

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): May 11, 2020

**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))

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.

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

## Item 1.01 Entry into a Material Definitive Agreement

On May 11, 2020, Adamis Pharmaceuticals Corporation (the “Company”) announced in a press release that it had entered into an agreement (the “Termination Agreement”) with Sandoz Inc. to terminate the Distribution and Commercialization Agreement dated as of July 1, 2018 (the “Sandoz Agreement”) previously entered into between the Company and Sandoz relating to the Company’s SYMJEPi<sup>®</sup> (epinephrine) Injection 0.3mg, SYMJEPi<sup>®</sup> (epinephrine) Injection 0.15mg products for the emergency treatment of allergic reactions (Type I) including anaphylaxis, which are currently marketed by Sandoz and available in the United States pursuant to the Sandoz Agreement, and reacquire the rights to the SYMJEPi products. The Company also announced that it had entered into an exclusive distribution and commercialization agreement (the “USWM Agreement”) with USWM, LLC (“USWM” or “US WorldMeds”) for the United States commercial rights for the SYMJEPi products, as well as for the Company’s ZIMHI<sup>™</sup> (naloxone HCl Injection, USP) 5mg/0.5mL product candidate intended for the emergency treatment of opioid overdose.

The Termination Agreement provides for the mutually agreed return to Adamis of the marketing, promotion, and distribution rights, and certain marketing and promotional materials, relating to the SYMJEPi products, and the termination of the Sandoz Agreement, following a transition period, supported by a transition services agreement that Sandoz and the Company or its designee agree to use commercially reasonable efforts to enter into, concerning certain transition services, activities and arrangements relating to the SYMJEPi products. As part of the Termination Agreement, Sandoz will continue to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize any potential impact to patients and customers. The Termination Agreement also provides for a future resolution following the end of the transition period and termination of the Sandoz Agreement of any amounts that may be payable or owed with respect to the net sales and profit sharing provisions of the Sandoz Agreement, and for survival of certain provisions of the Sandoz Agreement.

Under the terms of the USWM Agreement, the Company appointed USWM as the exclusive (including as to the Company) distributor of the SYMJEPi products in the United States and related territories (“Territory”) effective upon the termination of the Sandoz Agreement, and of the ZIMHI product, following receipt of regulatory approval, and granted USWM an exclusive license under the Company’s patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the products in the Territory, subject to the provisions of the USWM Agreement, in partial consideration of an initial payment by USWM and potential regulatory and commercial based milestone payments totaling up to \$26 million, if the milestones are achieved. There can be no assurances that any of these milestones will be met or that any milestone payments will be paid to the Company. The Company retains rights to the intellectual property subject to the USWM Agreement and to commercialize both products outside of the Territory. In addition, the Company may continue to use the licensed intellectual property (excluding certain of the licensed trademarks) to develop and commercialize other products (with certain exceptions), including products that utilize the Company’s injection device platform.

The USWM Agreement provides that, subject to certain adjustments, USWM will pay to the Company 50% of the net profit from net sales, as each such term is defined in the USWM Agreement, of the products in the Territory to third parties, determined on a quarterly basis. The Company will be the supplier of the products to USWM, and USWM will order and pay the Company a supply price for quantities of products ordered. Under the USWM Agreement, net profit is determined based on the amount of net sales less the supply price that USWM pays the Company for quantities of the products sold in the applicable period, less certain additional amounts relating to sales, distribution and other allocations and expenses and amounts allocable to the products and less certain other adjustments and amounts, and net sales is determined based on the net sales recorded by USWM for sales of the products and reflecting a number of customary deductions allocable to the products including, without limitation, product recalls or returns, discounts and credits, rebates, and certain other items.

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The Company will be responsible for all manufacturing, component and supply costs related to manufacturing and supplying the products to USWM at a supply price based on Adamis' direct product costs. The Company is responsible for component sourcing and regulatory compliance in the supply chain and for testing of lots of products. The USWM Agreement includes customary provisions relating to ordering, delivering and payment for products ordered by USWM. The Company will also be responsible for all regulatory and registration activities related to the products in the Territory, including all costs of protecting and maintaining the Company's intellectual property and costs related to obtaining and maintaining regulatory approvals for the products.

