGLYCEMIA UNAWARENESS</td>
</tr>
<tr>
<td>LOCALLY IMMUNE-PROTECTED STEM CELL DERIVED CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>ANTICIPATED 2ND APPROVAL FOR DIABETES</td>
<td>ALL INSULIN DEPENDENT DIABETIC PATIENTS</td>
</tr>
<tr>
<td>CORRECTED PATIENT CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRE-CLINICAL</td>
<td>SEVERE HEMOPHILIA A PATIENTS</td>
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<tr>
<td>ALLOGRAFT IMMUNE-PROTECTED CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>EARLY DEVELOPMENT</td>
<td>BROADER HEMOPHILIA A PATIENTS</td>
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<tr>
<td>THYROID CELLS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PRE-CLINICAL</td>
<td>THYROIDECTOMY PATIENTS FOLLOWING HYPERTHYROIDISM</td>
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</table>

**T1D**

**Hemophilia A**

**Thyroid**
## Diabetes Market Opportunities

<table>
<thead>
<tr>
<th>IP Status</th>
<th>2020 Potential Patient Population (before market access considerations)</th>
<th>Potential Commercial Opportunity</th>
</tr>
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<tbody>
<tr>
<td></td>
<td><strong>T1D Severe HU with Human Donor Islets</strong></td>
<td><strong>T1D Severe HU with iPSC</strong></td>
</tr>
<tr>
<td><strong>U.S.</strong></td>
<td>~0.65 K Total Transplants</td>
<td>~240 K Patients</td>
</tr>
<tr>
<td>Granted</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>EU5</strong></td>
<td>~0.5 K</td>
<td>~195 K</td>
</tr>
<tr>
<td>Granted</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>APAC CHN &amp; JPN only</strong></td>
<td>~3.0 K</td>
<td>~1.0 M</td>
</tr>
<tr>
<td>Granted</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>~4.2 K Transplants</td>
<td>~1.4 M Patients</td>
</tr>
<tr>
<td>Sernova has a global IP portfolio across all key markets</td>
<td></td>
<td></td>
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</table>

HU = Hypoglycemia Unawareness  
Hypolgly. = Hypoglycemia
### Clinical Efficacy Data: Therapeutic C-peptide Levels Measured in Bloodstream

- **PEC-Direct**: Initiated Phase I/II in 2017 in high risk T1D patients; initial data released in 2019 demonstrated cells produce sub-therapeutic C-peptide\(^3\)
- **PEC-Encap**: Initiated Phase I/II in 2014, paused due to poor engraftment & restarted in 2019\(^4\)

### Device Vascularization Islet Engraftment Demonstrated in Humans

- **PEC-Direct**: Vascularizes directly\(^8\) & is verified in human trial\(^4\)
- **PEC-Encap**: Has surface diffusion\(^8\) but their trial was “paused” due to low levels of engraftment\(^9\) – to date human vascularization data is lacking

### Local Immune Protection Technology

- **PEC-Direct**: Program requires long-term immunosuppression\(^7\)
- **PEC-Encap**: Program may not require immunosuppression\(^7\) – to date human validation has not been demonstrated

### Financial Metrics (USD Millions)

- **Sernova’s market cap**: As of January 2021
- **As of August 2019**: Vertex acquired Semma for a $950 M cash payment\(^{11}\)
- **November 2018**: Raised $80 M Series D financing - undisclosed valuation\(^{11}\), total raised ~$240 M to date\(^{10}\)

### Further Information

- Pre-Clinical PoC data in pigs demonstrated the vascularization capability of stem cell encapsulating device\(^5\) – to date human vascularization data has not been generated

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HU: Hypoglycemia Unawareness; T1D: Type 1 Diabetes.
Entered clinic end of 2020 for hemophilia A using Shielded Living Therapeutics™ (SLTx™)

In experimental animal models, SLTx™ resisted fibrosis for up to 12 months to date human vascularization data has not been generated

Sigilon believes SLTx™ will negate the need for immunosuppression though human validation is lacking to date

