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Ticker (Exchange)	SBFM-NASDAQ
Recent Price (10/27/2023)	$0.31
52-week Range	$0.26 – 1.40
Shares Outstanding	25.3 million
Market Capitalization	$7.8 million
Average 10-day volume	51,600
Insider Ownership	39.6%
Institutional Ownership	—
EPS (Year ended 06/30/23)	($0.02)
Employees	48

Sunshine Biopharma Inc. (SBFM-NASDAQ)
One-year Stock Chart

PROPRIETARY DRUG DEVELOPMENT
Adva-27a - Oncology (small molecule)
K1.1 mRNA - Oncology (m-RNA)
SBFM-PL4 - Virology (small molecule)
NORA PHARMA INC.
Revenue Generating Operation
50 Generic Prescription Drugs
27 Products in the Pipeline
SUNSHINE BIOPHARMA CANADA INC.
OTC Products

COMPANY DESCRIPTION

Sunshine Biopharma Inc. ("Sunshine Biopharma" or "the Company") is a revenue-generating pharmaceutical company offering life-saving medicines within a variety of therapeutic areas, including oncology and antivirals. The Company's proprietary therapeutic drug development program includes three product candidates: (1) Adva-27a, a small chemotherapy molecule for pancreatic cancer, (2) K1.1, a **messenger RNA (mRNA) therapeutic** for liver cancer, and (3) SBFM-PL4, a **PLpro** inhibitor for the treatment of COVID-19. Sunshine Biopharma's proprietary pharmaceutical pipeline addresses large markets with significant unmet needs in oncology and anti-viral indications, creating a diversified portfolio with a combined market potential of over $30 billion for the initial targeted indications. In addition to its proprietary drug development efforts, the Company also operates two wholly-owned subsidiaries: Nora Pharma Inc., a Canadian corporation with a portfolio of over 50 **generic prescription drugs**; and Sunshine Biopharma Canada Inc., a Canadian corporation, which sells **over-the-counter (OTC)** supplements. According to the Company, the growth of its revenue-generating generic pharmaceutical business, through the operations of Nora Pharma, places Sunshine Biopharma on track to achieve profitability by FY 2025, with the generated cash flow expected to support and facilitate the development of its proprietary pharmaceutical pipeline. Sunshine Biopharma's revenue generating generic pharmaceutical business, in conjunction with its focused proprietary drug development efforts, provides a low-risk model where the lengthy pharmaceutical development and approval process is supported by revenue generating activities.

KEY POINTS

- On October 20, 2022, Sunshine Biopharma acquired Nora Pharma Inc., a generic pharmaceutical company that currently offers 50 generic prescription drugs in Canada with another 27 drugs scheduled to be launched in 2023 and 2024.
- In preclinical trials, both Adva-27a and K1.1 have been effective against **multidrug resistant (MDR) cancer** cells in vitro, including pancreatic and breast cancer cells, among others.
- In February 2023, the Company signed a research agreement with the Jewish General Hospital in Montreal, Canada, to advance the development of Adva-27a through **IND**-enabling studies as well as negotiated terms for a subsequent Phase I clinical trial in patients with Stage 4 pancreatic cancer.
- The Company is conducting a proof-of-concept mice study to assess K1.1 in vivo effect on liver cancer, with results expected by October/November 2023. Follow up toxicology studies are scheduled for 2Q 2024.
- The Company plans to conduct explorative toxicity studies for SBFM-PL4 (expected 4Q 2023 to 2Q 2024).
- As of June 30, 2023, Sunshine Biopharma had a cash and cash equivalent position of $19.7 million.

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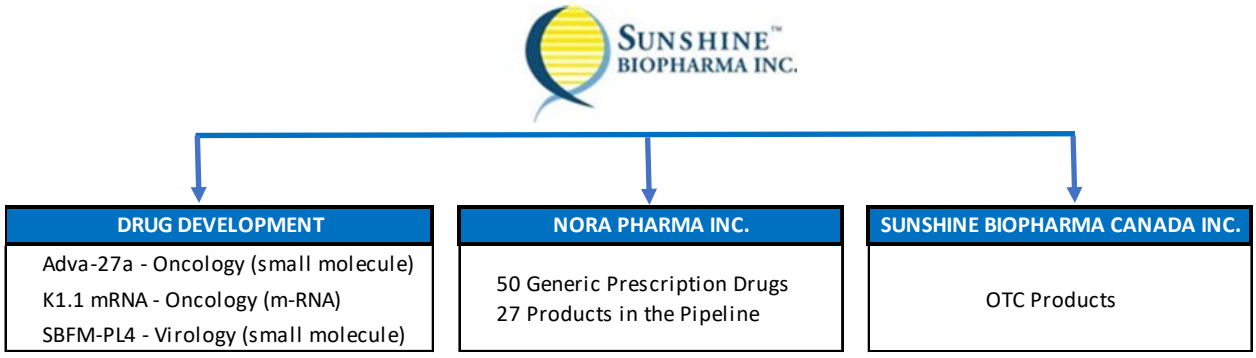
Executive Overview

Sunshine Biopharma Inc. ("Sunshine Biopharma" or "the Company") is a revenue-generating pharmaceutical company offering and researching life-saving medicines within a variety of therapeutic areas, including oncology and antivirals. In addition to its own drug development efforts, the Company operates two wholly-owned subsidiaries: Nora Pharma Inc., a Canadian corporation with a portfolio of 50 generic prescription drugs; and Sunshine Biopharma Canada Inc., a Canadian corporation, which develops and sells OTC supplements. Figure 1 summarizes the Company's business segments as well as an overview of its product offerings.

Figure 1

PRODUCTS AND SEGMENTS



Source: Sunshine Bipharma Inc.

Sunshine Biopharma's business and growth strategy is based on a two-pronged approach: (1) expansion of its revenue-generating generic pharmaceutical business through the operation of its subsidiary, Nora Pharma; and (2) advancement of its proprietary drug development programs. According to the Company, the growth of its generic pharmaceutical business places Sunshine Biopharma on track to achieve profitability by FY 2025, with the long-term goal of using revenues generated through the operations of Nora Pharma to support and facilitate the development of its proprietary pharmaceutical pipeline.

Sunshine Biopharma believes that the combination of its revenue generating generic pharmaceutical business in conjunction with its focused proprietary drug development efforts provides a low-risk model, where the lengthy pharmaceutical development and approval process is supported by its generic activities.

Nora Pharma—Generic Pharmaceutical Business

On October 20, 2022, with a view towards becoming a profitable and fully integrated pharmaceutical company, Sunshine Biopharma acquired Nora Pharma Inc., a Canadian generic pharmaceuticals company. Nora Pharma currently offers 50 generic prescription drugs in Canada with another 27 additional drugs schedule to be launched in 2023 and 2024, as well as a portfolio of 11 nonprescription over-the-counter (OTC) products. Figure 5 (page 14) lists the Company's generic prescription drug portfolio currently available in the Canadian market.

The strategic acquisition expands the Company's revenue stream and is expected to propel revenue growth going forward. The expected growth is driven by an expansion of both its product portfolio and its distribution network, an increase in the effectiveness of its marketing efforts, combined with plans to expand its geographic presence throughout North America and potentially other markets around the world.

The global generic drug market was estimated at $343.6 billion in 2022, and is expected to reach $460.5 billion by 2028 (a CAGR of 6.8%), with North America representing the largest segment (Source: Imarc's *Generic Drugs Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2023-2028*). Within the North American market, the U.S. represents the larger share, estimated at $86.9 billion in 2022, compared to Canada's $8.9 billion. However, the Canadian market is expected to reach $14.8 billion by 2028, representing an 8.5% CAGR, a growth rate higher than those for both the global and the U.S. market during the same period (Source: Imarc's *Canada Generic Drug Market: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2023-2028*).

Proprietary Pharmaceutical Development

Sunshine Biopharma is also engaged in developing proprietary pharmaceutical candidates within the areas of oncology and antivirals. The Company's pipeline includes three novel therapeutic product candidates:

(1) Adva-27a—a **small molecule** effective against multidrug resistant cancers;

(2) K1.1 mRNA—an mRNA anticancer agent; and

(3) SBFM-PL4—a small molecule antiviral against **coronaviruses**.

Sunshine Biopharma's product candidates address large markets with significant unmet needs in oncology and anti-viral indications, creating a diversified proprietary drug pipeline with a combined market potential of over $30 billion for the initial targeted indications. Furthermore, the Company is assesing the use of its oncology product technologies (both small molecule and mRNA) for additional indications.

Adva-27a

The Company's most advanced proprietary oncology product candidate is Adva-27a, a small chemotherapy molecule for the treatment of aggressive forms of cancer. In preclinical trials, Adva-27a has been found to be effective against multidrug resistant (MDR) cancer cells, including pancreatic cancer cells, breast cancer cells, and small-cell lung cancer cells, among others. Sunshine Biopharma is currently developing Adva-27a as a standalone chemotherapeutic agent for the treatment of pancreatic cancer.

Pancreatic cancer is currently the third leading cause of cancer death in the U.S., behind lung cancer and colorectal cancer. This is due primarily to a high mortality rate of the disease. In the U.S., pancreatic cancer represents 8.3% of all cancer deaths despite accounting for only 3.3% of new cases (Source: American Cancer Society's *Cancer Facts and Figures 2023*). The pancreatic cancer treatment market size was valued at $2.47 billion in 2022, and is expected to reach $7.88 billion by 2030 (a CAGR of 15.6%) driven by the rising prevalence of pancreatic cancer and an expected increase in research (Source: Market Research Community's *Pancreatic Cancer Treatment Market Size, Share & Trends Analysis, Forecast Period 2023 – 2030*).

Adva-27a was designed as a novel chemotherapy similar in structure and function to **etoposide** but with improved pharmacokinetic properties and the ability to overcome and evade MDR. Etoposide is one of the most widely used agents in human cancer chemotherapy, currently used to treat various types of cancer. However, despite the clinical success of etoposide, its effectiveness has been hampered by the lack of activity of the drug on certain tumor types, particularly MDR tumors—a shortcoming shared with many other chemotherapeutic agents.

MDR, defined as the resistance of cancer cells to a variety of anticancer chemotherapeutic agents (with cancer cells no longer responding to the treatment) represents a significant obstacle to effective therapeutic interventions against cancer. MDR is responsible for over 90% of deaths in cancer patients receiving traditional chemotherapeutics or novel targeted drugs.

Preclinical studies have identified Adva-27a as a novel chemotherapy agent with superior **cytotoxic** activity against MDR human **cancer cell lines**, including pancreatic cancer cells (Panc-1), breast cancer cells (MCF-7/MDR), small-cell lung cancer cells (H69AR), and uterine sarcoma cells (MES-SA/Dx5), displaying more desirable **pharmacokinetic** properties than etoposide. Compared to etoposide, Adva-27a was found to be substantially more potent against two MDR human cancer cell lines, and to have better metabolic stability and pharmacokinetic properties. The fact that Adva-27a is equally potent in killing drug-sensitive human cancer cells, but more effective than etoposide in killing MDR cancer cells, implies that Adva-27a could form the basis of a new therapy to overcome MDR in human cancer.

In February 2023, the Company signed a research agreement with McGill University Health Center's Jewish General Hospital in Montreal, Canada, to advance the development of Adva-27a through the IND-enabling studies. The research partnership also includes negotiating terms for a subsequent Phase I clinical trial in patients with Stage 4 pancreatic cancer, also to be conducted at the Jewish General Hospital. All aspects of the clinical trials in Canada will employ FDA standards at all levels.

