Edesa Biotech

# Corporate Presentation

Edesa Biotech, Inc.
Nasdaq: EDSA

September 2020

# Forward Looking Statements

**This presentation may contain forward-looking statements** within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by the use of words such as "anticipate," “believe,” "plan," “estimate,” "expect," "intend," "may," "will," "would," "could," "should," “might,” “potential,” or "continue" and variations or similar expressions. You should not place undue reliance on these forward-looking statements, which are not a guarantee of future performance. There can be no assurance that forward-looking statements will prove to be accurate, as all such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results or future events to differ materially from the forward-looking statements. Such risks include: the ability of Edesa to obtain regulatory approval for or successfully commercialize any of its product candidates, the risk that access to sufficient capital to fund Edesa's operations may not be available or may be available on terms that are not commercially favorable to Edesa, the risk that Edesa's product candidates may not be effective against the diseases tested in its clinical trials, the risk that Edesa fails to comply with the terms of license agreements with third parties and as a result loses the right to use key intellectual property in its business, Edesa's ability to protect its intellectual property and the timing and success of submission, acceptance and approval of regulatory filings. Many of these factors that will determine actual results are beyond the company's ability to control or predict. For a discussion of further risks and uncertainties related to Edesa’s business, please refer to the Company’s public company reports filed with the B.C. Securities Commission and the U.S. Securities and Exchange Commission. All forward-looking statements are made as of the date hereof and are subject to change. Except as required by law, the Company assumes no obligation to update such statements. This presentation does not constitute an offer or solicitation of an offer for sale of any securities in any jurisdiction, including the United States. Note: All financial and share price information is presented in U.S. dollars.

# Advancing Clinical-Stage Drug Candidates

## Focus on Immune Modulation Therapies and Inflammatory Diseases

**Exploring new ways to treat diseases, including alternatives to topical steroids**

- **Novel anti-inflammatory technology**
  Topical sPLA2 inhibitor with demonstrated efficacy in two previous clinical studies
- **Expanding portfolio**
  Two biologics acquired April 2020
  Compelling data for ARDS associated with COVID-19
- **Phase 2b study initiated for lead candidate**
  Targeting allergic contact dermatitis
- **CTA approvals**
  Phase 2/Phase3 study in ARDS
  Proof-of-concept study in hemorrhoids
- **Entrepreneurial leadership**
  Multiple successful start-ups and exits

EDSA
Nasdaq
LISTED

| | |
|---|---|
| **Sector:** | Biotechnology |
| **Headquarters:** | Toronto, Ontario |
| **Established:** | 2015 |
| **Public:** | 2019 |

# Edesa Development Pipeline

## Advancing and Expanding Our Growth Opportunities

| Drug Candidates | | Indications | Pre-Clinical | Phase 1 | Phase 2 | Phase 3 | |
|---|---|---|---|---|---|---|---|
| **EB01** | sPLA2 Inhibitor | **Allergic Contact Dermatitis** | | | | **Enrollment Continuing** | |
| **EB02** | sPLA2 Inhibitor | **Hemorrhoids** | | | | **CTA Approved** | |
| **EB04** | Not Disclosed | **Anal Fissures** | | | | **Growth Opportunity** | |
| **EB05** | Anti-TLR4 mAb | **ARDS and Other Indications** | | | | **CTA Approved June 2020** | |
| **EB06** | Anti-CXCL10 mAb | **ARDS and Other Indications** | | | | **Growth Opportunities** | |
| **Immunotherapy** | Not Disclosed | **Vitiligo** | | | | **Producing mAbs for Novel Targets** | |

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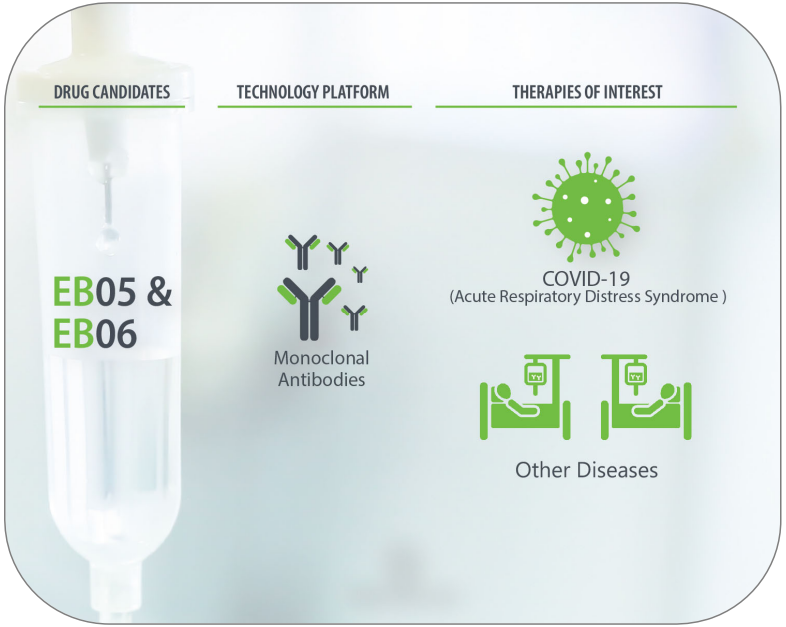
# Edesa Monoclonal Antibodies

## Compelling Data for Use in COVID19 & Beyond

- **Potential to reduce the number of ICU patients, intubation procedures and death**
  - Compelling evidence of activity in acute lung injury
  - Favorable human safety data (>120 subjects)
- **Ability to quickly move into the clinic**
  - Approved protocol from Health Canada
  - Drug product already manufactured
  - IND application filed
  - Seeking government grants to rapidly advance
- **Broad potential utility**
  - By targeting ARDS, could be effective against future strains of coronaviruses and other respiratory pathogens

