

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

**FORM 8-K**

**CURRENT REPORT**

**PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): March 2, 2021

**ADAMIS PHARMACEUTICALS CORPORATION**

(Exact Name of Registrant as Specified in Charter)

**Delaware**

(State or other jurisdiction  
of incorporation)

**0-26372**

(Commission File Number)

**82-0429727**

(IRS Employer  
Identification No.)

**11682 El Camino Real, Suite 300**

**San Diego, CA**

(Address of Principal Executive Offices)

**92130**

(Zip Code)

Registrant's telephone number, including area code: **(858) 997-2400**

(Former name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ADMP	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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## Item 7.01 Regulation FD Disclosure

On March 2, 2021, Adamis Pharmaceuticals Corporation (the “Company”) posted a corporate presentation to its website. The corporate presentation is available under the “Events and Presentations” tab in the “Investors” section of the Company’s website, located at [www.adamispharma.com](http://www.adamispharma.com).

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as may be expressly set forth by specific reference in such filing or document. Item 7.01 of this Report and the furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the presentation is summary information that is intended to be considered in the context of more complete information included in the Company’s filings with the U.S. Securities and Exchange Commission and other public announcements that the Company has made and may make from time to time by press release or otherwise. Except to the extent required by applicable law, the Company undertakes no duty or obligation to update or revise the information contained in this report or in the presentation.

## Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Exhibit Description
<a href="#">99.1</a>	<a href="#">Corporate Presentation dated March 2021</a>
104	Cover page interactive data file (embedded within the Inline XBRL document).

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**SIGNATURES**

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

**ADAMIS PHARMACEUTICALS CORPORATION**

Dated: March 2, 2021

By: /s/ Robert O. Hopkins

Name: Robert O. Hopkins

Title: Chief Financial Officer

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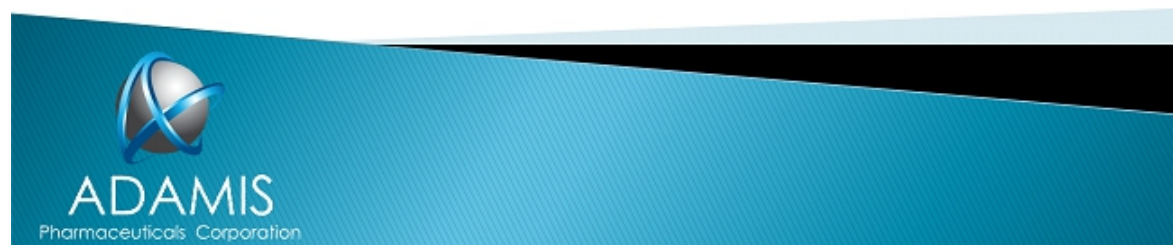


# Adamis Pharmaceuticals

## Corporate Presentation

with Overview of Products & Development Pipeline

March 2021



# Safe Harbor Statement

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This presentation contains "forward-looking statements" as that term is defined under the Private Securities Litigation Reform Act of 1995 (PSLRA), including statements regarding expectations, beliefs or intentions regarding our business, financial position, technologies, products, product candidates, strategies and prospects. These statements are made based upon current expectations that are subject to risk and uncertainty and information available to the Company as of the date of this presentation. Actual events or performance may differ materially from our expectations indicated by these forward-looking statements due to a number of risks and uncertainties, including, but not limited to, the commercial success of our products, regulatory actions taken by the FDA or other federal or state agencies, results of our pending and future clinical studies, the timeline for clinical and manufacturing activities, regulatory approvals and commercialization activities, particular regulatory pathways to approval for our product candidates, developments in current or future legal proceedings, our ability to raise additional capital as needed, and other risks and uncertainties more fully described in our filings with the Securities and Exchange Commission (SEC), including the factors referenced in the "Risk Factors" section of the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC, and other reports that we file with the SEC, which are all available at <http://www.sec.gov>.

We caution you not to place undue reliance on any of these forward-looking statements, which speak only as of the date of this presentation. Except as may be required by law, the Company does not undertake to update forward-looking statements in this presentation to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking information. The Company intends that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA, to the extent applicable.



# Corporate Overview

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- ▶ Adamis Pharmaceuticals Corporation (Adamis) is a specialty biopharmaceutical company primarily focused on developing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease
- ▶ Adamis' epinephrine injection products are approved by the U.S. Food & Drug Administration (FDA) for use in the emergency treatment of acute allergic reactions, including anaphylaxis and launched in 2019
- ▶ Adamis' high-dose naloxone injection product candidate is intended for the reversal of opioid overdose; the Company has submitted responses to the deficiencies identified in the CRL received in November 2020
- ▶ The Company has other pipeline products in varying stages of development



## Q1 Corporate Highlights

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- ▶ FDA cleared the Company to proceed with the clinical investigation of Tempol for the treatment of coronavirus in COVID-19 positive patients
- ▶ Positive data from Stanford University study showing Tempol suppressed cytokine production in cells from COVID-19 patients
- ▶ Walgreens added both SYMJEPI products to its Prescription Savings Club, offering members the lowest price for epinephrine devices (\$99.99) in the U.S.
- ▶ Submitted responses to issues raised in CRL for ZIMHI NDA and awaiting Type A meeting with the FDA
- ▶ Announced intent to sell substantially all of the assets of US Compounding to a strategic buyer



