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): January 28, 2021

ADAMIS PHARMACEUTICALS CORPORATION

(Exact Name of Registrant as Specified in Charter)

Delaware	**0-26372**	**82-0429727**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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. ☐

Item 2.02 Results of Operations and Financial Condition

On January 28, 2021, Adamis Pharmaceuticals Corporation (the "Company") filed with the Securities and Exchange Commission ("SEC") a preliminary prospectus supplement (the "Preliminary Prospectus Supplement"), pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act") in connection with a proposed public offering of shares of its common stock, which contained information regarding the Company's preliminary estimates of its cash and cash equivalents as of December 31, 2020. The Company preliminarily estimates that its cash and cash equivalents as of December 31, 2020 was approximately $6.9 million. This preliminary estimate is not a comprehensive statement of the Company's financial results for the fiscal year ended December 31, 2020, has not been reviewed by our independent registered public accounting firm and is subject to change upon completion of our financial statement closing procedures. The Company expects to complete its audited consolidated financial statements for the year ended December 31, 2020 subsequent to the completion of the Offering. It is possible that we or our independent registered public accounting firm may identify items that require us to make adjustments to the estimate of our cash and cash equivalents balance set forth above and those changes could be material. Accordingly, undue reliance should not be placed on this preliminary estimate.

The information provided in this Item 2.02 of this Form 8-K shall not be deemed "filed" for 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, or Sections 11 and 12(a)(2) of the Securities Act, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events

The Preliminary Prospectus Supplement contained an updated summary description of certain aspects of the Company's business. Accordingly, the Company is filing this information with this Current Report on Form 8-K for the purpose of supplementing and updating disclosures contained in the Company's prior filings with the SEC, including those discussed in the Company's most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as supplemented by the Company's subsequent filings with the SEC. The updated disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Updated Summary Business Information
104	Cover page interactive data file (embedded within the Inline XBRL document).

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: January 28, 2021

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

Exhibit 99.1

Updated Summary Business Information

*In the preliminary prospectus supplement to be used in connection with a proposed public offering of shares of its common stock by Adamis Pharmaceuticals Corporation (the "*company*"), the company provided the following updates or supplements to the summary description of certain aspects of the company's business provided in the company's previous periodic filings with the Securities and Exchange Commission (the "*SEC*"). The information below should be read in conjunction with the information in the company's other filings made from time to time with the SEC.*

Unless otherwise stated or the context requires otherwise, references to "Adamis," the "company," or the "Company," "we," "us," or "our" refer to Adamis Pharmaceuticals Corporation and our subsidiaries, taken together.

Company Overview

Adamis Pharmaceuticals Corporation ("we," "us," "our," "Adamis" or the "company") is a specialty biopharmaceutical company focused on developing and commercializing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease. Our products and product candidates in the allergy, respiratory, and opioid overdose markets include: SYMJEPI™ (epinephrine) Injection 0.3mg, which was approved by the U.S. Food and Drug Administration, or FDA, in 2017 for use in the emergency treatment of acute allergic reactions, including anaphylaxis, for patients weighing 66 pounds or more; SYMJEPI (epinephrine) Injection 0.15mg which was approved by the FDA in September 2018, for use in the treatment of anaphylaxis for patients weighing 33-65 pounds; a naloxone injection product candidate, ZIMHI™, based on the approved Symject™ injection device and intended for the treatment of opioid overdose for which the company resubmitted its New Drug Application, or NDA, in May 2020, received a Complete Response Letter, or CRL, from the FDA in November 2020; a Beclomethasone metered dose inhaler product candidate (APC-1000) intended for the treatment of asthma for which the company submitted an Investigational New Drug application, or IND, in January 2018 but has suspended the start-up phase of Phase 3 studies; and a fluticasone (APC-4000) dry powder inhaler, or DPI, product candidate for the treatment of asthma. In June 2020, we entered into a license agreement with a third party to license rights under patents, patent applications and related know-how relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. In January 2021, the company submitted an IND to the FDA for the investigational use of Tempol for the treatment of coronavirus (COVID-19). Our goal is to create low cost therapeutic alternatives to existing treatments. Consistent across all specialty pharmaceuticals product lines, we intend to submit NDAs under Section 505(b)(2), of the U.S. Food, Drug & Cosmetic Act, as amended, or FDCA, or Section 505(j) Abbreviated New Drug Applications, or ANDAs, to the FDA, whenever possible, in order to potentially reduce the time to market and to save on costs, compared to those associated with Section 505(b)(1) NDAs for new drug products.