USWM will purchase all the products from the Company at a supply price and will be responsible for the marketing, sales, and distribution of the products in the Territory, subject to the provisions of the USWM Agreement. USWM will also be responsible for regulatory compliance with federal, state, and local government purchasing, pricing, and reimbursement programs. USWM will record revenues from sales of the products and will be responsible for marketing and sales costs, and is also responsible for developing, and regulatory compliance regarding, promotional materials.

The Company and USWM will appoint an equal number of representatives to a joint project team that will meet periodically to discuss and make certain decisions regarding launch and commercialization strategies of the products. The joint project team will, among other things, determine the allocation of USWM's direct marketing and sales expenses that will be included in the quarterly net profit calculation. The USWM Agreement also provides that USWM will enter into a quality agreement relating to the products, and that USWM and the Company will enter into a pharmacovigilance agreement relating to exchange of safety information and regulatory reporting requirements.

The USWM Agreement contains customary representations, warranties and covenants of the Company, including without limitation relating to matters such as rights to grant the licenses under the USWM Agreement, compliance with applicable laws, absence of infringement or violation of third party rights, conformity of the products and components with applicable laws and specifications, and other matters. The USWM Agreement includes a number of other provisions dealing with product recalls, delivery requirements, safety reporting, intellectual property, quality control, audits, recordkeeping, consequences of sustained continued delays or inability to deliver products, and other matters and agreements by the Company and USWM.

The USWM Agreement includes customary indemnification provisions between the parties. The Company has agreed to indemnify USWM against losses and expenses paid or payable by USWM to third parties as a result of any third party claim related to certain matters, including (a) breach by the Company of any representations, warranties, covenants, or agreements made by the Company in the USWM Agreement or certain related agreements, (b) negligence or willful misconduct by the Company or certain related persons relating to the USWM Agreement, (c) the development, processing or manufacturing of the products, (d) certain product liability actions arising from the sale or use of the products, (e) certain amounts relating to failure to supply required quantities of the products, (f) third party intellectual property infringement claims, with certain exceptions, or (g) certain matters relating to the products in respect of periods before the date of the USWM Agreement. USWM has agreed to indemnify the Company against losses and expenses paid or payable by the Company to third parties as a result of any third party claim related to any breach by USWM of any representations, warranties, covenants, or agreements made by USWM in the USWM Agreement or certain related agreements, negligence or willful misconduct by USWM or certain related persons relating to the USWM Agreement, or the commercialization of products by USWM, except where the Company is obligated to indemnify USWM for such matter.

The initial term of the USWM Agreement will, unless otherwise terminated as permitted by the agreement, continue for ten years from the launch of the first product in the Territory pursuant to the agreement, and will thereafter be automatically renewed for consecutive five year renewal terms unless the agreement is otherwise terminated by mutual agreement of the parties with respect to either or both of the SYMJEPi and ZIMHI products, or unless otherwise terminated by a party as permitted by the agreement.

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Either party may terminate the USWM Agreement, with respect to either the SYMJEPi products or the ZIMHI product or both (as applicable), by reason of an uncured breach of a material provision of the USWM Agreement, or following bankruptcy-related events affecting the other party. In addition, USWM may terminate the USWM Agreement for other reasons, such as withdrawal of the product from the Territory due to certain regulatory actions of the FDA including FDA requirements, issuance of a voluntary recall or mutually agreed safety considerations, certain uncured quality deficiencies relating to the supply or manufacture of the products, if the Company is unable to supply products to USWM for certain periods of time, the occurrence of certain intellectual property related matters within certain periods of time, certain uncured quality deficiencies, or with respect to ZIMHI failure to achieve regulatory approval within certain periods of time. The Company has the right to terminate the USWM Agreement following the occurrence of certain events relating to progress in launching or commercializing the products.

The foregoing description of certain terms of the USWM Agreement does not purport to be complete and is qualified in its entirety by reference to the USWM Agreement that the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the period ended June 30, 2020, or other report that the Company may file with the Securities and Exchange Commission (the "SEC"). The Company intends to seek confidential treatment for certain portions of the USWM Agreement pursuant to a confidential treatment request submitted to the SEC pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

**Item 1.02 Termination of a Material Agreement**

See the disclosure under Item 1.01 above regarding termination of the Sandoz Agreement between the Company and Sandoz Inc., which is incorporated herein by reference.