K1.1 mRNA

Sunshine Biopharma's second oncology product candidate is based on the Company's research project assessing the use of certain messenger RNA (mRNA) molecules as anticancer agents. The project led to the identification of a selected group of mRNA molecules—bearing the laboratory name K1—that have shown the ability to destroy MRD cancer cells in vitro.

The Company is developing its first product candidate from this technology—K1.1—for the treatment of liver cancer, the sixth most prevalent type of cancer diagnosed worldwide and the third leading cause of cancer death. The global liver cancer therapeutic market was estimated at $1.8 billion in 2021, and is expected to reach $8.9 billion by 2030, driven by rising rates of liver cancer coupled with a robust investment in R&D activities by the pharmaceutical industry aimed at developing novel innovative therapeutic drugs (Source: Growth Plus Market Reports' *Liver Cancer Therapeutics Market*, 2022).

Sunshine Biopharma had previously shown that its K1.1 mRNA is capable of destroying cancer cells in vitro, including MDR breast cancer cells (MCF-7/MDR), ovarian adenocarcinoma cells (OVCAR-3), and pancreatic cancer cells (SUIT-2). Results of additional parallel studies using normal human cells (HMEC) also showed that K1.1 mRNA had little or no cytotoxic effects.

In November 2022, Sunshine entered into a collaboration agreement with a leading mRNA **lipid nanoparticle (LNP)** company for the purposes of formulating the Company's K1.1 mRNA molecules into lipid nanoparticles, which Sunshine Biopharma is using in its ongoing proof-of-concept mice study. The study involves the administration of K1.1 to mice that have received liver cancer cells by subcutaneous injections, resulting in tumor growth, in order to assess K1.1's in vivo effect on liver cancer. The last dose for the study is expected by October 10, 2023, with results expected by the end of October 2023. Furthermore, the Company is planning to conduct toxicology studies in two species of rodents by 2Q 2024. Should these mouse studies prove successful, the Company plans to file an IND application to begin Phase 1 trials. The LNP formulated K1.1 mRNA can be readily adapted for delivery into patients using the recently gained knowledge from the mRNA vaccine technology used during the COVID-19 pandemic.

SBFM-PL4

Sunshine Biopharma is developing a late-preclinical injectable therapeutic candidate to treat coronavirus infections, with an initial focus on **SARS-CoV2** (COVID-19) infections in patients who could not use the currently approved treatments (i.e., Paxlovid, Molnupiravir, or Remdesivir) due to concerns about drug interaction and other side effects. These efforts have been focused on the development of a first-in-class small molecule PLpro inhibitor. PLpro is a viral enzyme essential for viral replication and maturation, a key part of the coronavirus' life cycle during infection. In addition, PLpro is of particular interest as a coronavirus therapeutic target in that it is also responsible for suppression of the human immune system, a special feature of coronaviruses that limits the body's reaction against the pathogen, making the virus more effective (Source: *Fundamental Research, Vol. 1 (2): 151-165*, 2021). As such, the Company believes that PLpro represents an attractive anti-viral drug development target for the inhibition of the early stages of COVID-19 infection.

In August 2020, the Company synthesized its first group of PLpro small molecule inhibitors. Furthermore, in February 2021, Sunshine Biopharma strengthened its PLpro program by signing an exclusive license agreement with the University of Georgia for two PLpro inhibitors developed there.

The Company has also been conducting research on this project in collaboration with the University of Arizona for the purposes determining the in vivo safety, pharmacokinetics, and dose selection properties of three University of Arizona-owned PLpro inhibitors, and has recently entered into an exclusive worldwide license agreement with the University of Arizona for all of the technology related to the collaboration.

Sunshine Biopharma plans to begin explorative toxicity studies and proof-of-concept efficacy studies in hamsters (expected 4Q 2023 to 2Q 2024), with additional ADME (absorption, distribution, metabolism, and excretion) in other species expected to begin 2Q 2024. Following these studies, the Company expects to nominate a lead candidate formulation for an IND enabling study by 3Q 2024.

The Company believes that its PLpro inhibitor technology could be effective for the treatment, not only of COVID-19, but also of other coronavirus infections with no effective treatment. This stems from the fact that in addition to SARS-CoV-2 (COVID-19), PLpro is found in different coronaviruses, including **SARS-CoV (SARS)** and **MERS-CoV (MERS)** (Source: *Encyclopedia of Cell Biology, Vol. 1: 930–941*, 2023).

Pfizer has an Mpro specific inhibitor on the market, called Paxlovid, which is used as a treatment for COVID-19 and is expected to generate $8 billion in sales during 2023. The successful development of the Company's SBFM-PL4 product candidate as the first PLpro inhibitor could become a significant competitor to Paxlovid, joining the very select and scarce options to treat severe COVID-19.

Sunshine Biopharma Canada

Sunshine Biopharma also sells OTC products in both Canada and the U.S. through the operations of its fully-owned subsidiary Sunshine Biopharma Canada Inc. The Company sells products in Canada and the U.S. through Amazon.ca and Amazon.com, respectively. Sunshine Biopharma expanded its product range by the acquisition of Nora Pharma Inc., bringing an additional 11 nonprescription products into the OTC offerings.

CORPORATE INFORMATION (HEADQUARTERS, EMPLOYEES, AND HISTORY)

The Company was incorporated on August 31, 2006, and on October 15, 2009, acquired Sunshine Biopharma, Inc., the holder of an exclusive license for Adva-27a, in a transaction classified as a reverse acquisition. Upon completion of the reverse acquisition transaction, it changed its name to Sunshine Biopharma, Inc. On October 20, 2022, Sunshine Biopharma acquired Nora Pharma Inc. The Company is headquartered in Montreal, Canada and has 48 employees.

Company Leadership

Members of Sunshine Biopharma's executive management team and Board of Directors are listed in Figure 2 and profiled thereafter.

Figure 2

MANAGEMENT AND BOARD OF DIRECTORS

MANAGEMENT	
Dr Steve Slilaty	Chief Executive Officer and Chairman of the Board
Dr. Abderrazzak Merzouki	Chief Operating Officer and Director
Mr. Camille Sebaaly	Chief Financial Officer

BOARD OF DIRECTORS	
Dr. Steve Slilaty	Chief Executive Officer and Chairman of the Board
Dr. Abderrazzak Merzouki	Chief Operating Officer and Director
Dr. Rabi Kiderchah	Director
M. David Natan	Director
Dr. Andrew M. Keller	Director

Source: Sunshine Bipharma Inc.

Officers

Dr. Steve Slilaty, Chief Executive Officer and Chairman of the Board

Dr. Slilaty is an accomplished scientist and business leader whose scientific publications are widely cited. Sunshine Biopharma is the third in a series of biotechnology companies that he has founded and led. The first, Quantum Biotechnologies Inc. later known as Qbiogene Inc., was founded in 1991 and is now part of a family of companies owned by MP Biomedicals, one of the world's largest suppliers of biotechnology reagents and other research products. The second company founded by Dr. Slilaty, Genomics One Corporation, completed an initial public offering (IPO) in 1999 and, through its ownership of Dr. Slilaty's patented TrueBlue® technology, Genomics One has become one of the main participants in the human genome project, reaching a market cap of one billion dollars in 2000. Previously, Dr. Slilaty was a research team leader at the Biotechnology Research Institute (Montreal), a division of the National Research Council of Canada. Dr. Slilaty is one of the pioneers of gene therapy, having developed the first gene delivery system applicable to humans in 1983. During his scientific career, Dr. Slilaty notably discovered a new class of enzymes, the S24 family of proteases. In addition, Dr. Slilaty developed the first site-directed mutagenesis system applicable to double-stranded DNA, cloned the gene for the first yeast lytic enzyme, developed a new molecular strategy to increase the rate of enzymatic reactions, and built a powerful new cloning system for genomic sequencing. More recently, Dr. Slilaty, in collaboration with the National Institute of Applied Sciences (France), the State University of New York at Binghamton (USA) and the École polytechnique, Université de Montréal (Canada), designed, patented, and advanced the development of the first and currently only known anti-cancer compound (Adva-27a) capable of destroying multi-drug resistant cancer cells. This and other works by Dr. Slilaty are cited in research papers, editorials, review articles, and textbooks. Dr. Slilaty is the author of 18 original research articles and 10 published or pending articles. He received his doctorate in molecular biology from the University of Arizona in 1983 and a BS in genetics and biochemistry from Cornell University in 1976. Dr. Slilaty has received research grants from the NIH and the NSF and in 1981 received the University of Arizona Foundation Award for meritorious performance in teaching.

Dr. Abderrazzak Merzouki, Chief Operating Officer and Director

Dr. Merzouki was appointed Director and Chief Operating Officer in February 2016. Since January 2016, he has been an independent consultant in the fields of biotechnology and pharmacology. From July 2007 to December 2016, Dr. Merzouki worked at the Institute of Biomedical Engineering within the Department of Biomedical Engineering Chemical Engineering at Ecole Polytechnique de Montreal, where he taught and acted as a senior scientist involved in research and development of plasmid and siRNA-based therapies. Dr. Merzouki is a molecular biologist and immunologist with extensive experience in the field of gene therapy. He has performed several preclinical studies for pharmaceutical companies regarding the use of adenoviral vectors for cancer therapy and plasmid vectors for the treatment of peripheral arterial occlusions. Dr. Merzouki also has extensive expertise in the design of expression vectors, as well as the production and purification of recombinant proteins. He has developed technologies for the production of biogeneric therapeutic proteins for the treatment of various diseases, including cancer, diabetes, hepatitis, and multiple sclerosis. Dr. Merzouki obtained his doctorate in virology and immunology at the Armand-Frappier Institute in Quebec and completed post-doctoral training at the University of British Columbia and the British Columbia Center of Excellence for Research on HIV/AIDS. Dr. Merzouki has published over 30 articles and 70 communications in various highly respected scientific journals in the field of cellular and molecular biology.

Mr. Camille Sebaaly, Chief Financial Officer

Mr. Camille Sebaaly was appointed as chief financial officer, secretary, and a director on October 15, 2009. He resigned as a director of the Company in October 2021. Since 2001, Mr. Sebaaly has been self-employed as a business consultant, primarily in the biotechnology and biopharmaceutical sectors. He held a number of senior executive positions in various areas, including financial management, business development, project management, and finance. As an executive and entrepreneur, he combines expertise in strategic planning and finance with strong skills in business development and deal structure and negotiations. In addition, Mr. Sebaaly worked in operations, general management, investor relations, marketing, and business development with an emphasis on international business and marketing of advanced technologies, including hydrogen generation and energy saving. In the area of marketing, Mr. Sebaaly has evaluated market demands and opportunities, created strategic marketing and business development plans, designed marketing communications, and launched market penetration programs. Mr. Sebaaly graduated from State University of New York at Buffalo with an Electrical and Computer Engineering Degree in 1987.

Board of Directors

Dr Steve Slilaty, Chief Executive Officer and Chairman of the Board

Biography on page 7.

Dr. Abderrazzak Merzouki, Chief Operating Officer and Director

Biography on page 8.

Dr. Rabi Kiderchah, Director

Dr. Kiderchah has been a director of the Company since October 2021. He is a licensed physician in Canada. From 2000 to August 2021, he worked at Argenteuil Hospital, in Lachute, Quebec, Canada, as an emergency physician. He also worked as what is known in Canada as a “dépanneur doctor”, in rural areas where there are not enough emergency doctors. Since August 2011, he has been working for Rabi Kiderchah Medecin Inc. as an independent doctor in the region of Quebec, Canada. He obtained a bachelor's degree in science in 1994 and a medical degree in 1998 from the University of Montreal.