## 2021 Target Milestones

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- ▶ Begin patient enrollment for the clinical study of Tempol as a treatment for COVID-19
- ▶ Publish data from Stanford study showing Tempol suppressed cytokine production from COVID-19 positive human cells
- ▶ Increased revenue for SYMJEPI as USWM continues to ramp sales and marketing efforts
- ▶ Obtain a favorable outcome from FDA Type A meeting for naloxone NDA
- ▶ Obtain government and/or non-government funding for additional clinical studies of Tempol for the treatment of radiation dermatitis





# Products and Pipeline

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## ▶ Injectable Products – Using patented, FDA-approved device




















- **SYMJEPI®** (epinephrine) Injection 0.3mg & 0.15mg
  - Both doses FDA approved, launched in 2019
  - Licensed U.S. commercial rights to USWM
- **ZIMHI™** (naloxone) Injection 5mg
  - Intended for rapid reversal of opioid overdose
  - Licensed U.S. commercial rights to USWM

## ▶ Specialty Products

- **APC-400** (tempol) Topical Gel
  - In development for treating radiation induced dermatitis
- **APC-410** (tempol) Oral Capsule
  - In development for treating acute respiratory diseases, including COVID-19



# Products and Pipeline Continued

PRODUCT	DELIVERY	POTENTIAL INDICATION	PHASE I	PHASE II	PHASE III	NDA	APPROVED
<b>SYMJEPI® (epinephrine)</b> Injection 0.3mg	Injectable	Anaphylaxis					 (1)
<b>SYMJEPI® (epinephrine)</b> Injection 0.15mg	Injectable	Anaphylaxis					 (1)
<b>ZIMHI™ (naloxone)</b> Injection 5mg	Injectable	Opioid Overdose					 (1)(2)
<b>APC-400 (tempol)</b> Topical Gel	Topical	Radiation Dermatitis		 (3)			
<b>APC-410 (tempol)</b> Oral Capsule	Oral	Respiratory Disease / Anti-Inflammatory		 (4)			

Footnotes: <sup>1</sup> Licensed U.S. commercial rights to US WorldMeds  
<sup>2</sup> Submitted responses to issues raised in [CRL](#)  
<sup>3</sup> Phase II completed, Phase III ready  
<sup>4</sup> Phase II/III ready

## U.S. Commercial Partner

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- ▶ In 2020, Adamis reacquired U.S. commercial rights for SYMJEPI from Sandoz and licensed U.S. rights for both SYMJEPI and ZIMHI to US WorldMeds (USWM) for milestones and 50% of profits
- ▶ USWM is a privately held specialty pharmaceuticals company focused on developing and commercializing unique branded drug products
- ▶ Built a product portfolio over more than 20 years in the areas of malignant hyperthermia, opioid withdrawal, oral mucositis, and CNS
- ▶ Promoting SYMJEPI through 50+ sales professionals, including 30 outside sales reps, with plans to increase following ZIMHI approval
- ▶ Preparing for a commercial launch of ZIMHI following approval



# SYMJEPI® (epinephrine) Injection

Indication: Anaphylaxis

Status: Marketing (US); Under Review (AU)

Dose/Route: 0.3mg & 0.15mg IM or SC injection

Market (US): \$1.5 billion <sup>(1)</sup>



High dose  
(66 lbs. or more)



Low dose  
(33–66 lbs.)

- ▶ First products developed on patented, FDA-approved injection platform
- ▶ Both doses approved in U.S. and under regulatory review in Australia
- ▶ Commercial partners: US WorldMeds (US); Chiesi Australia (AU & NZ); terms 50% of net profits and potential performance milestones
- ▶ Continuing to explore additional ex-US opportunities

<sup>1</sup> Source: Bloomberg Intelligence

# Large Opportunity Still Exists in U.S.

## People with Allergies

50 million

## Food Allergies

32 million (1 in 13 children)

## Drug Allergies

Up to 10%

## Insect Venom Allergies

Up to 5%

## Latex Allergies

Up to 6%

## Low Penetration of Total Available Market



- At Risk people with epinephrine products
- At Risk people without epinephrine products



Sources: Asthma and Allergy Foundation of America; Food Allergy Research & Education; Gupta, R, et al. The Prevalence, Severity and Distribution of Childhood Food Allergy in the United States. *Pediatrics* 2011; 10.1542/ped.2011-0204

# ZIMHI (naloxone) Injection (APC-6000)

Indication: Opioid Overdose

Status: Type A Meeting pending

Dose/Route: 5mg IM or SC injection

Market (US): \$330 million <sup>(1)</sup>



**5mg Dose**  
(IM Injection)

- ▶ Third product developed on proprietary injection platform
- ▶ Naloxone is a fast-acting opioid antagonist
- ▶ Overdose epidemic: highest number of overdose deaths (81K) ever recorded in a year (ending May 2020) in US; greater than 40% caused by more potent synthetic opioids like fentanyl <sup>(2)</sup>
- ▶ Higher dose of naloxone needed because more potent opioids cause high mortality and require repeat dosing – incidences up to 83% noted in multiple studies <sup>(3)</sup>