Our US Compounding Inc. subsidiary, or USC, which we acquired in April 2016 and which is registered as a human drug compounding outsourcing facility under Section 503B of the FDCA and the U.S. Drug Quality and Security Act, or DQSA, provides prescription compounded medications, including compounded sterile preparations and nonsterile compounds, to patients, physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables. USC's compounded formulations in many circumstances are offered as alternatives to drugs approved by the FDA. USC also provides certain veterinary pharmaceutical products for animals.

To achieve our goals and support our overall strategy, we may need to raise a substantial amount of funding and make significant investments in, among other things, new product development and working capital.

The current status of our products, product candidates and development programs is as follows:

Product Portfolio

Specialty Pharmaceutical Products	Target Indication	Status
SYMJEPI (epinephrine) Injection 0.3mg	Anaphylaxis	FDA Approved, June 2017
SYMJEPI (epinephrine) Injection 0.15mg	Anaphylaxis	FDA Approved, September 2018
ZIMHI™ (naloxone) Injection (APC-6000)	Opioid Overdose	CRL received November 2020 (1)
Tempol		
(APC-400)	Radiation induced dermatitis	Phase 2/3 ready (2)
(APC-410)	Treatment of COVID-19	Phase 2/3 ready; IND submitted January 2021 (3)
Beclomethasone Metered Dose Inhaler Product (APC-1000)	Asthma	Phase 3, December 2018 (4)
Fluticasone Dry Powder Inhaler Product (APC-4000)	Asthma	Phase 3 ready (5)

(1) The company resubmitted its NDA to the FDA in May 2020 and received a CRL from the FDA in November 2020. The company intends to submit responses to the deficiencies identified in the CRL and will request a Type A meeting with the FDA to discuss the CRL and the company's responses.

(2) Phase 2 trial completed by the licensor. Represents the next anticipated development or regulatory stage for the product candidate that we may pursue, assuming the availability of adequate funding.

(3) In January 2021, the company submitted an IND to the FDA for the investigational use of Tempol in a Phase 2/3 clinical trial examining Tempol in COVID-19 patients.

(4) The start-up phase of a Phase 3 trial was initiated after consultation with the FDA, but enrollment and the study has been suspended in light of among other factors, the availability of adequate funding to resume and complete the study. There are no assurances that we will pursue this opportunity, for financial or other reasons, and we do not intend to devote substantial resources to pursue this opportunity at the present time.

(5) Following completion of product development and submission and acceptance of an IND, one or more Phase 3 trials may represent the anticipated next product development stage, assuming that we have the financial resources to pursue this opportunity and determine to pursue the opportunity, although additional trials such as pharmacokinetic, or PK, and/or other studies may be required before or in connection with any Phase 3 trials. We are not currently devoting, and do not intend to devote, any substantial financial resources to development of this product candidate at the present time. We may consider alternatives for this product including seeking a development and commercialization partner or other strategic alternatives.

Anaphylaxis; Epinephrine Injection Pre-Filled Single Dose Syringe

The American Academy of Allergy Asthma and Immunology, or AAAAI, defines anaphylaxis as a serious life-threatening allergic reaction. The most common anaphylactic reactions are to foods, insect stings, medications and latex. According to information published by AAAAI reporting on findings from a 2009-2010 study, up to 8% of U.S. children under the age of 18 had a food allergy, and approximately 38% of those with a food allergy had a history of severe reactions. Anaphylaxis requires immediate medical treatment, including an injection of epinephrine.

We estimate that sales of prescription epinephrine products in 2020 were more than $2.0 billion, based on assumptions and estimates utilizing industry data. We cannot provide any assurances concerning any possible future rates of annual growth or whether annual prescription sales will decline or grow. The market for prescription epinephrine products is increasingly competitive, and a number of factors have resulted in, and could continue to result in, downward pressure on the pricing of, and revenues from sales of, our SYMJEPI (epinephrine) Injection 0.3mg and 0.15mg prescription epinephrine products.