**Item 2.06 Material Impairments**

As a result of entering into the Termination Agreement described in Item 1.01 above, providing for the termination of the Sandoz Agreement with Sandoz, the Company has determined that its financial results for the quarter ending June 30, 2020, will include an impairment of the capitalized cost to obtain a contract reflected on its consolidated balance sheets as of December 31, 2019 and March 31, 2020. The total amount of \$1,750,000 as of March 31, 2020, represented the remaining unamortized portion of the \$2.0 million fee paid by the Company to a financial advisor in connection with the entering into of the original Sandoz Agreement with Sandoz. Such capitalized cost will no longer be capitalized and amortized over the 10-year estimated economic benefit period of the contract and will instead be recognized as an expense during the quarter ended June 30, 2020. For further information, see Note 4 to the financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, and the notes to the financial statements that will be included in the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2020.

**Item 1.02 Termination of a Material Definitive Agreement**

See the disclosure under Item 1.01 above regarding termination of the Sandoz Agreement with Sandoz, which is incorporated herein by reference.

**Item 8.01 Other Events**

On May 11, 2020, the Company issued a press release announcing the execution of the Termination Agreement with Sandoz and the USWM Agreement with US WorldMeds described in Item 1.01 above. The press release is filed as Exhibit 99.1 to this Current Report on Form 8-K.

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## Forward Looking Statements

This Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may relate to future events or our future results of operations and may include, without limitation, the following statements: the Company's beliefs concerning the ability of its Symjepi product and, if approved by the FDA, its ZIMHI product, to compete successfully in the market; the Company's beliefs concerning the safety and effectiveness of its product candidates; whether a transition services agreement will be entered into as contemplated by the Termination Agreement and the services and activities undertaken pursuant to any such transition services agreement; the timing of commercialization activities undertaken by US WorldMeds concerning the SYMJEPi and ZIMHI products; future levels of sales of the SYMJEP products and, if approved for marketing by the FDA, the ZIMHI product; the amount of milestone payments and net profit share payments that may become payable to the Company under the USWM Agreement; and whether the FDA will approve the Company's ZIMHI product. These statements are only predictions and involve known and unknown risks, uncertainties and other factors beyond the Company's control, which may cause the Company's actual results to be materially different from those anticipated by such forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. There can be no assurances, among other factors: (i) regarding whether a transition services agreement will be entered into; (ii) what activities may be undertaken pursuant to a transition services agreement; (iii) regarding the date by which USWM will undertake commercialization activities pursuant to the USWM Agreement relating to the SYMJEPi or ZIMHI products; (iv) regarding the amount of future sales of the products or net profit or milestone payments to the Company under the USWM Agreement; (v) regarding any particular level of sales of SYMJEPi products or, if approved, ZIMHI products; (vi) regarding the success of commercialization activities undertaken by USWM pursuant to the USWM Agreement; (vii) that the Company will be able to supply the quantities of products that are required under the USWM Agreement; (viii) that unexpected labeling, manufacturing, supply, safety, recall, or other regulatory issues will not arise; or (ix) that the FDA will approve the Company's New Drug Application relating to the ZIMHI product, or concerning the timing of any such approval. We cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not place undue reliance on any forward-looking statements. In addition, the forward-looking statements included in this Form 8-K represent the Company's views as of the date of this Form 8-K. The Company anticipates that subsequent events and developments may cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as required by applicable laws. These forward-looking statements should not be relied upon as representing the Company's views as of any date after the date of this Form 8-K. Certain of these risks, uncertainties, and other factors are described in greater detail in the Company's filings from time to time with the SEC, all of which are available free of charge on the SEC's web site at <http://www.sec.gov>.

### Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

99.1 [Press release dated May 11, 2020.](#)

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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: May 13, 2020

By: /s/ Robert O. Hopkins  
Name: Robert O. Hopkins  
Title: Chief Financial Officer

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**Adamis Pharmaceuticals Provides Update on SYMJJEPI Products and Announces Distribution and Commercialization Agreement for SYMJJEPI and ZIMHI Products**

**SAN DIEGO--(May 11, 2020)-** Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced it is reacquiring from Sandoz Inc. the rights to its SYMJJEPI<sup>®</sup> (epinephrine) Injection 0.3mg, SYMJJEPI<sup>®</sup> (epinephrine) Injection 0.15mg products currently marketed and available in the United States. Adamis has simultaneously entered into an exclusive distribution and commercialization agreement with US WorldMeds, LLC for the United States commercial rights for the SYMJJEPI products, as well as its ZIMHI<sup>™</sup> (naloxone HCl Injection, USP) 5mg/0.5mL product candidate.