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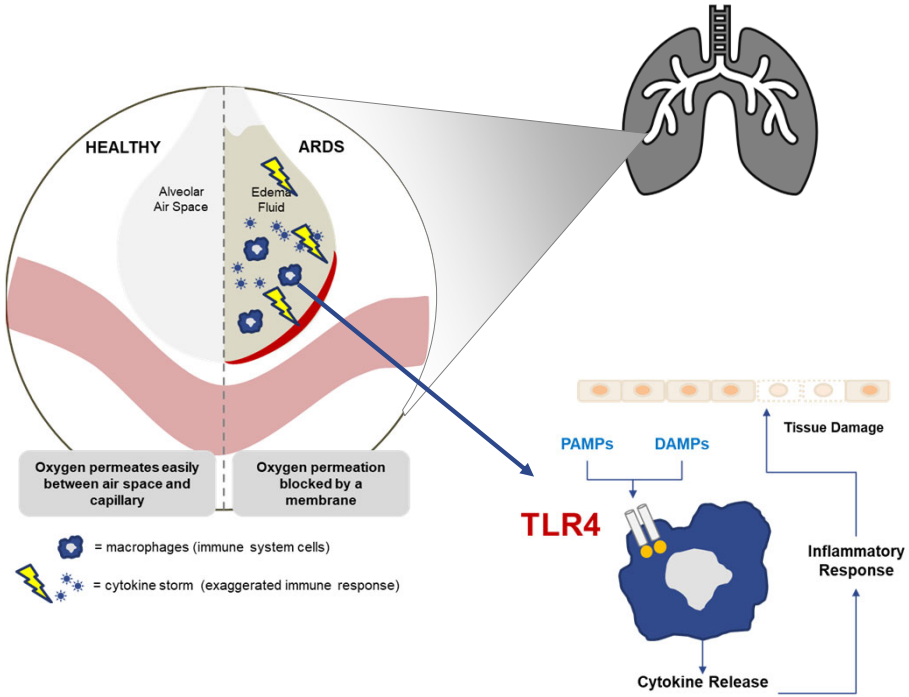
# Acute Respiratory Distress Syndrome (ARDS)

## Leading Cause of Death in COVID-19 Patients




- **A life-threatening form of respiratory failure**
  - Exaggerated immune response
  - Inflammation and injury to the lungs
  - Edema that deprives the body of oxygen
- **Other causes**
  - Sepsis, bacterial and viral infection
  - Smoke/chemical inhalation and chest injury
- **Standard of care**
  - Few meaningful treatments, other than supplemental oxygen and mechanical ventilation
- **Disease incidence**
  - Prior to COVID-19: 10% of ICU admissions
  - 3 million patients globally/year, including 200K in US
  - 75,000 deaths annually in US
- **Substantial evidence that multiple causes of ARDS are mediated by the TLR4 pathway**

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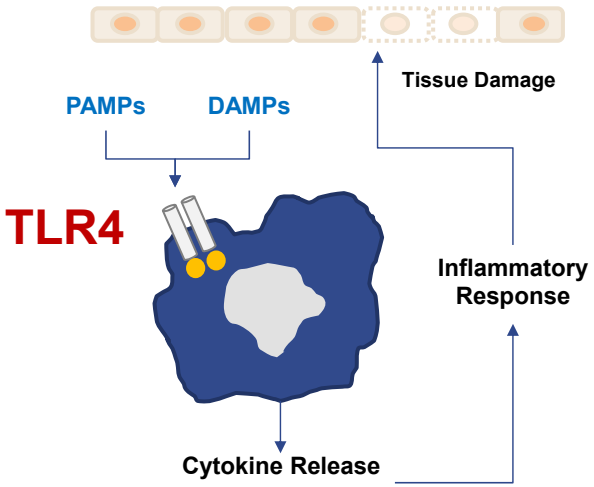
# Toll-like Receptor 4 (TLR4)

## A Key Component of Innate Immune Response




- Key receptor as part of the innate immune response, discovered in 1997. A Nobel prize was awarded in 2011
- TLR4 is activated both by pathogen-associated molecular patterns (PAMPs) such as LPS, and damage-associated molecular patterns (DAMPs)
- TLR4 is expressed on activated macrophages and neutrophils which are part of the innate immune system
- Activation leads to release of cytokines that trigger inflammation to help fight the infection, and chemokines that help activate and direct the adaptive immune response
- TLR4 plays a critical role in the first few days of infection, before the adaptive response is primed

**TLR4 has been shown to be important in the pathogenesis of ARDS**

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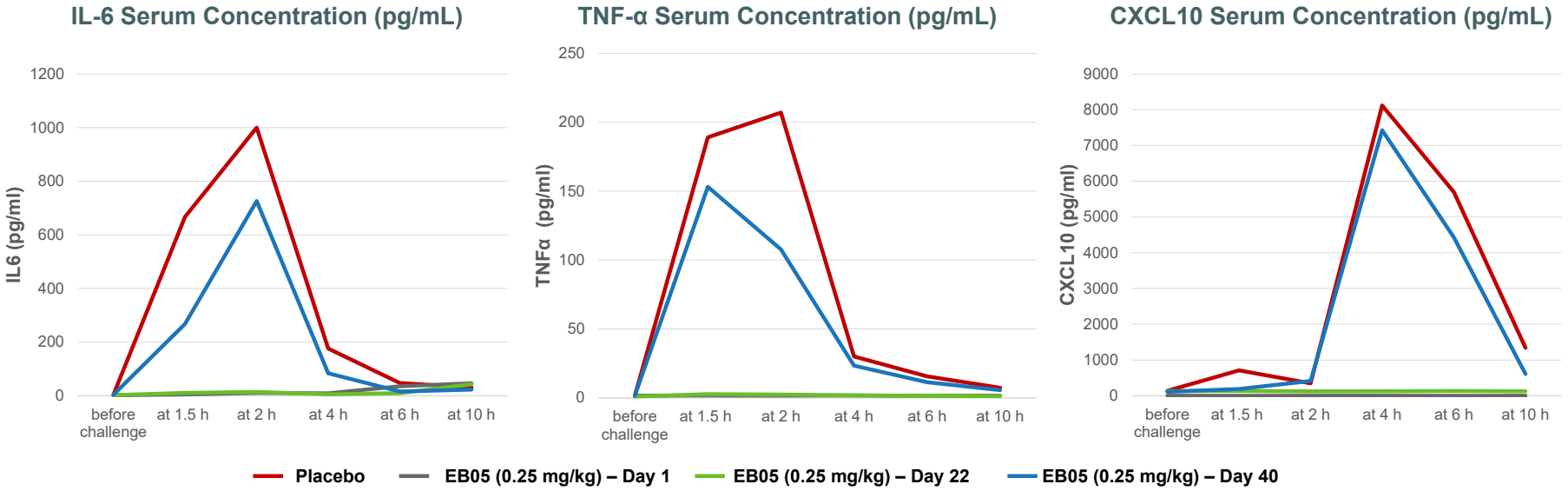
# Evidence of Activity in Humans