On June 15, 2017, the FDA approved our SYMJEPI (epinephrine) Injection 0.3mg product for the emergency treatment of allergic reactions (Type I) including anaphylaxis. SYMJEPI (epinephrine) Injection 0.3mg is intended to deliver a dose of epinephrine, which is used for emergency, immediate administration in acute anaphylactic reactions to insect stings or bites, allergic reaction to certain foods, drugs and other allergens, as well as idiopathic or exercise-induced anaphylaxis for patients weighing 66 pounds or more. On September 27, 2018, the FDA approved our lower dose SYMJEPI (epinephrine) Injection 0.15mg product, for the emergency treatment of allergic reactions (Type I) including anaphylaxis in patients weighing 33 to 65 pounds.

In July 2018, we entered into a Distribution and Commercialization Agreement (the "Sandoz Agreement") with Sandoz Inc. ("Sandoz") to commercialize both of our SYMJEPI products. Under the terms of the agreement, we appointed Sandoz as the exclusive distributor of SYMJEPI in the United States and related territories, in all fields including both the retail market and other markets, and granted Sandoz an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the product in the licensed territory, subject to the provisions of the agreement, in partial consideration of an upfront fee by Sandoz and potential performance-based milestone payments. In January 2019, we announced that Sandoz had launched SYMJEPI (epinephrine) 0.3 mg Injection in the U.S. market, initially available in the institutional setting. On July 9, 2019, we announced the full launch (institutional and retail) by Sandoz of both dose forms of the SYMJEPI injection products.

On May 11, 2020, we announced that we entered into an agreement with Sandoz to terminate the Sandoz Agreement (the "Termination Agreement") following an initial transition period that ended as a result of the execution of a transition services agreement. The Termination Agreement provided for the mutually agreed return to us 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, supported by a transition services agreement that we entered into with Sandoz and USWM, LLC concerning certain transition services, activities and arrangements relating to the SYMJEPI products. As part of the Termination Agreement, Sandoz agreed to support the products in the U.S. under the Sandoz Agreement through the end of the transition period to help reduce or minimize potential impacts to patients and customers. The Termination Agreement also provided for a future resolution 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.

On May 11, 2020, we announced that we entered into an exclusive distribution and commercialization agreement, or the USWM Agreement, with USWM, LLC, or USWM or US WorldMeds, for the United States commercial rights for the SYMJEPI products, as well as for the company's ZIMHI product candidate. Under the terms of the USWM Agreement, we appointed USWM as the exclusive distributor of SYMJEPI in the United States and related territories, or the Territory, effective upon the termination of the Sandoz Agreement, and of the ZIMHI product if approved by the FDA for marketing, and granted USWM an exclusive license under our patent and other intellectual property rights and know-how to market, sell, and otherwise commercialize and distribute the products in the Territory, in partial consideration of an initial payment of $1,000,000 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 us. We retain rights to the intellectual property subject to the USWM Agreement and to commercialize both products outside of the Territory. In addition, we 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 our Symject™ syringe product platform.

The USWM Agreement provides that, after deducting the supply price and subject to certain other deductions and adjustments, including an allocation for USWM sales and distribution expenses from net sales of the products, USWM will pay to us 50% of the net profit from net sales, as each such term is defined in the USWM Agreement, of the product in the Territory to third parties, determined on a quarterly basis. We will be the supplier of the products to USWM, and USWM will order and pay us a supply price for quantities of products ordered. The agreement does not include minimum payments to us by USWM, minimum requirements for sales of product by USWM or, with certain exceptions, minimum purchase commitments by USWM. Commencing in July 2020, USWM began promoting the SYMJEPI products through its field sales force. On January 22, 2021, we announced that the SYMJEPI products added to the Walgreens Prescription Savings Club program and were available to members of the program. The Walgreens Prescription Savings Club offers customers, who pay an annual membership fee, savings off retail prices on a large variety of medications.

Opioid Overdose

ZIMHI (naloxone) Injection

Naloxone is an opioid antagonist used to treat narcotic overdoses. Naloxone, which is generally considered the drug of choice for immediate administration for opioid overdose, blocks or reverses the effects of the opioid, including extreme drowsiness, slowed breathing, or loss of consciousness. Common opioids include morphine, heroin, tramadol, oxycodone, hydrocodone and fentanyl.