Mr. David Natan, Director

Mr. Natan has been a director of the Company since February 2022. In addition, since 2007, he has held the following described position: President and CEO of Natan & Associates, LLC, a consulting firm providing CFO services to public and private companies in various business sectors. From February 2010 to May 2020, Mr. Natan served as the Managing Director of ForceField Energy, Inc. (OTCMKTS: FNRG), a company specializing in the solar industry and LED lighting products. From February 2002 to November 2007, he served as Executive Vice President, Reporting and Chief Financial Officer of PharmaNet Development Group, Inc., a drug development services company, and from June 1995 to February 2002, Chief Financial Officer and Vice President of Global Technovations, Inc. a manufacturer and marketer of oil analysis instruments, loudspeakers, and loudspeaker components. Previously, Mr. Natan held various positions of increasing responsibility at Deloitte & Touche LLP. Mr. Natan is currently a member of the Board of Directors and Chairman of the Audit Committee of Global Diversified Marketing Group, Inc. (OTCMKTS: GDMK), a manufacturer, marketer, and distributor of food and snack products, since February 2021, and Member of the Board of Directors and Chairman of the Audit Committee of Sunshine Biopharma, Inc. since February 2022. In addition, in December 2022, Mr. Natan was appointed as a member of the Board of Directors and chairman of the audit committee of Vivakor Inc. (NASDAQ: VIVK). Previously, he was Chairman of the Board of Directors of ForceField Energy, Inc. from April 2015 to May 2020, and a member of the Board of Directors of Global Technovations, Inc. from December 1999 to December 2001. Mr. Natan holds a bachelor's degree in economics from Boston University.

Dr. Andrew M. Keller, Director

Dr. Keller has been a director of Sunshine Biopharma since February 10, 2022. From 2016 to November 2019, he served as chief medical officer for Western Connecticut Medical Group, Bethel CT, a multi-specialty organization. Dr. Keller was employed by this group from 1989, and in 2003, became head of the cardiovascular disease section. In 2014, he was appointed Director of Medical Informatics. Previously, Dr. Keller was Assistant Professor of Medicine/Radiology at Columbia University, College of Physicians and Surgeons, New York. Dr. Keller retired as a physician in 2019 and in 2020 became a full-time student at Quinnipiac University School of Law, where he is currently in his third year. Dr. Keller received an MD in 1979 from Ohio State University and a BS in Physics, Magna Cum Laude, from Ithaca College in 1975.

Milestones

Since its listing on NASDAQ in February 2022, the Company has achieved the following key milestones as it seeks to further expand its generic pharmaceutical business while advancing the development of its proprietary drug pipeline:

- Completed the acquisition of Nora Pharma Inc. in October 2022, giving the Company a portfolio of 50 prescription drugs on the market in Canada.
- Entered into a research agreement with McGill University Health Center's the Jewish General Hospital for the development of Adva-27a anticancer compound through the IND-enabling studies.
- Entered into a collaboration and worldwide license agreement with the University of Arizona, granting the Company worldwide rights for the University of Arizona technology derived from the collaboration pertaining to its coronavirus therapeutic program (SBFM-PL4).
- Advanced the development of the Company's anticancer K1.1 mRNA program by entering into collaboration and testing agreement with one of the leading lipid nanoparticle formulation companies in North America.
- Started K1.1's first proof-of-concept mice study in Q4 2023.

Potential Milestones

Moving forward, the Company has established the following objectives over the next 12-18 months:

- Achieve profitability by FY 2025.
- Launch of an additional 27 generic drugs in 2023 and 2024 through the operations of Nora Pharma.
- Aggressively advance the development of Adva-27a for pancreatic cancer, K1.1 mRNA for liver cancer, and SBFM-PL4 for COVID-19.

Intellectual Property

ADVA-27A

Sunshine Biopharma is the direct owner of all issued patents pertaining to Adva-27a, patent rights which are covered by PCT/FR2007/000697 and PCT/CA2014/000029. The patent applications filed under these two PCT's have been issued in the United States (U.S. Patent Number 8,236,935 and 10,272,065), Europe, and Canada.

K1.1

On April 20, 2022, the Company filed a patent application in the U.S. covering mRNA molecules capable of destroying cancer cells in vitro. The patent application contains composition and utility subject matter pertaining to the structure and sequence of the relevant mRNA molecules. The K1.1 lead anticancer mRNA molecule arising from this technology is targeted for liver cancer.

SBFM-PL4

On May 22, 2020, Sunshine Biopharma filed a provisional patent application in the U.S. for a new treatment for coronavirus infections. The Company's patent application covers composition subject matter pertaining to small molecules for inhibition of the coronavirus main protease, Mpro.

On April 30, 2021, the Company filed a PCT application containing new research results and extending coverage to include the Coronavirus Papain-Like protease, PLpro. The Company's lead anti-coronavirus compound arising from these patents bears the laboratory name SBFM-PL4.

In addition, on February 18, 2022, the Company entered into a research agreement with the University of Arizona for the purposes of conducting research focused on determining the in vivo safety, pharmacokinetics, and dose selection properties of three University of Arizona-owned PLpro inhibitors. The agreement granted the Company a first option to negotiate a commercial, royalty-bearing license for all intellectual property developed by University of Arizona personnel under this Project. Encouraged by the results to date, the Company submitted a Notice of Option Exercise to the University of Arizona on September 13, 2022.

NORA PHARMA

Sunshine Biopharma's wholly-owned subsidiary, Nora Pharma, owns 152 Drug Identification Numbers (DINs) issued by Health Canada for prescription drugs currently on the market in Canada. These DIN's were secured through in-licenses or cross-licenses from international manufacturers of generic pharmaceutical products. A DIN is a computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada.

In addition, the Company is the owner of two NPN's issued by Health Canada: NPN 80089663 authorizes to manufacture and sell Sunshine Biopharma's inhouse developed OTC product, Essential 9™; and NPN 80093432 authorizes to manufacture and sell the OTC product, Calcium Vitamin D, under the brand name Essential Calcium-Vitamin D™.

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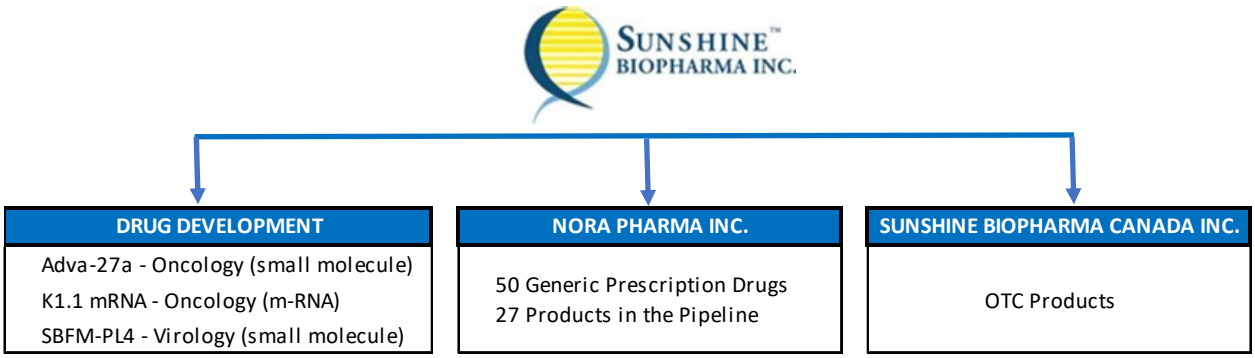
Core Story

Sunshine Biopharma Inc. ("Sunshine Biopharma" and "the Company") is a revenue-generating pharmaceutical company offering and researching life-saving medicines within a variety of therapeutic areas, including oncology and antivirals. In addition to its own drug development efforts, the Company operates two wholly-owned subsidiaries: Nora Pharma Inc., a Canadian corporation with a portfolio of 50 generic prescription drugs in Canada with another 27 additional drugs scheduled to be launched in 2023 and 2024; and Sunshine Biopharma Canada Inc., a Canadian corporation which develops and sells OTC supplements. Figure 3 summarizes the Company's business segments as well as an overview of its product offerings.

Figure 3

PRODUCTS AND SEGMENTS



Source: Sunshine Bipharma Inc.

Sunshine Biopharma's business and growth strategy is based on a two-pronged approach: (1) expansion of its revenue-generating generic pharmaceutical business, targeting a global market of $344 billion; and (2) advancement of its drug development programs, creating a diversified proprietary drug pipeline with a potential combined market of over $30 billion a year.

This strategy aims to generate revenue in the short- to medium-term through the Company's generic pharmaceutical business, conducted through the operations of its subsidiary Nora Pharma, which is expected to support and facilitate the mid- to long-term development of its proprietary pharmaceutical pipeline. Sunshine Biopharma believes that its current growth trajectory places it on track to achieve profitability by FY 2025, with the ultimate goal of being in a position to financially support its proprietary drug research and development efforts. The Company believes that its revenue generating generic pharmaceutical business, in conjunction with its focused proprietary drug development efforts, provides a low-risk model where the lengthy pharmaceutical development and approval process is supported by revenue generating activities.

Manufacturing

The Company's generic pharmaceuticals are manufactured by several different international partners under long-term contracts. Research quantities of Sunshine Biopharma's proprietary drug candidates are currently manufactured at the University of Arizona located in Tucson, Arizona (anti-coronavirus compounds), WuXi App Tech located in Hong Kong, China (Adva-27a compound), and Arranta Bio MA LLC located in Watertown, Massachusetts and other U.S.-based companies (K1.1 mRNA). The Company's OTC products are manufactured under contract by INOV Pharma Inc. located in Montreal, Canada.

Nora Pharma Inc.

On October 20, 2022, with a view towards becoming a profitable and fully integrated pharmaceutical company, Sunshine Biopharma acquired Nora Pharma Inc. ("Nora Pharma"), a Canadian generic pharmaceutical company. As summarized in Figure 4, Nora Pharma currently offers 50 generic prescription drugs in Canada with another 27 additional drugs scheduled to be launched in 2023 and 2024, as well as a portfolio of 11 nonprescription OTC products. The strategic acquisition expands the Company's revenue stream and is expected to drive revenue growth going forward.

Long term, the Company plans to utilize the revenue generated by Nora Pharma's operations to financially support its proprietary drug research and development efforts (detailed in pages 16-28), facilitating the mid- to long-term development of its proprietary pharmaceutical pipeline and reducing the need for external revenue sources to complete the lengthy approval process.

Figure 4

NORA PHARMA OVERVIEW

- 50 prescription drugs on the market
- 27 additional drugs in the pipeline
- $14.7 million sales in 2022
- $21 million projected sales in 2023
- 41 employees

Source: Sunshine Bipharma Inc.

GENERIC MARKET

The acquisition of Nora Pharma gives the Company a solid position in the generic prescription pharmaceutical industry. A generic drug is a pharmaceutical product that is bioequivalent to a brand-name drug in terms of dosage, strength, safety, efficacy, route of administration, and intended use. Generic drugs are produced and marketed after the patent protection of the original brand-name drug expires and are typically sold at substantial discounts from the branded price. These medications contain the same active ingredients as their brand-name counterparts and undergo rigorous testing by regulatory authorities to ensure their quality, safety, and effectiveness.