## EB05 Inhibited “Cytokine Storm” after *In Vivo* LPS Challenge




**A single low dose provided a measurable protective response to the LPS challenge for more than 22 days. At Day 40, response returning to normal.**

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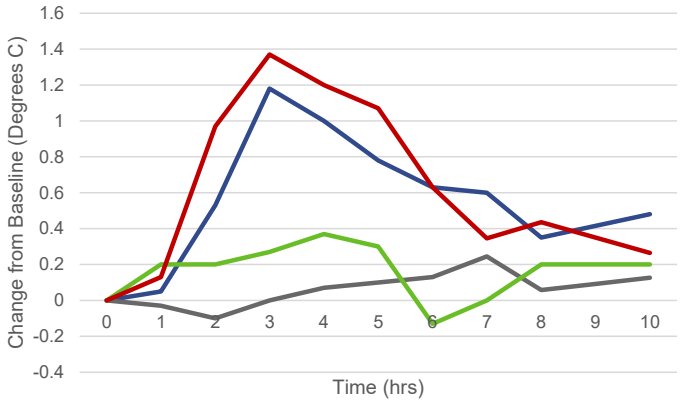
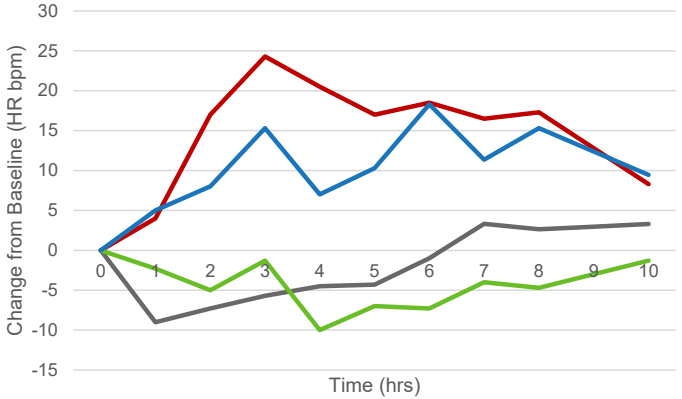
# Evidence of Activity in Humans

## EB05 Lowered Fever and Stabilized Vital Signs after *In Vivo* LPS Challenge

### Mean Change from Baseline of Temperature




### Mean Change from Baseline of Heart Rate




Placebo — EB05 (0.25 mg/kg) – Day 1 — EB05 (0.25 mg/kg) – Day 22 — EB05 (0.25 mg/kg) – Day 40

**A single low dose blocked fever by more than 1 degree Celsius and maintained heart rate during LPS challenges for more than 22 days. At Day 40, response returning to normal.**

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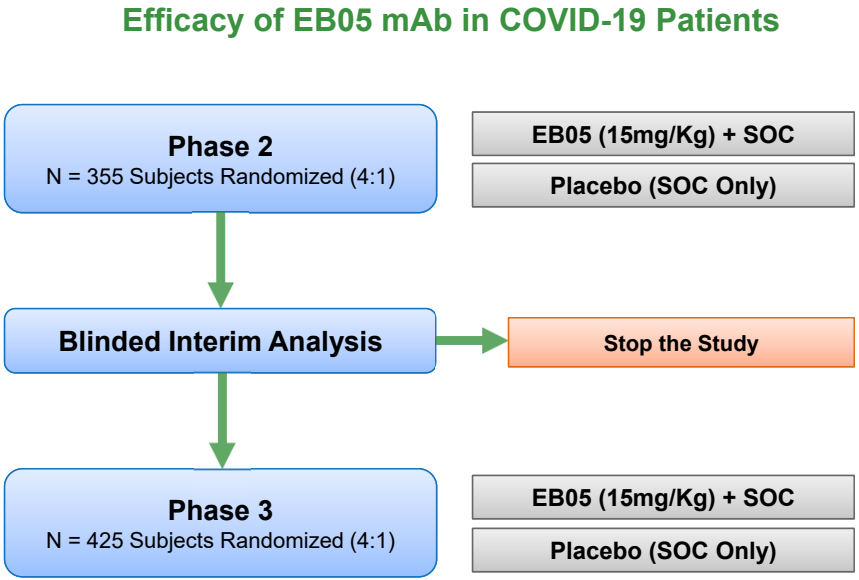
# Overview of Clinical Trial Design

## A Phase 2/3 Adaptive Design to Study Prevention and Treatment of ARDS




- **Sequential adaptive design with interim analysis**
  - Targeting COVID-19 patients at greatest risk of progressing to ARDS
- **Primary Endpoint**
  - Proportion of patients with clinical improvement at 28 days of follow-up
- **Randomization**
  - EB05+SOC to Placebo (SOC alone)
  - Option to rescue Placebo with EB05
- **Up to 30 sites in North America**