The number of deaths due to opioids has increased over five-fold compared to 1999. According to statistics published by the Centers for Disease Control and Prevention (CDC), in 2018 drug overdoses resulted in approximately 67,000 deaths in the United States – greater than approximately 185 deaths per day. Drug overdoses are now the leading cause of death for Americans under 50, and the proliferation of more powerful synthetic opioids, such as fentanyl and its analogues, could result in future increases in the number of deaths resulting from opioid overdoses. Recent studies have revealed an approximately 87% increase in deaths associated with synthetic opioids, whereas, death rates due to natural and semisynthetic opioids remained relatively stable. With this significant increase in synthetic opioid abuse are published studies that have suggested that the current recommended doses of naloxone may be inadequate in that frequent redosing is required. Repeat dosing of the commonly utilized dose of naloxone suggests the need for a higher dosage product.

In December 2018, we filed an NDA with the FDA relating to our higher dose naloxone injection product, ZIMHI, for the treatment of opioid overdose. On November 22, 2019, we received a CRL from the FDA regarding our NDA for ZIMHI. The CRL stated that the FDA determined that it could not approve the NDA in its present form and provided recommendations needed for resubmission. A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The questions raised by the FDA related generally to Chemistry, Manufacturing and Controls (CMC). No other clinical safety or efficacy issues were raised. In December 2019, we provided responses to the FDA to the comments included in the CRL. In February 2020, we had a Type A meeting with the FDA to discuss our response to the CRL and the process and timeline for resubmission of the NDA to the FDA. At the meeting, we obtained concurrence from the agency on the CMC information required for resubmission of the NDA, including additional information involving extractables and leachables testing from the syringe and glassware. On May 15, 2020, we resubmitted to the FDA the NDA for ZIMHI. On November 13, 2020, we received a second CRL from the FDA regarding the resubmitted NDA. The deficiencies and questions raised in the CRL related generally to new CMC issues. We intend to submit responses to the deficiencies identified in the CRL and request a Type A meeting with the FDA to discuss the CRL and the company's responses. If the matters raised in the CRL cannot be resolved with the FDA division that sent the CRL, we may appeal the matter within the agency through a Formal Dispute Resolution process. There can be no assurances regarding the timing and outcome of our Type A meeting with the FDA or the FDA's review of our NDA relating to the ZIMHI product, or the timing or outcome of any Formal Dispute Resolution process that we may decide to initiate. The development of an intramuscular injection of naloxone for the treatment of opioid overdose will require commercial scale manufacturing subject to review and approval by the FDA.

Tempol (APC400)

On June 12, 2020, we entered into a license agreement with Matrix Biomed, Inc., or the Licensor, to license rights under patents, patent applications and related know-how of Licensor relating to Tempol, an investigational drug. The exclusive license includes the worldwide use under the licensed patent rights and related rights of Tempol for the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection. In addition, the exclusive license includes the use of Tempol as a therapeutic for reducing radiation-induced dermatitis in patients undergoing treatment for cancer. In consideration for the Licensor providing the rights under its patent rights and related know-how relating to Tempol within the licensed fields, we paid Licensor $250,000 and also issued to the Licensor 1,000,000 shares of our Series B Convertible Preferred Stock, which has converted into an equal number of shares of common stock.

Tempol is a redox cycling nitroxide that promotes the metabolism of many reactive oxygen species and improves nitric oxide bioavailability. It has been studied extensively in animal models of oxidative stress and inflammation. Overall, Tempol acts as both a super-oxide dismutase mimetic and also has anti-inflammatory activity. Inflammation and oxidative stress occur in various disease states including COVID-19. In July 2020, we submitted to the FDA a pre-IND package which provided a detailed protocol for a Phase 2/3 study examining Tempol in COVID-19 patients, and the FDA has provided comments regarding the prospective use of Tempol in a randomized placebo controlled trial. In January 2021, we submitted an IND to the FDA for the investigational use of Tempol for the treatment of COVID-19. The submission of the IND to the FDA followed a Pre-IND meeting with the FDA in which the agency gave specific recommendations on CMC and conduct of the clinical trial to be included in the IND. On January 28, 2021, we announced that in collaboration with the Human Immune Monitoring Center at Stanford University we conducted a study to investigate the effects of Tempol on immune cells from COVID-19 patients, and that preliminary data from that study showed that Tempol decreases cytokines from stimulated cells from COVID-19 patients. We intend to seek government and/or non-government funding to study the efficacy of Tempol as a therapeutic treatment for COVID-19.