Generic drugs play a crucial role in providing cost-effective alternatives to brand-name drugs, promoting competition in the pharmaceutical market and enhancing the overall efficiency of healthcare systems. In the U.S., for example, generic drugs accounted for 91% of prescriptions filled, translating into $373 billion in continued healthcare system savings (for patients, employers, and taxpayers), including $119 billion in Medicare savings (Source: Association for Affordable Medicines' *2022 U.S. Generic and Biosimilar Medicines Savings Report*).

The global generic drug market reached an estimated $343.6 billion in 2022 and is expected to reach $460.5 billion by 2028, a CAGR of 6.8%, behind the growing prevalence of various chronic diseases, rising investments in research-related activities in the pharmaceutical industry, and increasing numbers of patent expirations of brand name drugs (Source: Imarc's *Generic Drugs Market: Global Industry Trends, Share, Size, Growth, Opportunity and Forecast 2023-2028*). Of the total global market, North America continues to be the largest regional segment because of rising demand for generic drugs in developed economies, such as Canada and the U.S., flexible market players, a growing healthcare industry, and technological advancements.

In the North American generic trade market, the U.S. represents the larger share, with a market estimated at $86.9 billion in 2022, compared to Canada's $8.9 billion. However, the Canadian market is expected to reach $14.8 billion by 2028, representing a CAGR (8.5%), a growth rate higher than both the global and the U.S. market during the same period (Source: Imarc's *Canada Generic Drug Market: Industry Trends, Share, Size, Growth, Opportunity and Forecast 2023-2028*).

The growing number of hospitals and clinics, the rising prevalence of chronic diseases, as well as favorable government initiatives are the key factors driving the Canadian generic market growth. Governing agencies in Canada are promoting the use of generic drugs through various mechanisms, such as tax incentives, subsidies, and market access arrangements. In addition, the growing awareness among individuals with regard to the benefits of generic drugs is positively influencing the market.

Marketed Products

As a result of the acquisition of Nora Pharma, Sunshine Biopharma has the following generic prescription drugs, as shown in Figure 5, on the market in Canada.

Figure 5
GENERIC PRESCRIPTION DRUGS IN CANADA

Drug	Action/Indication	Reference Brand
Alendronate	Osteoporosis	Fosamax®
Amlodipine	Cardiovascular	Norvasc®
Apixaban	Cardiovascular	Eliquis®
Atorvastatin	Cardiovascular	Lipitor®
Azithromycin	Antibacterial	Zithromax®
Candesartan	Hypertension	Atacand®
Candesartan HCTZ	Hypertension	Atacand®
Celecoxib	Anti-inflammatory	Celebrex®
Cetirizine	Allergy	Reactine®
Ciprofloxacin	Antibiotic	Cipro®
Citalopram	Central nervous system	Celexa®
Clindamycin	Antibiotic	Dalacin®
Clopidogrel	Cardiovascular	Plavix®
Donepezil	Central nervous system	Aricept®
Duloxetine	Central nervous system	Cymbalta®
Dutasteride	Urology	Avodart®
Escitalopram	Central nervous system	Cipralex®
Ezetimibe	Cardiovascular	Ezetrol®
Finasteride	Urology	Proscar®
Flecainide	Cardiovascular	Tambocor®
Fluconazole	Antifungal	Diflucan®
Fluoxetine	Central nervous system	Prozac®
Hydroxychloroquine	Antimalarial	Plaquenil®
Lacosamide	Central nervous system	Vimpat®
Letrozole	Oncology	Femara®
Levetiracetam	Central nervous system	Keppra®
Mirtazapine	Central nervous system	Remeron®
Metformin	Diabetes	Glucophage®
Montelukast	Allergy	Singulair®
Olanzapine ODT	Central nervous system	Zyprexa®
Olmesartan	Cardiovascular	Olmetec®
Olmesartan HCTZ	Cardiovascular	Olmetec Plus®
Pantoprazole	Acid Reflux	Pantoloc®
Paroxetine	Central nervous system	Paxil®
Perindopril	Cardiovascular	Coversyl®
Pravastatin	Cardiovascular	Pravachol®
Pregabalin	Central nervous system	Lyrica®
Quetiapine	Central nervous system	Seroquel®
Quetiapine XR	Central nervous system	Seroquel XR®
Ramipril	Cardiovascular	Altace®
Rizatriptan ODT	Central nervous system	Maxalt® ODT
Rosuvastatin	Cardiovascular	Crestor®
Sertraline	Central nervous system	Zoloft®
Sildenafil	Urology	Viagra®
Tadalafil	Urology	Cialis®
Telmisartan	Cardiovascular	Micardis®
Telmisartan HCTZ	Cardiovascular	Micardis Plus®
Tramadol Acetaminophen	Central nervous system	Tramacet®
Zolmitriptan	Central nervous system	Zomig®
Zopiclone	Central nervous system	Imovane®

Source: Sunshine Biopharma Inc.

In addition, Nora Pharma's development pipeline includes an additional 27 generic pharmaceuticals scheduled to be launched in 2023 and 2024, encompassing multiple therapeutic areas, as listed in Figure 6.

Figure 6
GENERIC PRESCRIPTION PIPELINE

Generic Drugs	Therapeutic Area(s)	Development Stage	Launch Date
Group A (7 Products)	Central Nervous System, Gastrointestinal, Urology	Under Regulatory Review	2023Q3
Group B (1 Product)	Oncology	Under Regulatory Review	2023Q4
Group C (8 Products)	Central Nervous System, Cardiovascular, Metabolism	Under Regulatory Review	2024Q1
Group D (5 Products)	Cardiovascular, Urology, Endocrinology	Under Regulatory Review	2024Q2
Group E (6 Products)	Urology, Cardiovascular, Oncology, Anti-infectives	Under Regulatory Review	2024Q3

Source: Sunshine Biopharma Inc.

Proprietary Pharmaceutical Development

Sunshine Biopharma is engaged in the development of proprietary pharmaceutical candidates in the areas of oncology and antivirals. The Company's pipeline includes three product candidates, as shown in Figure 7.

Figure 7
PIPELINE

PROPRIETARY CANDIDATE	TYPE OF COMPOUND	THERAPEUTIC AREA	DEVELOPMENT STAGE
Adva-27a	Small Molecule	Oncology (Pancreatic Cancer)	IND-Enabling Studies
K1.1	mRNA LNP	Oncology (Liver Cancer)	Animal Testing
SBFM-PL$	Small Molecule	Antiviral (Coronavirus)	Animal Testing

Source: Sunshine Bipharma Inc.

Furthermore, the Company is assesing the use of its oncology product technologies (both the small molecule and mRNA) for additional indications, as detailed in the accompanying sections.

Sunshine Biopharma is planning to conduct clinical trials for its oncology products in Canada, with an application for marketing approval to Health Canada as the first step. However, the Company is planning to conduct the trials following FDA approved protocols, which means that the data collected in the Canadian trials could be used to submit an application in the U.S. Sunshine Biopharma believes that this strategy could accelerate the initial time to market (in the Canadian market) while setting the foundation for a subsequent FDA approval. For its antiviral product candidate—SBFM-PL4—Sunshine Biopharma expects to be conducting the clinical trials in the U.S. under FDA guidelines.

ADVA-27a ANTICANCER SMALL MOLECULE

Figure 8
ADVA-27a OVERVIEW

- Chemotherapy small molecule
- Effective against multidrug resistant cancer
- In vitro studies underway at the Jewish General Hospital

Source: Sunshine Bipharma Inc.

The Company's most advanced proprietary oncology product candidate is Adva-27a, a small chemotherapy molecule for the treatment of aggressive forms of cancer. In preclinical trials, Adva-27a has been found to be effective against multidrug resistant (MDR) cancer cells, including pancreatic cancer, breast cancer, small-cell lung cancer, and uterine sarcoma cells. Sunshine Biopharma is currently developing Adva-27a as a standalone chemotherapeutic agent for the treatment of pancreatic cancer. Figure 8 provides an overview of Adva-27a.

Multidrug Resistant Cancers

Cancer is a leading cause of death worldwide, accounting for nearly 10 million deaths in 2020, or nearly one in six deaths, derived from 19.3 million new cases (Source: World Health Organization). In the U.S., cancer is the second leading cause of death, with over 1.9 million new cancer cases expected in 2023, resulting in approximately 610,000 deaths (Source: American Cancer Society's *Cancer Facts and Figures 2023*).

The identification of effective cancer treatments remains an important goal for researchers. Currently, chemotherapy is viewed as one of the most promising cancer treatment modalities for reducing the cancer burden. However, chemotherapy fails in many cases because tumor cells develop resistance against the anticancer agent, with cancer cells no longer responding to the treatment (Source: *Frontiers of. Oncology, Vol. 12*, 2022). Unfortunately, once cancer cells become resistant to a chemotherapy drug, they are more likely to be resistant to many other chemotherapy agents as well—a process known as multidrug resistance (MDR). MDR is defined as the

resistance of cancer cells to a variety of anticancer chemotherapeutic agents with different structures and mechanisms of action.

MDR represents a major obstacle to effective therapeutic interventions against cancer. MDR is responsible for over 90% of deaths in cancer patients receiving traditional chemotherapeutics or novel targeted drugs. There are many mechanisms responsible for MDR, including decrease cell uptake and enhanced cell efflux of the drug (which reduces the drug absorption by cancer cells), individual genetic differences, as well as other molecular and cellular mechanisms—all of which lead to reduction of the therapeutic efficacy of administered drugs. Because of this, there is a growing number of oncology research and biomedical studies focused on designing chemotherapeutics that are able to evade or reverse MDR (Source: *International Journal of Molecular Science,* Vol.21(9):3233, 2020).

ADVA27a Small Molecule

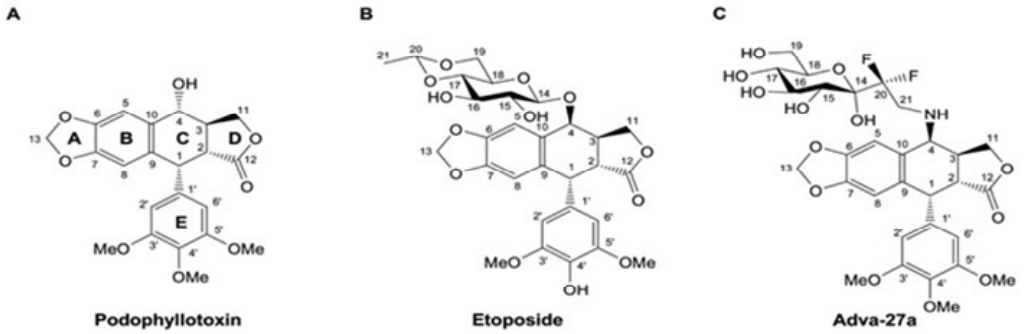
Etoposide, a synthetic derivative of **podophyllotoxin**, is one of the most widely used agents in human cancer chemotherapy, currently used to treat various types of cancer, including small-cell lung cancer, testicular cancers, leukemia, lymphoma, brain cancer, prostate cancer, bladder cancer, colon cancer, ovarian cancer, and liver cancer, among others. Etoposide acts as a **topoisomerase II** inhibitor. Topoisomerases are nuclear enzymes that catalyze the introduction of topological changes to the DNA molecule. Replication and transcription of DNA require the unwinding (or flattening) of the DNA helix, a process carried out by topoisomerases. Specific forms of topoisomerase II are overexpressed in proliferating cells and serve as a biomarker for cell proliferation, and as such it has been shown to be an effective target in treating a wide spectrum of cancers (Source: *Journal of Medicinal Chemistry*, *Vol 63 (3): 884–904*, 2020).