SOC = Standard of care

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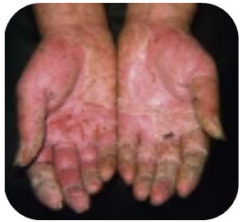
# Allergic Contact Dermatitis
## Disease State and current Treatments



**Allergic Contact Dermatitis (ACD) is a Type IV hypersensitivity reaction**

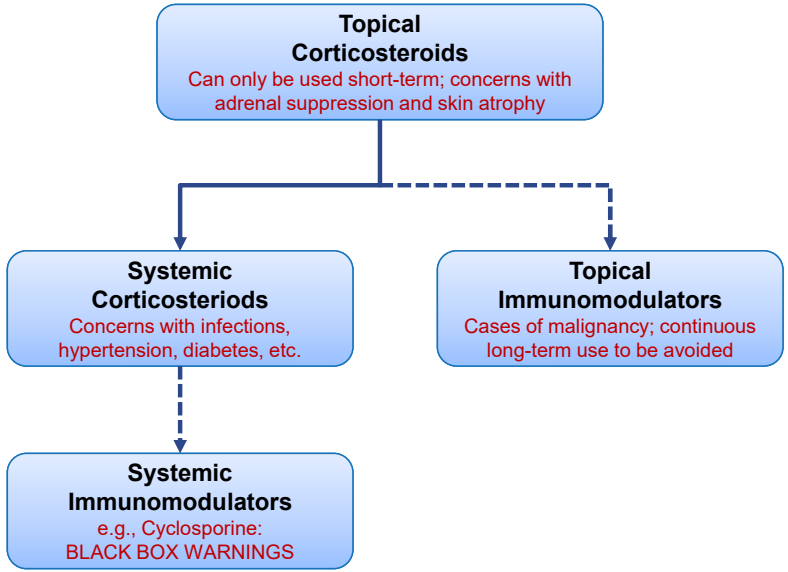
- Immune system sensitized with initial contact with allergen
- Subsequent contact results in cell-mediated allergic response at the point of contact
- Often highly visible on face & hands

**Shortcomings of current therapies***

- Low efficacy and high remission rates
- Steroids have significant side effects
- Physicians unable to identify the cause of ACD in about half of patients
- 71% of patients unable to fully avoid allergen (e.g., present at work)

### Current Limited Treatment Approaches for ACD

***Safety Issues Often Result in Discontinuation of Treatment***

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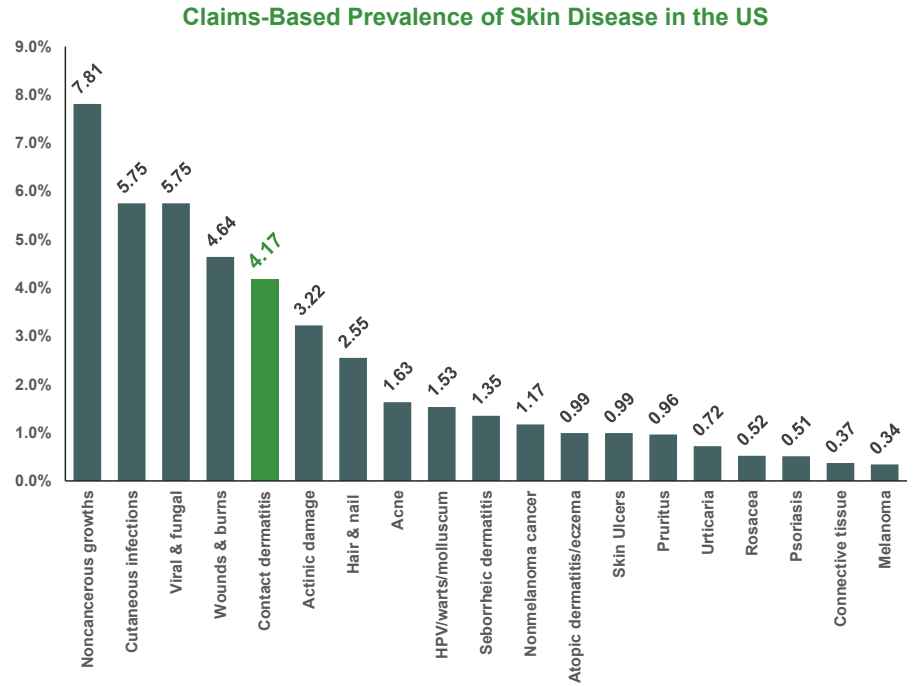
* Edesa Biotech quantitative market research

# Contact Dermatitis

## One of the most prevalent skin conditions in U.S.




- **Contact dermatitis is a leading occupational illness affecting 13.2 million people in U.S. at a cost of up to ~$2 billion annually**
- **ACD represents a submarket of contact dermatitis**
  - 2.5+ million with ACD in the U.S.
  - 1.0+ million of those patients with chronic ACD.
  - Literature points to potentially larger undiagnosed population

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Sources: The burden of skin disease in the United States. Lim, Henry W. et al., Journal of the American Academy of Dermatology, Volume 76, Issue 5, 958 - 972.e2; US 2012 (Cashman et al 2012); US 2002 (Rietshel et al 2002) and Edesa Biotech quantitative research estimates