Clinical Efficacy Data: Therapeutic C-peptide Levels Measured in Bloodstream

Device Vascularization Islet Engraftment Demonstrated in Humans

Local Immune Protection Technology

Company Press Release; Company Website; Company Press Release
Sernova Valuation Relative to Peers

- **Sernova’s peer group** - SIGILON and SEMMA

- **SVA Advancements over Peer Group**
  - Sernova US Phase I/II clinical trial with positive interim clinical results presented at ASTS Jan 15, 2021 vs. peer group lack of clinical data
  - Sernova: Diabetes + thyroid + hemophilia A – three indications with validated clinical/preclinical data vs. peer group single indication
  - SVA may well become a “must-have element” for ALL cell-based regenerative medicine providers and could thereby become a beneficiary of an a license fee from essentially the whole market of cell-based regenerative therapeutics

- **SVA’s value is “Peer Group Plus”** - members SIGILON and SEMMA valued at approximately USD1bn

<table>
<thead>
<tr>
<th>Sernova Valuation Calculation</th>
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<tbody>
<tr>
<td>SEMMA Vertex sale September 2019</td>
<td>USD$950M</td>
</tr>
<tr>
<td>SIGILON NASDAQ Listing - Market cap as of Jan. 15 2021</td>
<td>USD$1.1B</td>
</tr>
<tr>
<td>SUM</td>
<td>USD$2.079B</td>
</tr>
<tr>
<td>Average Valuation</td>
<td>USD$1.039.5</td>
</tr>
<tr>
<td>Sernova Equivalent US/CDN share price</td>
<td>USD$3.47; Canadian $4.40</td>
</tr>
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The Device Conundrum

“We thought the cells would be the hard part and focused our efforts there. It’s obvious now having a functional device will be the limiting factor and there are few current options.”

Big Pharma executive at 2020 JPM

The challenging device issues and hurdles conquered by Sernova:

- Scalability
- Vascularization
- Natural cell environment
- Fibrosis
- Cell engraftment
- Biocompatibility
- Versatility: human cells & tissue, stem cell derived islet cells
Immune Protection

Conformal Coating Technologies:

- Sernova’s proprietary cellular conformal coating technology - developed and optimized with years of research
- It consists of a thin biocompatible porous polymer hydrogel coating surrounding therapeutic cells (islets, stem cells)
- Proven to allow for physiological transfer of insulin and glucose unlike other encapsulation technologies
- Sernova is preparing for use within its Cell Pouch for islets, stem cell derived cells for multiple applications
- The potential to eliminate the need for anti-rejection medications significantly increases the number of treatable patients for Sernova’s clinical products

Gene-Editing Technologies:

- Sernova entered in a collaboration to evaluate the potential of Sernova’s pluripotent stem cell-derived pancreatic islet beta cells, and hemophilia cells engineered with AgeX’s UniverCyte technology, to evade human immune detection.
- UniverCyte uses a modified form of HLA-G, a potent immunomodulatory molecule, which in nature protects an unborn child from their mother’s immune system. AgeX’s modified HLA-G has the potential to allow for long-term, stable and high expression of the immunomodulatory effect.
- The complementary combination of technologies could enable the transplantation of therapeutic cells in patients with T1D in an off-the-shelf manner using Sernova’s Cell Pouch, without human leukocyte antigen (HLA) tissue matching or concurrent administration of immunosuppressive medications
Proprietary Cell Pouch is placed deep under the skin, allowing for vascularization & creating a natural environment for long-term function of therapeutic cells.

Therapeutics cells are transplanted directly into the vascularized tissue chambers of the proprietary Cell Pouch.