Despite the clinical success of etoposide for the treatment of cancer, its effectiveness has been hampered by the lack of activity of the drug on certain tumor types, particularly MDR tumors, a shortcoming shared with many other chemotherapeutic agents. To solve this issue, Sunshine Biopharma designed and synthetized Adva-27a, a novel derivative of podophyllotoxin with similar structure and function to etoposide but with improved pharmacokinetic properties and the ability to overcome MDR of human cancer cells.

Adva-27a is a GEM-difluorinated C-glycoside derivative of podophyllotoxin. The structure of Adva-27a differs from etoposide in that it has an amino linked GEM-difluoro glycoside at the C4 position and a methoxyl group at the E4' position (as illustrated in Figure 9). The C4 and E4 changes in Adva-27a have resulted in improved cytotoxic activity against MDR cancer cells, such as breast and lung cancer cells.

Figure 9

ADVA27-a STRUCTURE



Source: *Anticancer Research*.

Although the precise mechanism that allows Adva-27a to overcome MDR is not fully understood, the Company believes it is related to two key factors: (1) improved cancer cell selectivity; and (2) increased pharmacokinetic properties. The addition of the GEM-difluoro glycoside allows Adva-27a to improve its cancer cells selectivity. Adva27-a is designed as a traditional chemotherapy drug, administered intravenously. As the compound circulates in the body, it goes preferentially to cancer cells. Cancers of diverse origins exhibit marked glucose affinity. Understanding of this dysfunctional metabolism has resulted in the promising strategy of linking a therapeutic agent to glucose for improved cancer targeting (Source: *Chemical Science, Vol. 4(6): 2319–2333*, 2013).

Furthermore, it appears that Adva-27a is able to evade the innate efflux pump mechanisms normally responsible for the rapid ejection of the therapeutic compound from the cancer cell and a lead cause of MDR. The ability of Adva-27a to evade this mechanism results in prolonged exposure of the cancer cell to the therapeutic agent and increase cytotoxic activity.

Adva-27a Preclinical Testing

Preclinical studies have identified Adva-27a as a novel topoisomerase II inhibitor with superior cytotoxic activity against MDR human cancer cells, including pancreatic cancer cells, breast cancer cells, small-cell lung cancer cells, uterine sarcoma cells, and pancreatic cancer cells, displaying more desirable pharmacokinetic properties than etoposide. Adva-27a and etoposide are similar in that they both attack the same target in cancer cells—topoisomerase II. However, unlike etoposide, Adva-27a has the advantage of being able to penetrate and destroy MDR cancer cells.

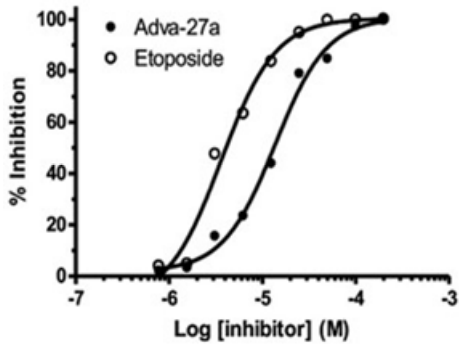
In one specific study, Adva-27a activity was evaluated in a variety of assays, including inhibition of topoisomerase IIα, cytotoxic activity in drug-sensitive and drug-resistant cancer cell lines, metabolic stability, and pharmacokinetic properties in rats (Source: *Anticancer Research, Vol. 32: 4423-4432*, 2012).

Topoisomerase IIα Activity

Adva-27a was found to induce a dose-dependent inhibition of human topoisomerase IIα activity in vitro, as seen in Figure 10. The **IC50** of Adva-27a for inhibition of topoisomerase IIα was determined to be 13.7 µM. Under the same experimental conditions, etoposide was confirmed to be a topoisomerase IIα inhibitor with an IC50 of 4.0 µM. IC50 is the most widely used and informative measure of a drug's efficacy and potency, as it indicates how much of a particular inhibitory substance (e.g., drug) is needed to inhibit, in vitro, a given biological process or biological component by 50%.

Figure 10

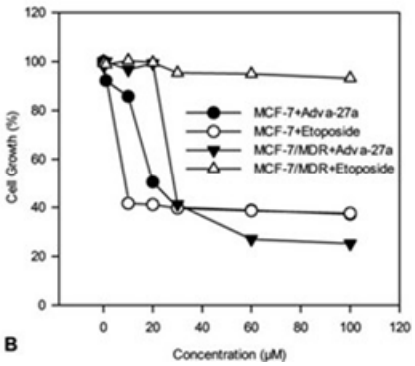
TOPOISOMERASEe IIα INHIBITION



Source: *Anticancer Research*.

Figure 11

BREAST CANCER ACTIVITY



Source: *Anticancer Research*.

Breast Cancer Line Activity

The study analyzed the growth inhibitory activity of Adva-27a compared to etoposide in the drug-sensitive breast cancer cell line, MCF-7, and in a MDR variant of MCF-7, MCF-7/MDR. With the drug-sensitive MCF-7 cell line, the growth inhibitory activity of Adva-27a was similar to that of etoposide starting at approximately 20 µM. With the MCF-7/MDR cell line however, it had little effect on cell growth even at 100 µM etoposide, while Adva-27a caused a dramatic reduction in cell growth starting at a concentration between 20 and 30 µM (Figure 11 [page 18]).

The fact that Adva-27a is equally potent in killing drug-sensitive human cancer cells (MCF-7), but more effective than etoposide in killing MDR cancer cells (MCF-7/MDR) implies that Adva-27a could form the basis of a new therapy to overcome MDR in human cancer.

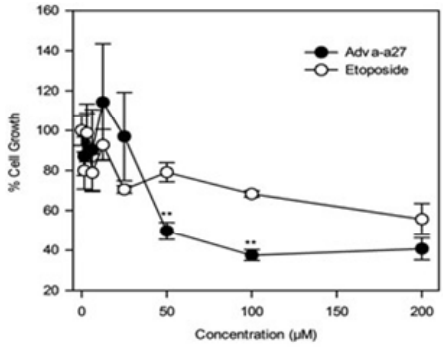
Lung Cancer Line Activity

To investigate if Adva-27a could also overcome MDR in a human cancer cell line of a different cancer type and tissue origin, the study performed cytotoxicity studies using the human MDR-resistant small-cell lung cancer cell line, H69AR. Figure 12 shows that Adva-27a can reduce the growth of H69AR cells significantly more than etoposide starting from a concentration of 50 µM.

The study also assessed the cytotoxic activity of Adva-27a, compared to etoposide, in A549 (a non-small-cell lung cancer cell line). Adva-27a exhibited dose-dependent growth inhibitory activity following 72 hours of incubation largely similar to that of etoposide.

Figure 12

LUNG CANCER ACTIVITY



Source: *Anticancer Research*.

Effect on Other Cancers

The study also assessed the cytotoxic activity and inhibitory activity of Adva-27a, compared to etoposide, in PC-3, a prostate cancer cell line. Adva-27a exhibited dose-dependent growth inhibitory activity in PC-3, although weaker than that of etoposide with IC50's of 3 µM and 42 µM, for etoposide and Adva-27a, respectively. Adva-27a had previously been shown to inhibit the growth of other cancer cell lines, including KB (pharyngeal cancer), SF-268 (brain cancer), HL-60 (leukemia), and HT-29 (colon cancer).

Pharmacokinetic Properties

Researchers also analyzed the pharmacokinetic properties of Adva-27a in rat models compared to etoposide. Collectively, results indicate that Adva-27a had a much better plasma accumulation and slower plasma clearance rate in rats compared to etoposide. Researchers believe that this combination may allow Adva-27a a better distribution into tissues and organs than etoposide, which can result in an improved. efficacy of cancer treatment.

Overall Findings

Compared to etoposide, Adva-27a was found to be substantially more potent against two MDR human cancer cell lines, and to have a better metabolic stability and pharmacokinetic properties than etoposide. Taken together, these results suggest that further development of Adva-27a is warranted as a novel topoisomerase II inhibitor for use in human cancer therapy with multidrug-resistant tumors.

Adva-27a Clinical Trials Plans

In February 2023, the Company signed a research agreement with McGill University Health Center's Jewish General Hospital in Montreal, Canada, to advance the development of Adva-27a through the IND-enabling studies. The research partnership also includes negotiating terms for a subsequent Phase I clinical trial in patients with Stage 4 pancreatic cancer to be conducted at the Jewish General Hospital. All aspects of the clinical trials in Canada will employ FDA standards at all levels.

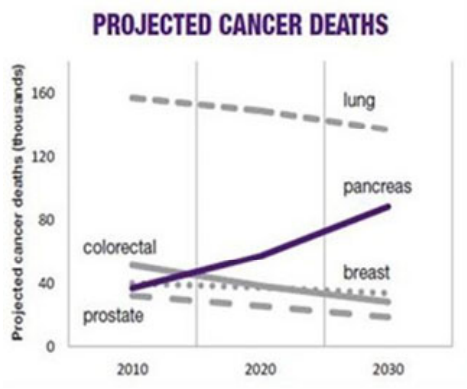
Pancreatic Cancer Market

Pancreatic cancer is currently the third leading cause of cancer death in the U.S., behind lung cancer and colorectal cancer. This is due primarily to a high mortality rate of the disease. In the U.S., pancreatic cancer represents 8.3% of all cancer deaths despite accounting for only 3.3% of new cases (Source: American Cancer Society's *Cancer Facts and Figures 2023*). A similar trend is present globally, where pancreatic cancer accounts for only 1.8% of all cancers, but 4.6% of all cancer deaths (Source: Pancreatic Cancer Research Network).

Two main factors contribute to this high mortality: (1) the fact that most cancers have already spread (metastasized) at the time of diagnosis; and (2) a lack of effective therapies for metastatic pancreatic cancer.

Figure 13

PANCREAS CANCER MORTALITY



Source: University of Pennsylvania.

Pancreatic cancer is not diagnosed until the later stages of the disease, as the symptoms only show up then. Pancreatic cancer is aggressive and a difficult diagnosis results in a high mortality rate. If the cancer is detected at an early stage when surgical removal of the tumor is possible (about 12% of cases), the 5-year relative survival rate is 44%. If the cancer has spread to surrounding tissues or organs, the 5-year relative survival rate is 15%. For the 52% of people who are diagnosed after the cancer has spread to a distant part of the body, the 5-year relative survival rate is 3% (Cancer.net).

Because of a rising incidence in pancreatic cancer and improvements in detection and treatment of other cancers, pancreatic cancer is poised to become the second leading cause of cancer death in the U.S. by 2025, as shown in Figure 13 (Source: University of Pennsylvania's Perelman School of Medicine).

The pancreatic cancer treatment market size was valued at $2.47 billion in 2022, and is expected to reach $7.88 billion by 2030, a CAGR of 15.6%. One of the key factors driving this growth is the rising prevalence of pancreatic cancer across the globe. Because of a lack of effective treatments for the disease, as well as its growing financial and human burden, companies are expected to increase research in the race to develop novel therapies for treatment of advanced cases (Source: Market Research Community's *Pancreatic Cancer Treatment Market Size, Share & Trends Analysis, Forecast Period 2023 – 2030*).

K1.1 Anticancer mRNA

In June 2021, Sunshine Biopharma initiated a new research project to determine if certain mRNA molecules can be used as anticancer agents. The collected data has shown that a selected group of mRNA molecules are capable of destroying cancer cells in vitro, including MRD breast cancer cells (MCF-7/MDR), ovarian adenocarcinoma cells (OVCAR-3), and pancreatic cancer cells (SUIT-2).