# Occupational Contact Dermatitis

## Adversely Impacts Both Employers and Employees

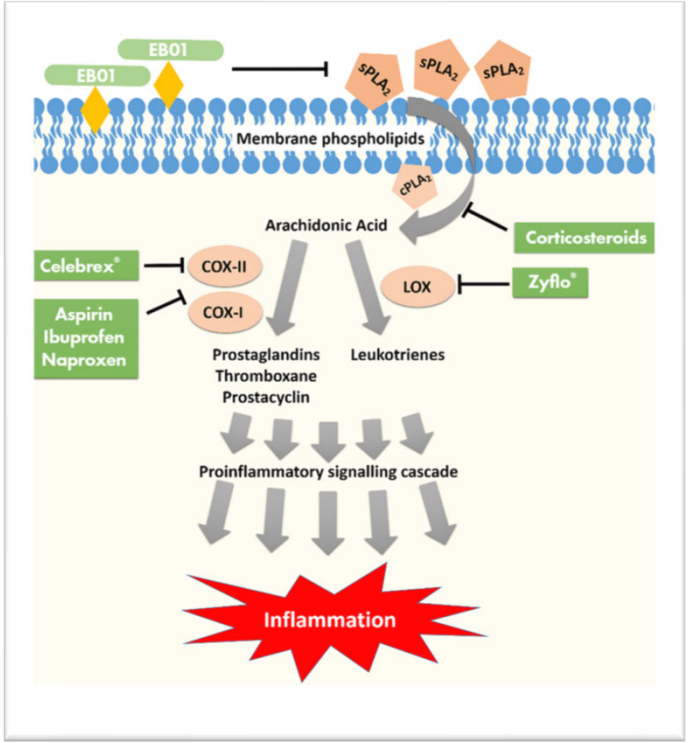
- **Loss of Productivity**
  - Physical and emotional distress
  - Multiple physician visits
  - Prolonged sick leaves
- **Complexity of Mitigation**
  - Time to identify allergen
  - Allergen avoidance measures
    - Change in work responsibilities
    - Substitution of materials
  - Changes not always feasible
- **Increased Legal Risk**
  - Lost income
  - Disability claims

| Industry | Substances |
|---|---|
| **Agriculture** | Daffodils, tulips, carrots, parsnips, parsley, celery |
| **Chemical** | Adhesives, paints, acrylates, acids/bases, solvents |
| **Cleaning** | Anti-bacterial wash/gels, disinfectants, bleaches |
| **Construction** | Cement, plaster, concrete |
| **Cosmetics and Hair** | Dyes, perming solutions, shampoos, lotions, bleaches |
| **Engineering** | Soluble metal-working fluids |
| **Healthcare** | Biocides, latex, glutaraldehyde, formaldehyde |
| **Restaurant & Food** | Orange/lemon peel, shellfish, meat, sugar, flour |
| **Printing** | Inks, solvents, cleaners |
| **Rubber** | Thiurams and related chemicals |

# Novel Approaches to Chronic Conditions

## Treating Inflammation without the Safety Concerns of Current Therapies

- **Inhibiting the Inflammation Cascade**
  - **sPLA2 inhibitors** are designed to inhibit the inflammatory process at its inception
  - Exerts its anti-inflammatory activity upstream of currently approved NSAIDs
  - Positive data from two clinical studies
  - Positioning as alternative to topical corticosteroids




Inflammation inhibitors were developed to inhibit sPLA2 from degrading phospholipids to produce arachidonic acid. Arachidonic acid is processed via the LOX-COX pathway to produce several pro-inflammatory signaling molecules

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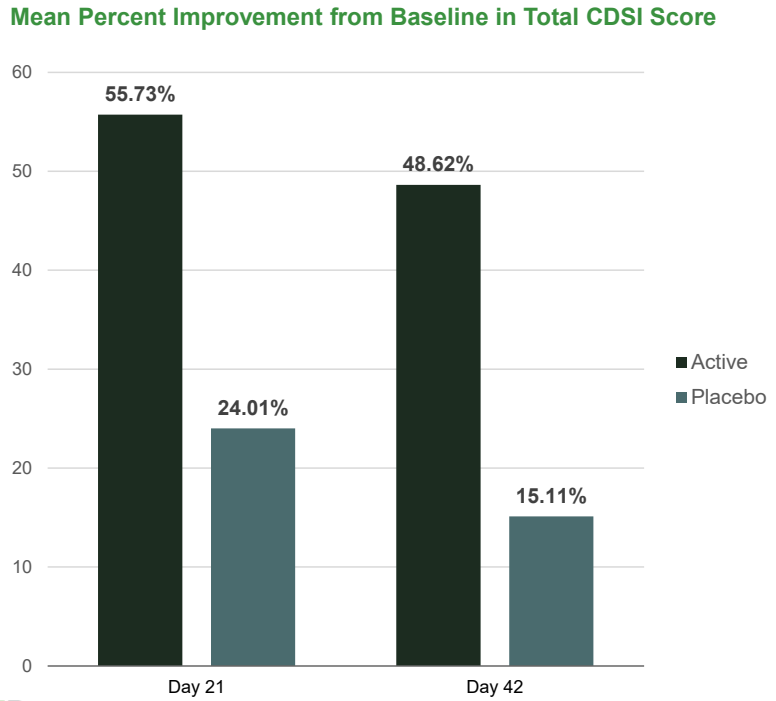
# EB01 Efficacy in Humans Established

## Phase 2 Study Demonstrated Efficacy & Safety in ACD Patients




### Phase 2 Efficacy Study of EB01

For the treatment of allergic contact dermatitis
— 30 Patients Bilateral Design —

- ***Efficacy:*** At Day 21, EB01 Cream 2% treated hands had a significantly lower Contact Dermatitis Severity Index (CDSI) score compared to Vehicle ($p < 0.001$)
- ***Durability:*** At Day 42, EB01 Cream 2% treated hands maintained a significantly lower total CDSI score compared to Vehicle ($p = 0.003$)
- ***Safety:*** no serious adverse events or discontinuations due to adverse events