Asthma

According to the National Institute of Health, or NIH, asthma is a chronic lung disease that inflames and narrows the airways. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. Asthma affects people of all ages, but it most often starts during childhood. According to information published by Centers for Disease Control & Prevention (CDC) reporting on findings from 2017, the number of people in the U.S. with asthma is approximately 25.2 million and growing. We estimate that global sales of asthma and bronchospasm prescription products were in excess of approximately $7.2 billion in 2019, based on industry data.

Asthma; Metered Dose Inhaler (APC-1000)

Our APC-1000 product candidate is a steroid hydrofluoroalkane, or HFA, metered dose inhaler product, intended for the treatment of asthma. Our product candidate, if approved for marketing, would be intended to target a small niche within the larger market for respiratory products. We estimate that the annual global sales of prescription steroid HFA and similar products were approximately $3.0 billion in 2019, of which our product candidate would target a subset of that market.

In January 2018, we submitted an IND to the FDA to begin Phase 3 efficacy studies for a new formulation of APC-1000, and in December 2018, we initiated the start-up phase of the Phase 3 trial of APC-1000. However, we terminated the start-up phase and start of patent enrollment for the studies, and have suspended the study, in light of, among other factors, the availability of adequate funding to continue and complete the studies and the competitive landscape for the product. There are no assurances that we will pursue this opportunity, for financial or other reasons, and we do not intend to devote substantial resources to pursue this opportunity at the present time. The timing of enrollment for, and the pace of conduct, progress, and completion of, any studies that we may determine to conduct, and our decisions concerning such matters, are affected by a number of factors, including without limitation the availability of adequate funding, the absence of unexpected regulatory issues or delays, the time period required to enroll a sufficient number of patients in the study, the time required to complete and analyze the results of the studies, and the competitive landscape for the product.

Dry Powder Inhaler (DPI) Device Platform

In December 2013, we acquired assets relating to 3M's patented Taper dry powder inhaler (DPI) technology under development by 3M for the treatment of asthma and bronchospasm. The Taper DPI technology was designed to efficiently deliver dry powder by utilizing a 3M proprietary microstructured carrier tape. We are utilizing the Taper DPI assets to develop the DPI device. We believe that, if successfully developed, the device can be utilized to deliver a variety of different drug compounds and be used as a platform delivery device to develop products that will compete in the respiratory markets, which may include combination products. Our agreement with 3M contemplates that the microstructured carrier tape will be supplied by 3M under a separate commercial supply agreement to be negotiated with 3M. We believe that one advantage of the technology is that it can deliver drug particles without the need for lactose or formulation excipients. The majority of current dry powder products use lactose carrier excipients to enhance flowability; however, they have the disadvantage of increased bulk and require a mechanism for detaching the drug from the surface of the lactose. Lactose carrier formulations require a complicated blending process and delivery that is highly sensitive to excipient powder properties. To our knowledge, there are currently no excipient-free dry powder inhalers in the U.S. market.

Fluticasone DPI (APC-4000). Our first product candidate utilizing the DPI technology platform, APC-4000, is intended to deliver Fluticasone Propionate (fluticasone) as a dry powder formulation for the treatment of asthma. Fluticasone belongs to the family of medicines known as corticosteroids or steroids. It works by preventing certain cells in the lungs and breathing passages from releasing substances that cause asthma symptoms. APC-4000 is designed to deliver the same active ingredient as GlaxoSmithKline's Flovent® Diskus® for the treatment of asthma. We estimate that Flovent® Diskus® generated more than $469 million in U.S. sales and $802 million in global sales in 2019, based on GSK's publicly announced results. We conducted proof of concept studies with the DPI for APC-4000 in 2018 and 2019. We are not currently devoting, and do not intend to devote, any substantial financial resources to development of this product candidate at the present time. Our decisions regarding additional studies or product development will be affected by a number of factors, including without limitation the availability of adequate funding, the costs and results of any additional studies or development efforts that we may determine to undertake, and the competitive landscape for the product. In considering development and commercialization alternatives for APC-4000, we may seek to enter into development or commercialization agreements, license agreements, or other strategic agreements with third parties relating to development, commercialization and marketing of this product candidate.