These new mRNA molecules, bearing the laboratory name K1, are readily adaptable for delivery into patients using the mRNA vaccine technology. On April 20, 2022, the Company filed a patent application in the U.S. for this technology. The Company is assessing K1.1, the lead anticancer mRNA molecule arising from this technology, as a therapeutic agent for liver cancer. An overview of K1.1 is provided in Figure 14.

Figure 14
K1.1 OVERVIEW

- Capable of destroying cancer cells in vitro
- Liver cancer, ovarian adenocarcinoma, pancreatic cancer
- LNP formulation completed
- Mice studies underway

Source: Sunshine Bipharma Inc.

mRNA Therapeutic Overview

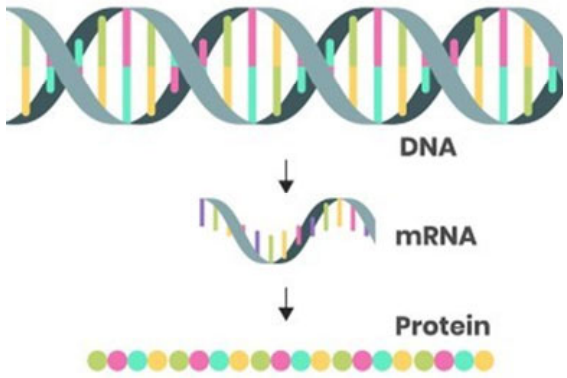
The coronavirus pandemic has thrown a spotlight on messenger RNA (mRNA). Hundreds of millions of people worldwide have received mRNA vaccines (made by Pfizer or Moderna) that provide powerful protection against severe COVID-19. The development of the COVID-19 vaccine was based on prior research to assess the use of mRNA vaccines to treat cancer. In fact, mRNA-based cancer treatment vaccines have been tested in small trials for nearly a decade, with some promising early results. Now, in turn, the success of the mRNA COVID-19 vaccines could help accelerate clinical research on mRNA vaccines to treat cancer. Although therapeutic mRNA-based cancer vaccines have not yet been approved for standard treatment, dozens of clinical trials are testing mRNA treatment vaccines in people with various types of cancer, including pancreatic cancer, colorectal cancer, and melanoma (Source: U.S. National Institutes of Health [NIH]).

What is mRNA?

DNA, containing the genetic instructions for the development, functioning, growth, and reproduction of all known organisms, is found inside a protected part of the cell called the nucleus. The instructions within the DNA include information for the creation of proteins, which carry out the many processes necessary for the body to function, including the workings of the immune system. However, the information contained in the DNA needs to get from the nucleus of the cell to the main part of the cell (the cytoplasm) where proteins are assembled. This is the function of mRNA.

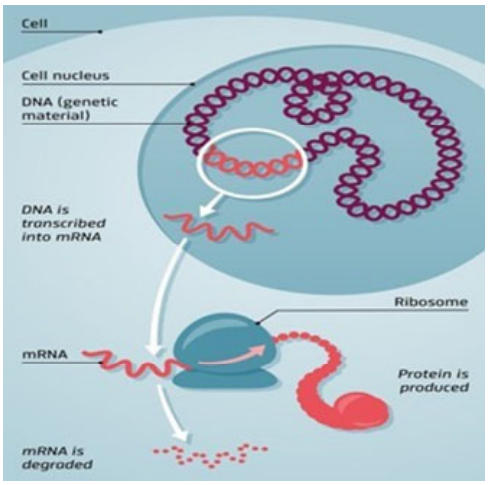
The role of mRNA is to transfer genetic information from the DNA in a cell's nucleus to the cell's cytoplasm, where the synthesis of proteins is carried out (Figure 15 [page 22]). The process, illustrated in Figure 16 (page 22), involves the creation of mRNA by enzymes in the cell's nucleus, where part of the DNA information is transcribed (copied) into the mRNA. This information contains the instructions for protein synthesis. Once created, the mRNA moves from the cell nucleus to the cytoplasm where it gets read by the **ribosome**, the machinery responsible for making proteins. Once this process is completed, the mRNA is then degraded by the body (Source: The Swiss Academy of Sciences).

Figure 15
mRNA FUNCTION



Source: The Conversation.

Figure 16
mRNA PROCESS



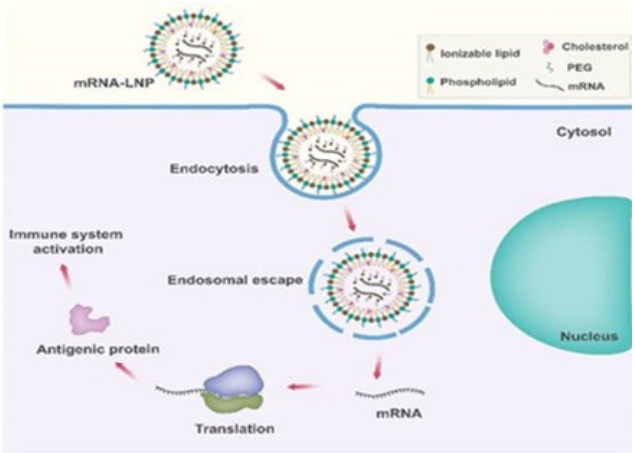
Source: The Swiss Academy of Sciences.

The Use of mRNA in Therapeutic Applications

Over the past 30 years, researchers have learned how to engineer stable forms of synthetic mRNA and deliver these molecules to the body's cells. The process starts by creating a carrier complex consisting of the mRNA encapsulated in a delivery matrix. If an mRNA sequence were injected into the body without some form of protection, the sequence would be recognized by the immune system as a foreign substance and destroyed. A solution employed by most investigational cancer vaccines is to encase the mRNA in lipid nanoparticles (LPN), which are tiny spheres that protect the mRNA molecules. This is also the technology used for the creation of both Pfizer's, BioNTech's, and Moderna's COVID-19 vaccines.

The carrier complex, which is positively charged, then binds to the negatively charged cell surface, where it is taken up by the cell via **endocytosis**. Once inside the cell, the mRNA instructs cells to produce specific proteins that mimic either part of the virus (in the case of a viral vaccine) or cancer cells. The immune system sees these foreign proteins as invaders, which stimulates an immune response against these same proteins when they are present in intact viruses or tumor cells, as shown in Figure 17 (Source: *Frontiers in Immunology*, Vol. 13, 2022).

Figure 17
THERAPEUTIC mRNA PROCESS



Source: Frontiers in Immunology.

In general, the primary difference in the use of mRNA-based vaccines for cancer compared to infectious disease (e.g., COVID-19, influenza) is that they are therapeutic vaccines, meaning the goal is treatment, not protection. In oncology applications, synthetic mRNA triggers the immune system to identify and attack cancer cells that already exist in the patient, rather than teaching the immune system to identify and attack a virus that a patient may be exposed to later.

Cancer vaccines are classified as either universal, where they are given to all patients of a particular population with a tumor type, or personalized, where the patient's tumor is profiled to find the best antigen match. In the case of personalized vaccines, the investigational mRNA vaccines are manufactured for each individual based on the specific molecular features of their tumors. It takes one to two months to produce a personalized mRNA cancer vaccine after tissue samples have been collected from a patient. With this approach, researchers try to elicit an immune response against specific abnormal proteins, or neoantigens, produced by the individual's cancer. A universal mRNA cancer vaccine follows a similar approach, but the mRNA construction is based on a collection of a few dozen neoantigens that have been linked with certain types of cancer. As such, universal mRNA cancer vaccines do not require the collection of samples from a patient and are designed to be readily available for treatment.

The use of mRNA-based therapeutic vaccine technology for the treatment of cancer provides several benefits when compared to other alternative options, specifically:

- it is well tolerated, with adverse events generally manageable and transient;
- the active ingredient (mRNA) is easily degraded, reducing risk of toxicity;
- the synthetic mRNA does not need to reach the nucleus (they are translated in the cytoplasm), eliminating the risk of being integrated and altering the host genome;
- it displays the potential to induce both humoral and cell-mediated immunity necessary for activating and sustaining anti-tumor responses; and
- it has a fast and inexpensive production process (Source: Lancet).

K1.1 Clinical Development

The Company is developing K1.1. for the treatment of liver cancer. Liver cancer is a form of cancer that begins in the liver. It is the sixth most prevalent type of cancer diagnosed worldwide and the third leading cause of cancer death.

Only a small percentage of liver cancers are discovered at an early disease stage where treatments are effective. The majority of people are diagnosed after the cancer has progressed too far to be removed or eradicated. Treatments, such as chemotherapy, will be used in these circumstances to try to halt the progression of cancer and relieve symptoms such as pain and discomfort (Source: Delveinsight's *Liver cancer— Market Insight, Epidemiology and Market Forecast – 2032*, 2023).

The global liver cancer therapeutics market was estimated at $1.8 billion in 2021, and is expected to reach $8.9 billion by 2030, a CAGR of 19.5%. This growth is driven by a high prevalence and rising incidence of liver cancer, coupled with a robust investment in R&D activities by the pharmaceutical industry aimed at developing novel innovative therapeutic drugs (Source: Growth Plus Market Reports' *Liver Cancer Therapeutics Market*, 2022).

K1.1 Mechanism of Action

K1.1 is an mRNA-based therapeutic that encodes an inhibitor of **Nrf-2 (nuclear factor erythroid 2-related factor 2)**, a transcription factor that plays a critical role in various cellular processes, including cell proliferation and cell defense mechanisms, as well as regulation of antioxidant, anti-inflammatory, drug metabolizing, and other homeostatic functions.

Because of these cytoprotective roles, activating the Nrf-2 pathway has been considered an attractive strategy for cancer prevention, with abundant evidence that activation of Nrf-2 can suppress carcinogenesis, especially in its earliest stages. Alternatively, as Nrf-2 promotes cell survival under stress, it is also logical to assume that increased Nrf-2 activity could be tumor promoting by being protective for cancer cells (Source: *Nature Reviews Cancer, Vol. 12(8)*, 2013).

In fact, recent genetic analysis has shown that mutations affecting the Nrf-2 activation pathway have been discovered in many human cancers, including lung cancer and liver cancer. These Nrf-2 mutations enhance Nfr-2 activity, with permanent activation of Nrf-2 associated with various cancer promoting properties, including proliferation of cancer cells, resistance to standard chemotherapy, and poor patient prognosis. Accumulating evidence has demonstrated that activation of the Nrf-2 pathway favors tumor growth and is associated with chemoresistance in specific tumor types (Source: *Molecular Cancer Therapeutics, Vol. 20 (9)*, 2021).

By temporarily inhibiting Nrf-2 activity with an mRNA injection immediately before or during chemotherapy, the Company hopes to achieve an enhanced performance of the anticancer drugs by sensitizing tumor cells to chemotherapies, overcoming chemoresistance, arresting tumor growth, and providing an improved patient outcome inflicted with Nrf-2-sensitive cancers.

K1.1 Development

Sunshine Biopharma had previously shown that its K1.1 mRNA is capable of destroying cancer cells in vitro, including MDR breast cancer cells (MCF-7/MDR), ovarian adenocarcinoma cells (OVCAR-3), and pancreatic cancer cells (SUIT-2). Results of additional parallel studies using normal human cells (HMEC) also showed that K1.1 mRNA had little or no cytotoxic effects.