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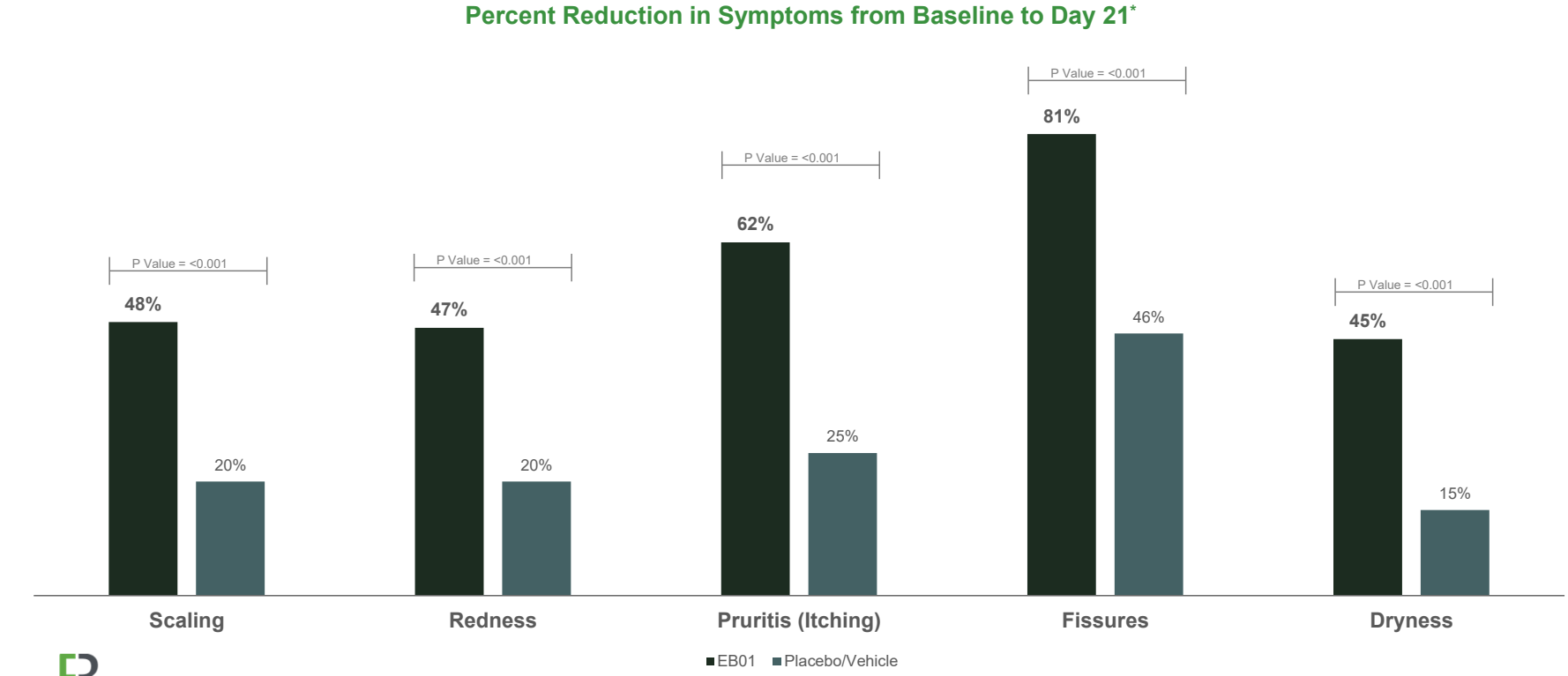
# Phase 2 Efficacy Study – Breakdown by Component

## EB01 Addressed All Aspects of CDSI Composite Score

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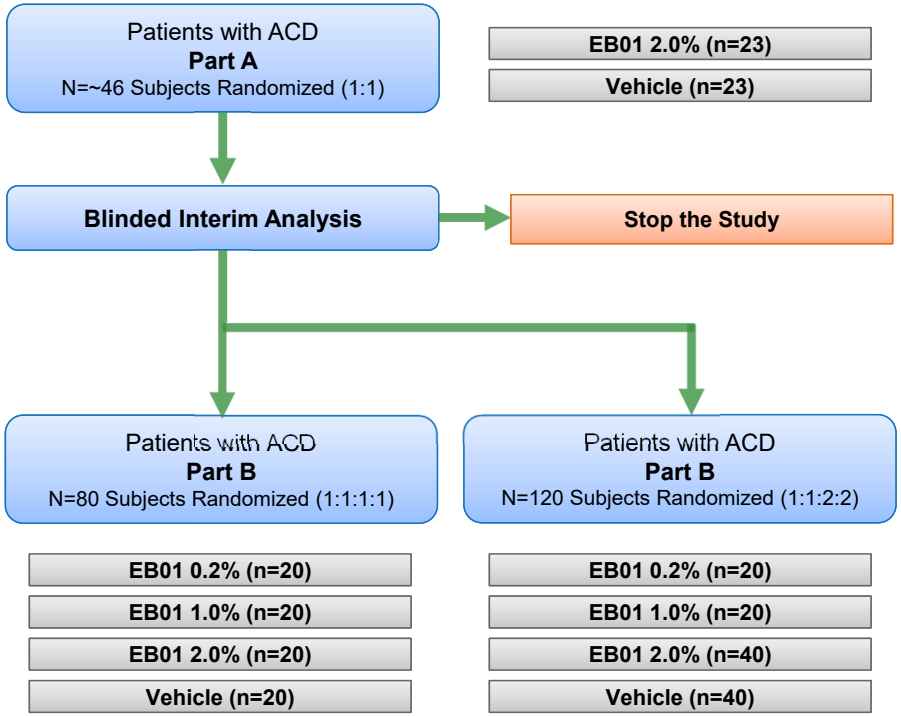
* Contact Dermatitis Severity Index (CDSI) score comparison between treatment groups using Paired T-test/Wilcoxon Rank Sum Test (n = 30). P Value = <0.001