Adamis and Sandoz have entered into an agreement providing for the mutually agreed return to Adamis of the marketing, promotion, and distribution rights of the SYMJJEPI products, and the termination of the commercialization agreement between Adamis and Sandoz, following a transition period, supported by a transition services agreement that is currently being negotiated. As part of the termination agreement, Sandoz will continue to support the products in the U.S. under the existing commercialization agreement through the end of the transition period to help minimize any potential impact to patients and customers.

Under the terms of the Adamis/US WorldMeds agreement, US WorldMeds obtained U.S. rights to commercialize and distribute the SYMJJEPI products, upon the termination of Sandoz' commercial rights, and ZIMHI, if approved by the U.S. Food and Drug Administration, in exchange for an upfront payment and potential regulatory and commercial milestones totaling up to \$26 million. Additionally, after deducting the supply price and certain other deductions, including an allocation for US WorldMeds sales and distribution expenses from net sales of the products, Adamis and US WorldMeds will share equally in the net profits, as defined in the agreement.

Adamis will be responsible for supplying the products to US WorldMeds at a supply price based on Adamis' direct product costs. Adamis will retain rights to commercialize the products outside the U.S. and may also continue to develop its injection platform for additional product candidates. Additional information concerning the agreement and the transaction is contained in a report on Form 8-K to be filed by the company with the Securities and Exchange Commission.

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, "We are pleased Sandoz is willing to assist us through this transition and we are very excited about working with US WorldMeds. They have a proven track-record of commercializing pharmaceutical products and have a First-in-Class and only FDA-approved product, LUCEMYRA<sup>®</sup> (lofexidine), for the treatment of withdrawal symptoms associated with abrupt opioid discontinuation. We believe US WorldMeds' existing infrastructure and current sales force positions it well to take over the marketing and distribution of our SYMJJEPI products and, after receiving FDA approval, quickly and effectively launching our ZIMHI product. We view this partnership as a synergistic fit that has the potential to maximize the value of the Products and create immediate lasting value to both shareholders and patients."

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P. Breckinridge Jones, Sr., CEO of US WorldMeds, added, “We are very excited to begin commercializing Adamis’ SYMJJEPI epinephrine products, and look forward to launching ZIMHI (naloxone) following its approval. We believe SYMJJEPI represents a meaningful new alternative in the epinephrine market that will benefit from our enhanced focus. Our strong presence in the opioid dependence market made us keenly aware of the growing need for repeat dosing of the currently approved naloxone products to combat the more powerful opioids in the market today. So, when we learned Adamis was developing a higher dose naloxone product, we knew it would be a perfect companion product for LUCEMYRA. We are confident we can leverage our existing commercial infrastructure to speed the uptake and maximize the impact of ZIMHI. I consider ZIMHI and LUCEMYRA a one-two punch that can strike a powerful blow in the fight against opioid overdoses and the management of withdrawal symptoms, and ultimately make a positive impact on the overall opioid epidemic. US WorldMeds expects to be in position to launch ZIMHI shortly after approval and delivery of product from Adamis.”

As a consequence of the above agreements, Adamis has filed or will file a Form 12b-25 with the Securities and Exchange Commission to give the company additional time to prepare and file its quarterly report on Form 10-Q for the period ended March 31, 2020, to assess and reflect this subsequent event and its impact in the Form 10-Q. The company expects to file its Form 10-Q within the five additional days provided for by Rule 12b-25.

#### **About the SYMJJEPI Products**

SYMJEPI® (epinephrine) Injection 0.3mg and SYMJJEPI® (epinephrine) Injection 0.15mg products are approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis. In July 2018, Adamis announced that it had licensed commercial rights for the US to Sandoz. Please refer to [www.SYMJJEPI.com](http://www.SYMJJEPI.com) for additional product information.