Therapeutic cells release missing proteins or hormones in the bloodstream to correct biological dysfunction.
## Diabetes Clinical Progress Summary

<table>
<thead>
<tr>
<th>Year</th>
<th>Highlights</th>
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</table>
| Pre 2018 | - Completion of first-in-human proof-of-concept study for diabetic condition HU  
- Clinical protocol & regulatory package development for US Ph I / II clinical trial for HU (T1D Study)  
- FDA IND clearance to commence T1D Study  
- T1D Study funding grant awarded by JDRF |
| 2018 | - Prominent diabetes clinical investigator Dr. Witkowski joins T1D Study  
- UChicago IRB approval obtained  
- Medtronic contracted for T1D Study CGM  
- T1D Study patient screening & recruitment initiated, 1st patient enrolled |
| 2019 | - Cell Pouch implantation into first T1D Study patient  
- Human islet cells transplantation into Cell Pouch in first T1D Study patient  
- T1D Study positive early safety & efficacy indicators observed  
- Enduring level of fasting C-peptide in bloodstream observed |
| 2020 | - Positive DSMB Review & Recommendation for Continuation of Ph I/II clinical trial  
- Positive Efficacy Endpoint – Survival of Endocrine Tissue  
- Ongoing T1D Study patient enrollment, treatment & follow-up |
Diabetes First Clinical Indication: HU

Hypoglycemia unawareness (HU), the most critical unmet need in diabetes, affects 15% of T1D patients (~240 K patients in the US alone)

- clinically defined as a complication of diabetes in which the patient is unaware of a deep drop in blood sugar
- patients do not experience hypoglycemia warning symptoms (palpitations, anxiety, excessive sweating, light headedness)
- harmful effects: diabetic ketoacidosis (DKA), coma & death

1st study population for Sernova's integrated RM therapeutic solution for lead indication of insulin-dependent diabetes
**US Ph I/II Study Design**

**Study Design:** Company-sponsored IND. Open-label, single-arm study. Human donor islets are transplanted into the Cell Pouch after implantation & stable anti-rejection medication activity has been established.

**Primary Objective:** To demonstrate the safety & tolerability of islet transplantation into the Cell Pouch for the treatment of HU in T1D subjects with a history of severe hypoglycemic episodes.

**Secondary Objectives:** To establish islet release criteria that accurately characterize the islet product & are predictive of clinical transplant outcomes into the Cell Pouch, demonstrated through defined efficacy measures:

- Survival of endocrine tissue in the Cell Pouch
- Proportion of subjects with a reduction in severe hypoglycemic events
- Proportion of subjects with a reduction in HbA1c >1mg%
- Over 20 additional endpoint analyses will occur

**Status:** Study Active & Ongoing

- IND allowance by FDA & protocol approved by IRB
- Multiple subjects implanted & transplanted
- Positive early findings announced
- Patient enrolment & recruitment ongoing
Incidence & severity of adverse events associated with Cell Pouch were monitored:

- **No incidences of AEs or SAEs** determined to be probable or highly probable to the Cell Pouch
- **Cell Pouch well-tolerated & safe** during the implant & the time of transplant
- **No reactions** to the Cell Pouch implant
- Cell Pouch **well-incorporated with vascularized tissue** & deemed suitable to receive the islet transplant

**CONCLUSION:** Safety findings continue to meet the primary endpoint of the study

**DSMB Review Statement (2020):** Recommendation that study continue as designed.
90-day post-transplant glucose tolerance test (i.e. patient given a high sugar drink) was administered over several hours:

- showed **increase in blood levels of C-peptide**
- showed **increase in blood levels of insulin**

**Early Efficacy Findings**

<table>
<thead>
<tr>
<th>Islet Transplant Status:</th>
<th>Before</th>
<th>3 Mo. After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bodyweight</td>
<td>83kg</td>
<td>73kg</td>
</tr>
<tr>
<td>Hemoglobin A1C</td>
<td>6.5</td>
<td>5.6</td>
</tr>
<tr>
<td>Daily Use Of Long Acting Insulin Tresiba</td>
<td>14U</td>
<td>8U</td>
</tr>
<tr>
<td>Daily Use Of Short Acting Insulin</td>
<td>15 – 16</td>
<td>14 – 15</td>
</tr>
<tr>
<td>Severe Hypoglycem. Events</td>
<td>4 per week</td>
<td>1 per week</td>
</tr>
</tbody>
</table>