# EB01 Phase 2b Study Plan

## Adaptive Design up to 166 Patients




### Primary Efficacy Endpoint

*Mean Percent Change from Baseline in Contact Dermatitis Severity Index (CDSI) at Day 29*

### Protocol

- EB01 evaluated a randomized, double-blind, vehicle-controlled, sample size adaptive design.
- ACD patients in this study will be treated for 28 days with various strengths of EB01 cream.
- Interim analysis following the enrollment of the first cohort

### Primary Endpoints

- Primary outcome measures will evaluate efficacy and safety

### Secondary Endpoints

- Symptom reduction and quality of life
- Dose-relationships among various strengths of EB01 cream
- Number of TEAEs

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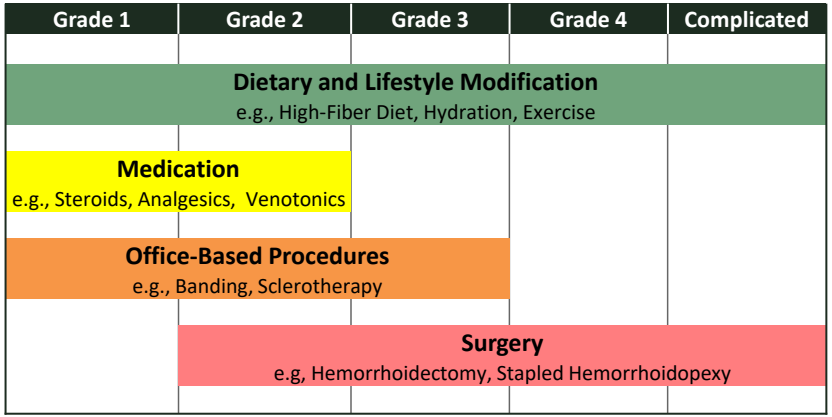
# Hemorrhoids Disease (HD)
## Extension of sPLA2 Anti-Inflammatory Tech

- **12.5 million adults affected in U.S.**[1]
  - By 50 years old, ~50% have experienced symptomatic hemorrhoids
- **Risk factors**
  - Aging, obesity, pregnancy & lifestyle
- **Drug treatments for HD entered market pre-1962**
  - 4 million physician visits
  - 20+ million over-the-counter units – limited empirical evidence of efficacy
  - General mechanisms of action: steroids & analgesics

**Treatments of Internal Hemorrhoids**[2]
**Based on their Severity and Degree of Prolapse**

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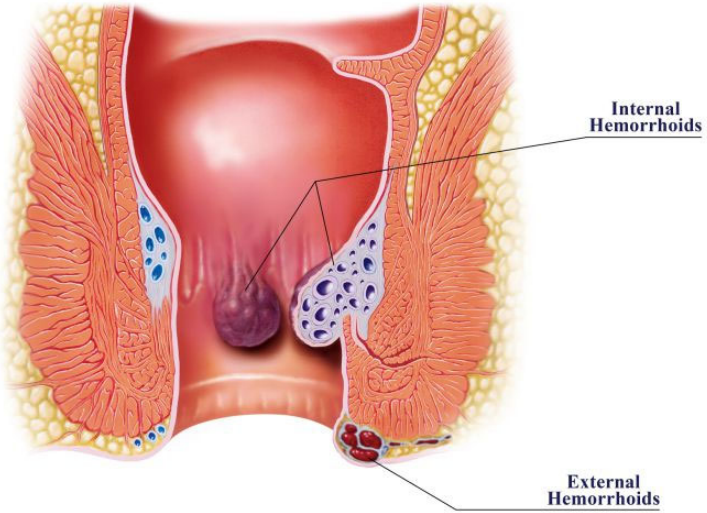
1) U.S. National Institutes of Health 2) World J Gastroenterol. Aug 21, 2015; 21(31): 9245-9252

# EB02 Program

## Targeting clinical relief of itching, pain and thrombosis of HD

- **Multifactorial etiology of HD**
  - Inflammation involving the vascular wall and surrounding connective tissue
  - Hyper-perfusion of hemorrhoid plexus
  - Prolapse
- **Hemorrhoidal tissue contains**
  - Inflammatory cells and
  - Newly formed microvessels
- **Inflammatory reaction is associated with key symptoms**
  - Mucosal ulceration
  - Ischemia
  - Thrombosis




**sPLA2 has been demonstrated to mediate processes that characterize hemorrhoidal pathophysiology, including inflammation and micro-vascularization**

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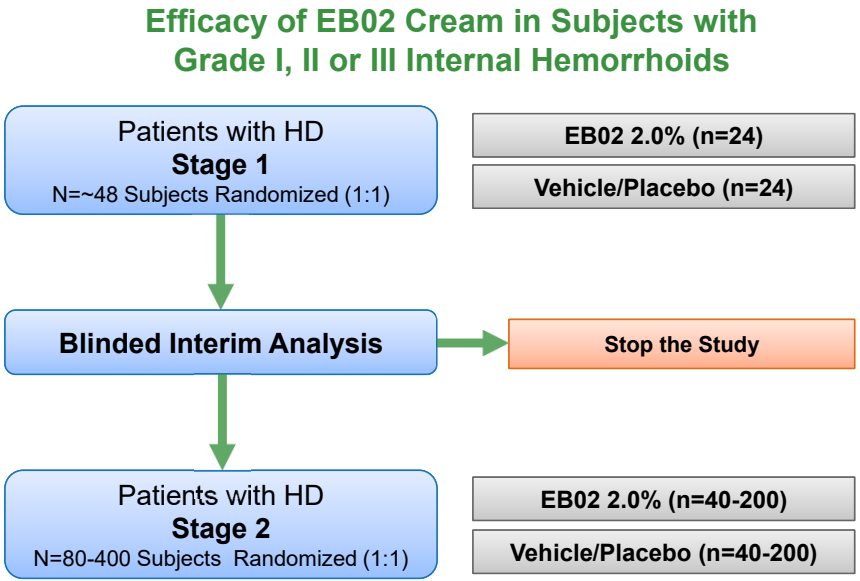
# EB02 Proof of Concept Phase 2a Study Plan




**Protocol**

- EB02 will be evaluated in a randomized, double-blind, vehicle-controlled, two stage design.
- Patients will be treated for 14 days and a 7-day follow-up exam.
- Patients will be assessed at baseline, 2, 7, 14 and 21 days after initiation of treatment.