#### **About the ZIMHI Product**

ZIMHI is a high-dose naloxone injection product candidate that is intended for the emergency treatment of opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and pediatric patients. It is intended for immediate administration in settings where opioids may be present and is not a substitute for emergency medical care. Naloxone is an opioid antagonist, which is generally considered the drug of choice for immediate administration for opioid overdose, and works by blocking or reversing the effects of the opioid, including extreme drowsiness, slowed breathing, or loss of consciousness. Drug overdoses are now the leading cause of death for Americans under 50, and more powerful synthetic opioids, like fentanyl and its analogues, are responsible for the largest number of deaths from opioid overdoses.

#### **About US WorldMeds and LUCEMYRA®**

US WorldMeds is a privately held specialty pharmaceutical company that develops, licenses, and markets unique healthcare products designed to improve the lives of patients with challenging conditions and unmet medical needs. US WorldMeds has built a branded product portfolio in the therapeutic areas of addiction medicine, hemophilia, malignant hyperthermia, and CNS. More information on US WorldMeds can be found at [USWorldMeds.com](http://USWorldMeds.com).

LUCEMYRA® (lofexidine) is the first and only FDA-approved, non-opioid, non-addictive treatment for relief of multiple symptoms of opioid withdrawal associated with abrupt opioid discontinuation. More information on LUCEMYRA, including prescribing and safety information, can be found at [Lucemyra.com](http://Lucemyra.com).

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## **About Adamis Pharmaceuticals**

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company primarily focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. The company's SYMJEPi (epinephrine) Injection 0.3mg and SYMJEPi (epinephrine) Injection 0.15mg products both use the same injection device as used for ZIMHI and were approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis, and both SYMJEPi products were fully launched in the U.S. in July 2019. Please refer to [www.SYMJEPi.com](http://www.SYMJEPi.com) for additional product information. In addition to its ZIMHI (naloxone) injection product candidate, Adamis is developing other products, including a metered dose inhaler and dry powder inhaler product candidates for the treatment of asthma and COPD. The company's subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs, and certain nonsterile drugs for patients, animals, hospitals, clinics and surgery centers throughout most of the United States.

## **Adamis Forward Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingencies, goals, targets or future development and/or otherwise are not statements of historical fact. These statements relate to future events or future results of operations, including, but not limited to, the following statements: the ability of the parties to negotiate and enter into a transition services agreement and the termination of the company's existing commercialization agreement with Sandoz; the timing and outcome of commercialization efforts by US WorldMeds regarding the SYMJEPi and ZIMHI products; the timing of the company's resubmission to the FDA of its New Drug Application ("NDA") relating to its ZIMHI product candidate; the timing or outcome of the FDA's review of the company's resubmitted NDA relating to its ZIMHI product candidate; the company's beliefs concerning the size of the markets in which the products compete; the company's beliefs concerning the safety and effectiveness of its products and product candidates; and other statements concerning our future operations and activities. Such forward-looking statements include those that express plans, anticipation, intent, contingencies, goals, targets or future development and/or otherwise are not statements of historical fact. These statements are only predictions, are not guarantees, involve known and unknown risks, uncertainties and other factors, and concern matters that could subsequently differ materially from those described in this press release, which may cause Adamis' actual results to be materially different from those contemplated by these forward-looking statements. There is no assurance that our commercialization agreement with Sandoz will be terminated. There is no assurance that the FDA will approve our NDA, once resubmitted, relating to our ZIMHI naloxone product candidate or that other matters or events will not differ from our expectations or result in delays in the regulatory approval process. In addition, forward-looking statements concerning our anticipated future activities assume that we are able to obtain sufficient funding to support such activities and continue our operations and planned activities. As discussed in our filings with the Securities and Exchange Commission, we may require additional funding, and there are no assurances that such funding will be available if required. We cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as may be required by applicable law we undertake no obligation to update or release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date of this press release. Certain of these risks, and additional risks, uncertainties, and other factors are described in greater detail in our filings from time to time with the SEC, including our annual report on Form 10-K for the year ended December 31, 2019, and our subsequent filings with the SEC, which Adamis strongly urges you to read and consider, all of which are available free of charge on the SEC's web site at <http://www.sec.gov>.

## **Contact Adamis:**

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& Corporate Communications  
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