*presented at IPITA Q3 2019 in Lyon, France

**SUBSEQUENT FINDING:** Enduring blood levels of C-peptide & ongoing evidence of islet engraftment & durable therapeutic effect detected post-second Cell Pouch islet dose
## US Ph I/II Case Study Early Findings

### Improvement in ALL CGM Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline</th>
<th>Post-transplant (90 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Glucose Value (mg/dL)</td>
<td>285</td>
<td>231</td>
</tr>
<tr>
<td>Low Glucose Value (mg/dL)</td>
<td>50</td>
<td>66*</td>
</tr>
<tr>
<td># Glucose Excursions</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td># High Excursions</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td># Low Excursions</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>37</td>
<td>31</td>
</tr>
</tbody>
</table>

* Lowest excursion was 66mg/dL and this occurred only once.
US Ph I/II 90-Days Post Transplant

Achievement of Secondary Endpoint

“Survival of endocrine tissue in the Cell Pouch™ (defined by positive staining of islets during histological analysis) [ Time Frame: 90±5 days post-transplant for sentinel Cell Pouch™ ]”

Independent Pathologist reported:

- abundant viable, organized islet cells
- intimately associated with blood vessels
- within a collagen matrix
- islet cells strongly express insulin

- Indicator of transplanted islet health in the therapeutic Cell Pouches remaining in the subject
- Ability to produce insulin and deliver to the bloodstream
- Previously demonstrated by reported findings of blood levels of both glucose-stimulated & fasting C-peptide plus other efficacy indicators
Clinical Study Update (Safety)

ENROLLMENT:

5 of the 7 patients have now been enrolled, implanted with Cell Pouches and are actively advancing through the transplantation phase of the study

➢ 5 of 7 patients have been implanted with the Cell Pouch

➢ 3 of 7 patients have received their first/one islet transplant

➢ 2 of 7 patients have received their first and second islet transplant

Pre-screening is ongoing for the final two patients and full enrollment of the study is anticipated to be completed in the first quarter of 2021

SAFETY (Primary Endpoint):

➢ Following implantation, consistent incorporation of the Cell Pouch with vascularized tissue providing a suitable environment for transplant of islets (insulin-producing cells)

➢ No incidence of Severe Adverse Events (SAEs) related to the Cell Pouch or islet transplant
Clinical Study Update (Efficacy)

Highlighting some of the trial efficacy findings with focus on clinical benefits to the T1D patients, the following trends have also been observed as of the presentation of Sernova’s clinical investigator on January 15, 2021 at the ASTS Winter Symposium.

**EFFICACY (Secondary Endpoint):**
- Absence of life threatening severe hypoglycemic events;
- Sustained blood levels of C-peptide (a biomarker for insulin produced by cells in the Cell Pouch);
- Reduction in HbA1c (a measure of long-term glucose control); and,
- Improvement in overall Continuous Glucose Monitoring (CGM) measured glucose control parameters (e.g., blood glucose ‘Time in Range’).

With the positive clinical benefit achieved in patients with Cell Pouch islets, one patient was later provided a single infusion of islets (portal vein). This top-up to the islets already received in the Cell Pouch contributed to this patient achieving and sustaining insulin independence. This patient has now been insulin free (requiring no injectable insulin) for nine months with optimal glucose control.
Earlier First-in-Human Study

Study Design
- T1D subjects with HU & a history of severe hypoglycemic episodes
- Open-label, single-arm
- Donor islet transplantation 2 – 24 weeks post Cell Pouch implantation
- Primary Endpoint: Safety post Cell Pouch implantation & 1-month post islet transplantation