**Primary Endpoints**

- Primary outcome measures will evaluate efficacy, symptom reduction

**Secondary Endpoints**

- Safety and tolerability

**Stage 2**

- Total sample size based on interim analysis

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# Cash Position

## Historical Overview and Future Outlook

- **Balance sheet**
  - Working capital focused on clinical programs
  - No long-term debt
- **Flexibility**
  - Use of CROs and CMOs
  - Adaptive study design
  - Timing of clinical opex aligned with study advancements

| Selected Financials<br>As of June 30, 2020 | |
|---|---|
| **Cash & Cash Equiv.** | $5.64 M* |
| **Total Assets** | $8.92 M |
| **Working Capital** | $5.24 M |
| **Debt** | $0.00 M |

* Does not include cash proceeds of $2.42 million from exercises of common share purchase warrants as of August 10, 2020

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# Capitalization Table

## As of August 10, 2020

| Description | Weighted Average Exercise Price | Common Shares and Common Share Equivalents |
|---|---|---|
| **Common Shares** | | **9,414,278** |
| A-1 Convertible Preferred Shares | $2.26[1] | 1,106,000 |
| Options Outstanding[2] | $3.17 | 671,677 |
| Warrants | $4.78 | 1,189,112 |
| **Fully Diluted Shares** | | **12,381,067** |

[1] Fixed conversion price; convertible beginning October 18, 2020
[2] 2019 Equity Incentive Compensation Plan as of June 30, 2020

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# Current Holders of Common Shares

## Simplified Beneficial Ownership Table as of August 2020

| Holders | Shares | Percent Shares Outstanding | Share Options | Warrant Shares | Percent Fully Diluted |
|---|---|---|---|---|---|
| **Directors and Officers** | | | | | |
| Par Nijhawan | 2,885,430 | 30.7% | 49,110 | 11,570 | 23.8% |
| Lorin Johnson | 8,524 | 0.1% | 11,389 | 10,655 | 0.3% |
| Sean MacDonald | 14,369 | 0.2% | 11,389 | | 0.2% |
| Frank Oakes | 7,383 | 0.1% | 12,341 | 1,523 | 0.2% |
| Paul Pay | 2,436 | - | 43,788 | 3,045 | 0.4% |
| Carlo Sistilli | 2,436 | - | 11,389 | 3,045 | 0.1% |
| Peter van der Velden | 2,002,568* | 21.3% | 11,389 | 175,784 | 17.7% |
| Michael Brooks | 4,327 | - | 231,323 | 2,285 | 1.9% |
| Kathi Niffenegger | 1,218 | - | 90,674 | 1,523 | 0.8% |
| **All directors and officers** | **4,928,691** | **52.4%** | **472,792** | **209,430** | **45.3%** |

Early Series Financing from Life Science Specialists

LUMIRA VENTURES

pharma science

INVEREADY Technology Investment Group

Edesa Biotech

* Held by Lumira Capital II, L.P. and Lumira Capital II (International), L.P.

# Experienced Leadership Team

## Pharmaceutical Pipelines, Corporate Development & Strategic Transactions

### Senior Management Team

| | |
|---|---|
| **Par Nijhawan, MD, FRCPC, AGAF**<br>CEO and Board Director | • Board-certified gastroenterologist and hepatologist • Successful track record of building life science businesses, including Medical Futures (sold to Tribute Pharma) |
| **Michael Brooks, PhD, MBA**<br>President | • Experienced pharma corporate development • Led multiple engagements and technology acquisitions • Previously at Cipher Pharma. • Science to Business Scholar at Univ. of Toronto |
| **Kathi Niffenegger, CPA**<br>Chief Financial Officer | • 30+ years in acct. & finance, including pharma • Previously partner at Glenn Burdette CPAs and CFO at Stellar Biotechnologies and Martin Aviation. |
| **Blair Gordon, PhD**<br>VP, Research & Development | • Leads mgmt. of Edesa clinical studies • Previously med affairs and bus. dev. at Cipher Pharma and ArcticDX. • Univ. of Toronto Alexander Graham Bell Fellow |
| **Gary Koppenjan**<br>VP, Investor Relations & Comm | • 25 years of experience in marketing and business development in the life sciences • Multiple private & public financings and merger transactions |

### Edesa Board of Directors

**Sean MacDonald**
Chief Executive, Corbin Therapeutics Inc.

**Paul William Pay**
Chief Business Development Officer, Norgine

**Peter van der Velden**
Managing General Partner, Lumira Ventures

**Frank Oakes**
Former CEO, Stellar Biotechnologies

**Lorin Johnson, PhD**
CSO, Glycyx; co-founded Salix Pharma

**Carlo Sistilli**
CFO, Arista Homes

# Edesa Biotech Highlights

- **Novel technologies**
  - Inflammation inhibitor: positive evidence from two previous clinical studies
  - TLR4 and CXCL10 antagonists
- **Targeting patient populations with unmet medical needs**
  - Chronic ACD
  - ARDS, including COVID-19
- **Working capital flexibility**
- **Active calendar of clinical and corporate milestones**
  - Phase 2b study of EB01
  - Phase 2/3 ARDS study
  - Expanding indications for sPLA2 technology, including HD
  - Business development

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## Company Contacts


**Par Nijhawan**
Chief Executive Officer

**Michael Brooks**
President

**Gary Koppenjan**
Investor Relations

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