In November 2022, Sunshine entered into a collaboration agreement with a leading mRNA lipid nanoparticle company for the purposes of formulating the Company's K1.1 mRNA molecules into lipid nanoparticles, which the Company is using for its ongoing proof of concept mice studies. The first study involves the administration of K1.1 to mice that have received liver cancer cells by subcutaneous injections, resulting in tumor growth, in order to assess K1.1's in vivo effect on liver cancer. The last dose for the study is scheduled to take place on October 10, 2023, with results expected by the end of October 2023. Furthermore, the Company is planning to conduct toxicology studies in two species of rodents by 2Q 2024.

SBFM-PL4 COVID-19 TREATMENT

With the evolution of the COVID-19 pandemic to its current state, Sunshine Biopharma is developing a late-preclinical injectable therapeutic candidate to treat SARS-CoV2 (and potentially SARS-CoV and MERS-CoV) infection in patients who could not use the currently approved treatments (i.e., Paxlovid, Molnupiravir, or Remdesivir) due to concerns about drug interaction and possible 'rebound' infections and other side effects. These efforts have been focused on the development of a first-in-class small molecule PLpro inhibitor, the viral enzyme that mediates suppression of the human immune system. Figure 18 provides an overview of the Company's anti-viral efforts.

Figure 18
SBFM PL-4 OVERVIEW

- 2 viral proteases, Mpro and PLpro
- Pfizer's Paxlovid inhibits Mpro
- PLpro suppresses the immune system
- Developing a PLpro inhibitor with University of Arizona

Source: Sunshine Bipharma Inc.

Coronavirus Overview

Coronaviruses are a large family of respiratory viruses that cause diseases in mammals and birds, and are named for the crown-like spikes on their surface. There are four main sub-groupings of coronaviruses, known as alpha, beta, gamma, and delta, with only the alpha and beta group affecting humans. In humans, coronavirus infection can cause respiratory tract infections that can range from mild to lethal. Mild illnesses include some cases of the common cold, and are caused by infection of four different types of human coronavirus strains: Human coronavirus OC43, Human coronavirus HKU1, Human coronavirus 229E, and Human coronavirus NL63. More lethal varieties include Severe acute respiratory syndrome coronavirus (SARS—identified in 2003), Middle East respiratory syndrome-related coronavirus (MERS—identified in 2012), and Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2—identified in 2019). These cause the diseases commonly called SARS, MERS, and COVID-19, respectively. All three coronavirus strains causing the more serious conditions are beta coronaviruses.

The outbreak of COVID-19 has been declared a global pandemic by the World Health Organization. As of October 2023, more than 771 million cases had been reported worldwide, resulting in over 6.9 million deaths. The U.S. was considered one of the epicenters of the disease, with roughly 100 million cases and over a million deaths.

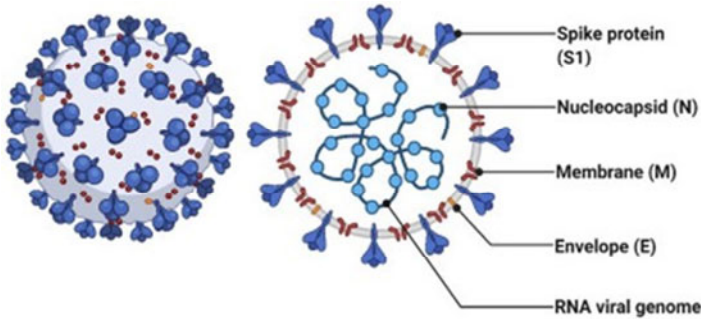
The global COVID-19 therapeutic market was valued at $30.7 billion in 2021. The development of effective vaccines and new therapies is expected to result in a decrease of the overall market, which is projected to be at $16.2 billion by 2031. However, the market is heavily influenced by the possibility of a new outbreak, and the rise of a new variant that could result in the need of alternative treatment options (Source: Transparency Market Research's *Covid -19 Therapeutic Market*, 2023).

Coronavirus Structure

As shown in Figure 19 (page 26), the coronavirus particles are organized with long RNA polymers tightly packed into the center of the particle and surrounded by a protective coat called a nucleocapsid (N). The coronavirus core particle is further surrounded by an outer membrane envelope made of lipids (fats). This membrane contains specific viral proteins, called structural proteins, including the spike (S), membrane (M), and envelope (E) proteins. The S proteins project out from the viral particle and are the main structures involved in the binding of the virus with the host cell, marking the beginning of an infection.

Figure 19

CORONAVIRUS STRUCTURE



Source: Elsevier Inc.

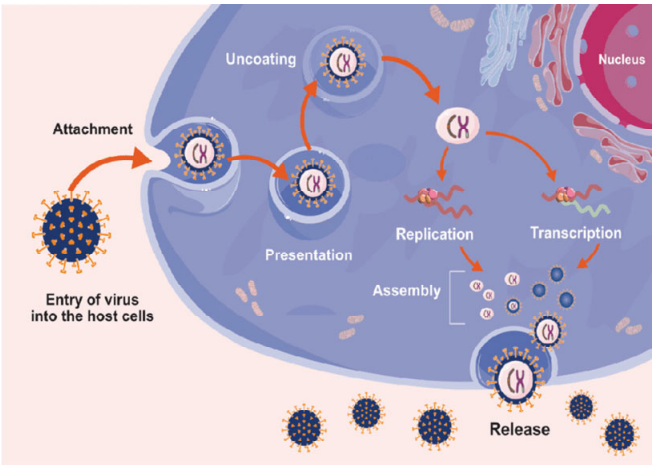
Coronavirus Virus Cycle

Viruses cannot replicate on their own, but rather depend on their host cell's protein synthesis pathways to reproduce. This typically occurs by the virus inserting its genetic material in the host's s cells and utilizing the cell's own protein-making mechanisms for viral replication and the release of new virions. The steps of the coronavirus life cycle are listed and illustrated in Figure 20.

Figure 20

CORONAVIRUS CELL CYCLE

1 Attachment: Virus attaches to the host cell.
2 Entry: Genetic material is injected into the host cell.
3 Replication: The virus takes over the cell's metabolism, causing the creation of new proteins and nucleic acids by the host cell's organelles.
4 Assembly: Proteins and nucleic acids are assembled into new viruses.
5 Release: Virus enzymes cause the cell to burst and viruses are released from the host cell. These new viruses can infect other cells.



Source: Nanomaterials.

The first stage involves the attachment of the virus to the host cell surface. In coronaviruses, this normally occurs with the binding of the spike (S) protein to specific receptors found on a cell's surface. This is followed by the virus entry into the cell. Upon entry, the viral RNA genome is uncoated and released into the host cells cytoplasm. This enables the start of viral replication through **translation**, a process where mRNA is converted into proteins by ribosomes in the cell's cytoplasm.

The coronavirus RNA genome structure allows it to act like a messenger RNA and be directly translated by the host cell's ribosomes into two viral **polyproteins**, pp1a and pp1ab. These, in turn, are processed by two essential viral **proteases** also encoded in the virus RNA—the main protease (Mpro), also known as 3CLpro, and papain-like protease (PLpro)—to generate 16 mature non-structural proteins (NSPs). The NSPs include various replication proteins and facilitate further processing of the-genomic viral RNA to form all the structural viral proteins needed for virion assembly. Following assembly, the virions are released from the host cell into the surrounding environment to repeat the infection cycle (Source: *Encyclopedia of Cell Biology*, Vol. 1: 930–941, 2023).

As one of the essential viral enzymes, SARS proteases—Mpro and PLpro—are indispensable for the processing of viral polypeptides and for the replication of the virus. Addressing the health hazards of coronavirus infections would benefit greatly by therapeutic agents that act to block the replication of the virus within infected cells. Antivirals that interfere with the viral life cycle without significantly impacting normal cellular functions are critical to combating viral infections. Such therapies are in use for other RNA viruses, like influenza, and are administered generally as small molecules, taken in pill form. These antivirals act by binding to and interfering with viral proteins needed to replicate the viral RNA (Source: Biophysical Society).

Coronavirus Virus Proteases—PLpro

A protease is an enzyme that catalyzes proteolysis, breaking down proteins into smaller polypeptides or single amino acids, and spurring the formation of new protein products. The coronaviral genome encodes for two essential viral proteases: the main protease (Mpro) and the papain-like protease (PLpro), which are conserved among different coronaviruses and are absent in humans.

Both Mpro and PLpro are essential for viral replication and maturation. As such, they represent attractive anti-viral drug development targets for the inhibition of the early stages of COVID-19 infection. PLpro is of particular interest as a therapeutic target in that, in addition to processing viral proteins, it is also responsible for suppression of the human immune system making the virus more life-threatening (Source: *Fundamental Research, Vol. 1 (2): 151-165*, 2021). Sunshine Biopharma's COVID-19 research efforts have been focused on developing an inhibitor of PLpro.

One of the reasons the Sars-CoV-2 virus is so successful and dangerous is that it can suppress the non-specific or innate immune response, the first line of defense against invading pathogens. During an innate immune response, infected body cells release messenger substances (type 1 interferons) that attract natural killer cells, which kill the infected cells. However, PLpro has been found to have a dual function in coronavirus infections: a key role in the maturation and release of new viral particles, and suppression of the development of type 1 interferons, inhibiting the innate immune response. This dual role was confirmed by research led by the Max Planck Institute of Biophysics in Germany. The research team discovered that the pharmacological inhibition of this viral enzyme not only blocks virus replication but also strengthens the anti-viral immune response at the same time (Source: Max-Planck-GesellschafT's *Covid-19: Anti-viral strategy with double effect*, 2020).

SBFM PL-4 Development

In August 2020, the Company synthesized its first group of PLpro small molecule inhibitors. The small molecules were computer modelled and designed by Dr. Steve N. Slilaty, CEO of Sunshine Biopharma. Additionally, in February 2021, Sunshine Biopharma strengthened its PLpro program by signing an exclusive license agreement with the University of Georgia for two PLpro inhibitors developed there.

The Company has also been conducting research on this project in collaboration with the University of Arizona and has recently entered into an exclusive worldwide license agreement with the University of Arizona for all of the technology related to the collaboration. In February 2022, the Company expanded its PLpro inhibitors program by entering into a research agreement with the University of Arizona for purposes of determining the in vivo safety, pharmacokinetics, and dose selection properties of three University of Arizona-owned PLpro inhibitors, to be followed by efficacy testing in mice infected with SARS-CoV-2. Under the agreement, the University of Arizona granted the Company a first option to negotiate a commercial, royalty-bearing license for all intellectual property developed by the University of Arizona personnel under the research collaboration.

Sunshine Biopharma plans to begin explorative toxicity studies and proof of concept efficacy studies in hamsters (expected between 4Q 2023 to 2Q 2024), with additional ADME (absorption, distribution, metabolism, and excretion) in other species expected to begin 2Q 2024. Following these studies, the Company expects to nominate a lead candidate formulation for an IND enabling study by 3Q 2024.

Market Potential and Flexibility

Pfizer has an Mpro specific inhibitor on the market, called Paxlovid, used as a treatment for COVID-19, which is expected to generate $8 billion in sales during 2023. The successful development of the Company's SBFM-PL4 product candidate as the first PLpro inhibitor could become a major competitor to Paxlovid, joining the very select and scarce options available for the treatment of severe COVID-19.

In addition, the Company believes that its PLpro inhibitor therapeutic molecule could be effective for the treatment, not only of COVID-19, but also of other coronavirus infections outlined below. This stems from the fact that in addition to SARS-CoV-2 (COVID-19). PLpro is found in different coronaviruses, including SARS-CoV (SARS) and MERS-CoV (MERS) (Source: *Encyclopedia of Cell Biology, Vol. 1: 930–941*, 2023).