Cell Pouch™ Clinical Histology
Insulin staining islets with microvessels

Cell Pouch and Islet Safety Endpoints Met
- Safety successfully met for the Cell Pouch
- Cell Pouch histology assessed by independent pathologists blinded to the treatment:
  - Islets housed within a natural tissue matrix
  - Islets were well-vascularized
  - Islet safety successfully met
  - Islets show evidence of insulin, somatostatin & glucagon
  - Cell Pouch & islet biocompatibility met
  - Proof of islet protection from immune system attack
Benefits of Sernova’s Cell Pouch with factor VIII releasing cells:

➢ Reduce / eliminate factor VIII infusions
➢ Maintain constant blood levels of factor VIII
➢ Reduce joint bleeds
➢ Improve long-term efficacy
➢ Improve QOL

Estimated Market

➢ ~20 K patients across North America & EU
➢ ~$10 B orphan indication

Standard of Care

➢ Patients receive regular infusions of missing clotting factors (i.e. factor VIII)
  • Infusions are highly expensive & burdensome
  • Select patients develop inhibitors, reducing the effectiveness of infusions

Therapeutic Goals

➢ Improved efficacy with prophylactic treatment; reduced cost; improved patient QOL; reduction of side effects

Sernova Approach

➢ Gene corrected own patient cells into the Cell Pouch (EU5.6M Horizon 2020 Consortium Grant)
➢ Potential treatment for all patients
  • Stem cell releasing factor VIII product

Status

➢ Completed pre-clinical proof-of-concept
  • Cell manufacturing process developed
  • Corrected patient cells survive & produce factor VIII in pre-clinical hemophilia model
➢ Further development being scoped
Thyroid Disease Program

Benefits of Sernova’s Cell Pouch with Thyroid releasing cells:

➢ Reduce / eliminate daily life long thyroid medications
➢ Recover natural feedback loop of thyroid hormones
➢ Reduce side effects from low thyroid hormone levels
➢ Improve long-term efficacy
➢ Improve QOL

Therapeutic Benefits

Estimated Market
➢ 150,000 thyroidectomies performed annually in US
➢ ~$2.2 B market opportunity

Standard of Care
➢ Patients require lifelong thyroid hormone replacement therapy
➢ Various oral / IV / other therapies may also be needed depending on underlying condition

Therapeutic Goals
➢ Improved efficacy with prophylactic treatment; improved patient QOL; reduction of side effects

Sernova Approach
➢ Thyroidectomy patient healthy tissue isolated & transplanted into the Cell Pouch
➢ Patient cells survive within the Cell Pouch & produce thyroid hormone

Status
➢ Completed pre-clinical proof-of-concept
➢ Clinical program under development
NEXT STEPS – Action Plan

➢ Develop licensed/acquired local immune-protection technologies for therapeutic cells
➢ Advance local immune-protected diabetes stem cell technology in preparation for First-in-Man (FIM) study
➢ Expand existing strong worldwide multi-family patent portfolio

➢ Complete T1D Study patient enrolment
➢ Continue T1D Study patient treatment & follow up
➢ Ongoing T1D Study safety & efficacy data evaluation
➢ Strategic pharma / medtech collaboration(s) expansion

➢ HemAcure study results conference presentation & publication
➢ Market & product positioning assessment
➢ Regulatory & Clinical plan development

➢ Complete Pre-Clinical studies
➢ Prepare & submit FIM regulatory package
Management Team

Dr. Philip Toleikis
PRESIDENT & CEO
- 20+ years experience in biotech management & product development in pharmaceutical & combination products.
- Previous Angiotech VP R&D (achieved $2 B market cap; product revenue $200 M per year).

David Swetlow CPA, CA
CFO
- 20+ years experience in life sciences (biopharma, combination products & devices) & high-tech industries, including Ondine, Protox, QLT, Xillix.
- Various senior management, board & advisory roles. Nasdaq & TSX experience.

Delfina M. Mazzuca-Siroen
SR. DIRECTOR & HEAD OF R&D / CLINICAL
- 20+ years senior management roles in R&D, clinical, regulatory, product development.
- Biochemistry, translational cell biology, device & transplantation expertise.
- Publications & patents author / co-author.

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