<sup>1</sup> Source: Bloomberg Intelligence

<sup>2</sup> Source: CDC – Centers for Disease Control and Prevention

<sup>3</sup> Source: Morbidity and Mortality Weekly Report, April 14, 2017

# U.S. Market for ZIMHI

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- ▶ Market growing in the midst of opioid and COVID-19 crises
  - Over the last five years, annual naloxone sales rose from \$44mm to \$330mm and units sold grew 28% year-over-year <sup>(1)</sup>
  - COVID-19 impact – 81K overdose fatalities in the U.S. between 6/2019 and 5/2020 – highest one year overdose deaths ever recorded <sup>(2)</sup>
- ▶ Market is in transition
  - Historically a non-retail market composed of non-branded injectables
  - New consumer-oriented products and enhanced awareness have created an emerging retail market channel
  - FDA now recommends HCPs co-prescribe naloxone with opioids
- ▶ Limited competitive activity
  - Only approved intramuscular injection (Evzio®) was discontinued
  - Remaining approved product (Narcan®) is a lower dosage, which may be sub-optimal due to the increasing strength of synthetic opioids <sup>(3)</sup>

<sup>1</sup> Source: Bloomberg Intelligence

<sup>2</sup> Source: CDC – Centers for Disease Control and Prevention

<sup>3</sup> Source: Moss RB, et. al. (2020) Higher naloxone dosing in a quantitative systems pharmacology model that predicts naloxone-fentanyl competition at the opioid mu receptor level. PLoS ONE 15(6): e0234683. <https://doi.org/10.1371/journal.pone.0234683>



# Tempol Gel (APC-400)

Indication: Radiation Induced Dermatitis (RID)

Status: Phase III Ready

Route: Topical Gel

Market (US): ~1.08 million patients annually <sup>(1)</sup>



- ▶ Novel anti-oxidant and anti-inflammatory synthetic compound which has shown efficacy in treatment of RID
- ▶ 1.08 million new cancer cases are diagnosed annually in the U.S. and 60% of those patients will undergo radiation treatment <sup>(1)</sup>
- ▶ 85% of patients will experience moderate to severe skin reactions <sup>(2)</sup>
- ▶ Currently no approved treatment for RID
- ▶ Phase II study of Tempol in treatment of RID completed; currently Phase III ready

<sup>1</sup> Source: American Cancer Society - 2020 Estimates

<sup>2</sup> Source: Salvo N, et. al, Prophylaxis and Management of Acute Radiation-Induced Skin Reactions: A Systematic Review of the Literature. Current Oncology. 2010 Aug;17(4):94-112



# U.S. Market for Tempol Gel

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- ▶ Main role intended as an adjuvant treatment to chemo and radiation therapies in cancer patients making treatment much more manageable and improving quality of life
- ▶ Radiation therapy is a common treatment for cancer patients and had a global market size of about \$5.6 billion in 2018 <sup>(1)</sup>
- ▶ One of the most common side effects of radiation is acute skin reaction (radiation dermatitis or RID) that ranges from a mild rash to severe ulceration
- ▶ Approximately 85% of patients treated with radiation therapy will experience an adverse skin reaction <sup>(2)</sup>

<sup>1</sup> Source: Radiotherapy Market by Type (External (IGRT, IMRT, 3D-CRT, Stereotactic), Brachytherapy (LDR, HDR)), Product (LINAC, CyberKnife, Gamma Knife, Tomotherapy, Particle Therapy, Cyclotron), Application (Prostate, Breast), End User (Hospital) – Forecasts to 2023

<sup>2</sup> Source: Salvo N, et. al. Prophylaxis and Management of Acute Radiation-Induced Skin Reactions: A Systematic Review of the Literature. Current Oncology. 2010 Aug;17(4):94-112



# Tempol Capsule (APC-410)

Indication: Respiratory Disease

Status: Phase II/III ready

Route: Oral Capsule

Market (US): 14,647 daily COVID-19 cases <sup>(1)</sup>



- ▶ Tempol is a novel synthetic compound which reduces oxidative stress and inflammatory cytokines associated with the cytokine storm
- ▶ In animal models of LPS induced ARDS, Tempol demonstrated decreased lung pathology <sup>(2)</sup>
- ▶ In an animal model of a betacoronavirus, Tempol showed increased survival and decreased virus levels <sup>(3)</sup>
- ▶ Cleared by FDA to begin clinical studies of Tempol as a treatment for COVID-19

<sup>1</sup> Source: CDC – Average New Cases Reported as of February 12, 2021

<sup>2</sup> Source: El-Sayed NS, et al. European Journal of Pharmacology, 2011 August 1; 663 (1-3): 68-73

<sup>3</sup> Source: Tsubako MH, et al. Free Radical Biology and Medicine, 2010 March 1; 48(5): 704-712

## 2021 Target Milestones

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- ▶ Publish data from Stanford study showing Tempol suppressed cytokine production from COVID-19 positive human cells
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