Our development plans concerning our allergy and respiratory products, including APC-1000 and APC-4000, and our other product candidates are affected by developments in the marketplace, including the introduction of potentially competing new products by our competitors. As a result, our product development plans could be affected by such considerations. The anticipated future actions regarding development of products in our product pipeline will depend on a number of factors, including the availability of adequate funding to support product development efforts, the regulatory pathway for the product and, should we choose to seek commercialization partners for one or more of our products or product candidates, our success in negotiating and entering into development or commercialization agreements relating to our products, and the competitive landscape regarding such product candidates. We believe that should we continue and successfully complete product development efforts and decide to pursue such applications, we would be required to submit data for an application for approval to market APC-1000 and APC-4000 pursuant to Section 505(b)(2) of the FDCA, although there are no assurances that this will be the case. In considering development and commercialization alternatives for our products and product candidates and technologies, we may seek to enter into development or commercialization agreements, license agreements, or other strategic agreements with third parties relating to development, commercialization and marketing of one or more of our products or product candidates. We currently have no in-house manufacturing capabilities, and as a result we intend to rely on third-party contract manufacturers to manufacture the materials needed to produce DPI and HFA products.

Factors that could affect the development and launch dates for our products and product candidates include general market conditions, the outcome of discussions with the FDA concerning the regulatory approval pathway of the applicable product candidate including the number and kind of clinical trials that the FDA will require before the FDA will consider regulatory approval of the applicable product, any unexpected difficulties in licensing or sublicensing intellectual property rights that may be required for other components of the product, patent infringement lawsuits relating to Paragraph IV certifications as part of any Section 505(b)(2) or ANDA filings, any unexpected difficulties in the ability of our suppliers to timely supply quantities for commercial launch of the product, any unexpected delays or difficulties in assembling and deploying an adequate sales force to market the product, and receipt of adequate funding to support product development and sales and marketing efforts.

Prescription Compounded Medications

Overview

Our USC subsidiary, which is registered as a human drug compounding outsourcing facility under Section 503B of the FDCA and the DQSA, provides prescription compounded medications, including compounded sterile preparations or CSPs, and non-sterile compounds to physician clinics, hospitals, surgery centers and other clients throughout most of the United States. USC's product offerings broadly include, among others, corticosteroids, hormone replacement therapies, hospital outsourcing products, and injectables. USC also provides certain veterinary pharmaceutical products for animals.

USC sources raw materials and commercial products only from suppliers registered with the FDA. Utilizing these raw material components, USC prepares and provides a broad range of customized stock keeping units to meet the individual requirements of customers located throughout most of the United States.

The pharmacy sterile compounding industry arose in part because hospitals and other healthcare providers administering drugs require concentrations, dosage forms and delivery systems that are not readily commercially available from drug manufacturers in a ready-to-use, or RTU, form. Historically, safety and quality standards for compounded medications were not well defined or implemented, leading to demand for safer compounding practices, and the level of state regulation varied significantly. The 2012 nationwide fungal meningitis outbreak caused by a compounding pharmacy led to increased regulatory oversight of the industry which, among other things, led to the passage of the DQSA and its creation of Section 503B outsourcing facilities as a new, more highly FDA-regulated category of interstate outsourced CSP providers. Registration as a Section 503B outsourcing facility is currently voluntary. USC was incorporated in Arkansas in 2004, and registered with the FDA as a Section 503B outsourcing facility in December 2013.

USC's business is focused on marketing a portfolio of compounded preparations for hospital outsourcing and other clients, and animal health, including sterile injectable and non-sterile integrative therapies. Many of these formulations are offered in different formats than other available alternatives, such as in suspension or preservative free. Many hospitals and surgery centers look to outsourcing facilities to obtain medications in RTU format, with the specific packaging, volume, and strength often unique to individual facilities. Many facilities and practitioners also look to outsourcing facilities when medications are on temporary backorder from the manufacturer or are discontinued. USC's veterinary products include, without limitation, a formulation that we believe is novel, of an equine ulcer product that addresses what we believe is a significant market.

Compounding pharmacies and outsourcing facilities combine different ingredients, some of which may be FDA-approved drugs or components of FDA-approved drugs, to create specialized preparations prescribed by a practitioner Examples of compounded formulations include medications with alternative dosage strengths or unique dosage forms, such as topical creams or gels, suspensions, or solutions with more tolerable drug delivery vehicles. A practitioner may also work together with a pharmacist to repurpose or reformulate FDA-approved drugs via the compounding process to meet a patient's specific medical needs. These compounds are distributed to hospitals, surgery centers, and practitioners. Examples of compounded medications prepared by outsourcing facilities include sterile syringes used by hospital and surgery center operating rooms, sterile injectables administered by the practitioner in the office, and unit-dosed sterile and non-sterile medications. USC's outsourcing facility receives its active pharmaceutical ingredients from three main suppliers, which accounted for the majority of USC's drug and chemical purchases in 2019.

In recent years, there have been increases in the cost of certain injectable drugs and related products as a result of (i) enhanced oversight by the FDA and other regulatory bodies of manufacturers of injectable products, and the added costs associated therewith, (ii) decreased competition when drug manufacturers voluntarily cease producing certain drugs or face temporary regulatory suspension or permanent regulatory shut down of their operations, and (iii) consolidation among drug manufacturers. These factors have led some manufacturers to raise prices of some products and have also contributed to market shortages of injectable products, containers and diluents. These shortages and the potential inability to secure an adequate supply of necessary drug formulations can have a significant impact on the day-to-day business and operations of USC and its customers.

Since we acquired USC in April 2016, we have invested capital and taken several measures intended to support the growth of the business, including hiring additional personnel, expanding sales channels, and strengthening our production processes, to comply with new and anticipated FDA regulations applicable to its business and outsourcing facilities, to expand product offerings, enhance production capabilities, improve warehouse space, develop new packaging, labeling and processing solutions, refine quality and safety measures, and develop technology for the intake and management of customer orders.

Recent Developments

Financial Condition

Our financial statements for the year ended December 31, 2020, will not be available until after this offering is completed and consequently will not be available to you prior to investing in this offering. Based upon preliminary estimates and information available to us as of the date of this prospectus supplement, we estimate that we had approximately $6.9 million of cash and cash equivalents as of December 31, 2020. This estimate of our cash and cash equivalents as of December 31, 2020, is preliminary, has not been reviewed by our independent registered public accounting firm and is subject to change upon completion of our financial statement closing procedures. It is possible that we or our independent registered public accounting firm may identify items that require us to make adjustments to the estimate of our cash and cash equivalents balance set forth above and those changes could be material. Accordingly, undue reliance should not be placed on this preliminary estimate. The preliminary estimate is not necessarily indicative of any future period and should be read together with the sections titled “Risk Factors” and “Cautionary Note Regarding Forward-Looking Statements,” and under similar headings in the documents incorporated by reference into this prospectus supplement and the accompanying prospectus as well as our financial statements, related notes and other financial information incorporated by reference in this prospectus supplement.

Letter of Intent Regarding US Compounding Inc.

On January 26, 2021, we announced that we have entered into a non-binding letter of intent with a potential buyer for the sale of substantially all of the assets of our US Compounding Inc. subsidiary. Under the terms described in the letter of intent, the buyer would agree to acquire substantially all of the assets of USC in exchange for a total gross consideration that could range from approximately $10-$20 million, before transaction fees and expenses and other potential post-closing adjustments.

If a transaction is negotiated, reflected in definitive agreements entered into by the parties, and completed, the proposed purchase price consideration includes a combination of a cash payment at the closing of the transaction, a promissory note representing portion of the purchase price payable at a future date, and potential future performance-based milestone payments over a period of years. The amount and structure of consideration could change as a result of subsequent negotiations, due diligence or other factors.

Any definitive agreement would be subject to approval by the respective parties, including approval by our board of directors, and would likely include a number of customary provisions, including without limitation representations and warranties of USC and us, restrictive covenants and indemnification provisions.

The closing of a transaction would be contingent on the satisfaction of closing conditions which might include, among other things: (i) the receipt of required governmental, regulatory, and third-party consents and approvals, (ii) buyer obtaining required licenses, permits, registrations, or other approvals from the necessary state boards of pharmacy and other state and federal governmental authorities, and (iii) other customary closing conditions.

The letter of intent is non-binding other than with respect to certain customary confidentiality and exclusivity provisions. There can be no assurances that the parties will negotiate and enter into definitive transaction agreements or concerning the final terms that might be included in any definitive agreements, whether a transaction will be completed, concerning the timing of closing of any such transaction or concerning the amount of consideration that we might receive at the closing or over time from any such transaction.