- *Severe Acute Respiratory Syndrome (SARS).* SARS was first reported in Southern China in 2002, spreading to more than two dozen countries in North America, South America, Europe, and Asia. Symptoms include fever, chills, and body aches, and may progress to pneumonia. Infection with the SARS virus causes acute respiratory distress (severe breathing difficulty), with a mortality rate of about 10%.

- *Middle East Respiratory Syndrome (MERS).* MERS was first reported in 2012 in Saudi Arabia and spread to more than 25 other countries. Symptoms include fever, cough, and shortness of breath, and often progress to pneumonia. About 3 or 4 out of every 10 patients reported with MERS have died (Source: National Foundation of Infectious Diseases). There are no effective treatments for either disease.

Sunshine Biopharma Canada

Sunshine Biopharma additionally sells OTC products in both Canada and the U.S. through the operations of its fully-owned subsidiary Sunshine Biopharma Canada through Amazon.ca and Amazon.com, respectively. Sunshine Biopharma Canada expanded its product offering by the Company's acquisition of Nora Pharma, bringing an additional 11 nonprescription OTC products. Figure 21 lists the Company's full OTC offerings.

Figure 21

OTC PRODUCTS

Product	Description
Essential 9™	Essential Amino Acids capsules (761 mg)
L-Arginine	L-Arginine capsules (500 mg)
L-Carnitine	L-Carnitine capsules (667 mg)
Extreme-Mass™	Weight Gain powder
Iso-Whey™	Whey Protein powder
BCAA 2:1:1™	Branched-Chain Amino Acids capsules (600 mg)
L-Creatine	L-Creatine Monohydrate powder
Nora B12-1000	Vitamin B-12 tablets (Cyanocobalamine, 1,000 mcg)
Nora Calcium	Calcium Carbonate tablets (500 mg)
Nora Cal-D 400	Calcium Carbonate (500 mg) + Vitamin D (400 IU) tablets
Nora Cal-D 1000	Calcium Carbonate (500 mg) + Vitamin D (1,000 IU) tablets
Nora D-400	Vitamin D tablets (Calciferol 400 IU)
Nora D-1000	Vitamin D tablets (Calciferol 1,000 IU)
Nora Senna	Senna Alexandrina tablets (8.6 mg)
Nora Sennosides	Senna Alexandrina tablets (8.6 mg)
NRA-ASA	Acetylsalicylic Acid tablets (80 mg)
NRA-Docusate Sodium	Docusate Sodium capsules (100 mg)
NRA K-20	Potassium Chloride tablets (1,500 mg)

Source: Sunshine Biopharma Inc.

Essential 9™

The Company's main OTC product is Essential 9™ (Figure 22). It is composed of 9 out of 20 amino acids required for protein synthesis. Proteins are involved in all body functions. However, like vitamins, Essential Amino Acids cannot be made by the human body and must be obtained through diet. Deficiency in one or more of the 9 Essential Amino Acids can lead to loss of muscle mass, fatigue, weight gain, weakened immune system, and generally reduced wellness.

Sunshine Biopharma's Essential 9™ provides all 9 Essential Amino Acids ready for absorption, free-form, and in the proportions recommended by Health Canada. Essential 9™ contains the exact constituents of the scientifically proven essential amino acids and is suitable for everyone: vegans, athletes, seniors, dieters, and anyone wishing to increase their health.

Figure 22

ESSENTIAL 9™

Source: Sunshine Biopharma Inc.

Investment Highlights

- Sunshine Biopharma Inc. ("Sunshine Biopharma" or "the Company") is a revenue-generating pharmaceutical company focused on developing and marketing life-saving medicines in a wide variety of therapeutic areas, including oncology and antivirals.

- Sunshine Biopharma's proprietary therapeutic drug development program includes three product candidates: (1) Adva-27a, a small chemotherapy molecule for pancreatic cancer, (2) K1.1, a messenger RNA (mRNA) therapeutic for liver cancer, and (3) SBFM-PL4, a PLpro inhibitor for the treatment of COVID-19.

- The Company's proprietary pharmaceutical pipeline addresses large markets with significant unmet needs in oncology and antiviral indications, creating a diversified portfolio with a combined market potential of over $30 billion for the initial targeted indications.

    - In preclinical trials, both Adva-27a and K1.1 have been effective against multidrug resistant (MDR) cancer cells in vitro, including pancreatic and breast cancer cells, among others.

    - In February 2023, the Company signed a research agreement with the Jewish General Hospital in Montreal, Canada, to advance the development of Adva-27a through IND-enabling studies as well as negotiated terms for a subsequent Phase I clinical trial in patients with Stage 4 pancreatic cancer, which the Company expects to begin in 12 to 18 months (3Q 2025 to 1Q 2026).

    - Sunshine Biopharma is conducting a proof-of-concept mice study to assess K1.1's in vivo effect on liver cancer, with results expected by October/November 2023. Follow up toxicology studies are scheduled for 2Q 2024. Should these mouse studies prove successful, the Company plans to file an IND application to begin Phase 1 trials, potentially in 3Q 2024 or 4Q 2024.

    - The Company plans to conduct explorative toxicity studies and proof-of-concept efficacy studies in hamsters for SBFM-PL4 (4Q 2023 to 2Q 2024), with additional ADME (absorption, distribution, metabolism, and excretion) in other species to begin by 2Q 2024. Following these studies, the Company expects to nominate a lead candidate formulation for an IND enabling study by 3Q 2024.

- In addition to its proprietary drug development efforts, the Company also operates two wholly-owned subsidiaries: Nora Pharma Inc., a Canadian corporation with a portfolio of generic prescription drugs; and Sunshine Biopharma Canada Inc., a Canadian corporation, which sells OTC supplements.

- On October 20, 2022, Sunshine Biopharma acquired Nora Pharma Inc., a generic pharmaceutical company that currently offers 50 generic prescription drugs in Canada with another 27 drugs scheduled to be launched in 2023 and 2024.

    - According to the Company, the growth of its revenue-generating generic pharmaceutical business, through the operations of Nora Pharma, places Sunshine Biopharma on track to achieve profitability by FY 2025, with the generated cash flow expected to support and facilitate the development of its proprietary pharmaceutical pipeline. The Company believes that its revenue generating business, in conjunction with its focused proprietary drug development efforts, provide a low-risk model where the lengthy pharmaceutical development and approval process is supported by revenue generating activities.

- In 2022 and YTD, Sunshine Biopharma completed four rounds of financing, generating total net proceeds of $47.7 million, which has enabled the Company to expand its proprietary drug development program and complete the acquisition of Nora Pharma. Furthermore, on May 16, 2023, the company completed a private placement for gross proceeds of $5 million (net proceeds of $4.1 million).

- As of June 30, 2023, Sunshine Biopharma had a cash and cash equivalent position of $19.7 million.

Competition

Sunshine Biopharma's anti-coronavirus drug development efforts are in direct competition with several companies in the U.S., which have developed effective treatment options or vaccines for COVID-19. Leading companies focused on treatments include Pfizer, Merck, Gilead, Eli Lilly, and Regeneron. Currently, two vaccines (Pfizer and Moderna) and two antibody treatments (Regeneron and Eli Lilly) are in use. Gilead's Remdesivir, an antiviral injectable, was approved by the FDA for the treatment of COVID-19 in October 2020. In addition, in December 2021, Pfizer received Emergency Use Authorization (EUA) for its antiviral pill, Paxlovid, and, in the same month, the FDA granted Merck EUA for its antiviral pill, Molnupiravir. While the approved vaccines, pills, and injectable treatments are effective, Sunshine Biopharma believes that additional treatment options, which include that which the Company is developing (targeting a different mechanism of action) could potentially form an important component to the limited range of anti-coronavirus treatment options available to physicians. In addition, the Company believes that its coronavirus therapeutic molecule could be effective for the treatment not only of COVID-19 but also for other coronavirus infections, including SARS-CoV (SARS) and MERS-CoV (MERS), which provides an additional competitive advantage.

Within the area of anticancer drug development, Sunshine Biopharma competes with large publicly- and privately-held companies engaged in developing new cancer therapies. There are numerous other entities involved in oncology therapeutic development with greater resources than those of Sunshine Biopharma. Nearly all major pharmaceutical companies, including Merck, Amgen, Roche, Pfizer, Bristol Myers Squibb, and Novartis, among others, have ongoing anticancer drug development programs. Some of the drugs they may develop could be in direct competition with those being developed by Sunshine Biopharma. As well, a number of smaller companies are working to develop cancer therapeutics and could develop drugs that may be considered competitive to those being developed by the Company. While Sunshine Biopharma believes its approach is distinctive, there can be no guarantee that this proves to be the case and one or more competing products may reach the market faster with better outcomes for patients, thus reducing the potential market opportunity for Sunshine Biopharma's product candidates.

The Canadian generic pharmaceutical market is valued at approximately $8.9 billion. Generic pharmaceutical companies produce and deliver more than 70% of the prescribed medicines with high quality at affordable prices. There are more than 35 active generic participants in the market, of which the top 3 hold approximately 50% share of the market. Sunshine Biopharma's Nora Pharma (acquired in October 2022) is relatively new in this space but has demonstrated to be one of the fastest year-over-year sales increases amongst its peers. Nora Pharma currently offers 61 products, including 50 generic prescription drugs and 11 OTC products.

The biotech industry is capital intensive and highly competitive. As the Company continues to develop its technology, it may face competition from companies developing or marketing therapeutics for the coronavirus and cancer. The following summaries are not intended to be an exhaustive collection of potential competitors to Sunshine Biopharma; however, they are believed to be representative of the type of competition the Company may encounter as it seeks to further commercialize its products/technologies.

Pharmaceutical Products

Overview of mRNA for oncology (with trials)

The COVID-19 pandemic has propelled global attention toward mRNA-based vaccines. The rapid development and production of COVID-19 vaccines were made possible by years of prior research on mRNA vaccines, originally explored as a therapeutic strategy against cancer in both preclinical and clinical trials. mRNA vaccines offer several advantages in the vaccine setting. Firstly, they are well-tolerated and easily degraded, without integrating into the host genome. Secondly, mRNA molecules are non-infectious, and these vaccines have the potential to stimulate both humoral and cell-mediated immunity. Lastly, the production of mRNA vaccines is speedy and cost-effective.

Continued technological advancements have enhanced the stability, structural integrity, and delivery methods of mRNA-based vaccines. Currently, multiple clinical trials are actively enrolling patients with various cancer diagnoses, exploring the potential of mRNA vaccine therapy. While therapeutic mRNA-based cancer vaccines have yet to receive standard treatment approval, early clinical trials have yielded encouraging results, both when used as monotherapy as well as in combination with checkpoint inhibitors.

The accompanying section highlights some of the latest clinical breakthroughs in mRNA-based vaccines for cancer treatment and offers insight into the future prospects and challenges associated with this innovative and promising approach to cancer therapy. Sunshine Biopharma is one of a very few companies that have announced the use of m-RNA to treat cancer; the other companies include Pfizer and Moderna, which are the two leading companies in the area of COVID-19 vaccines as well as BioNTech and Genentech (as described in the accompanying section). Figure 23 highlights mRNA cancer vaccine candidates in different cancers that are in ongoing clinical trials.

Figure 23

ONGOING CLINICAL TRIALS OF MRNA CANCER VACCINE CANDIDATES IN DIFFERENT CANCERS

NCT number	Agent	Indication	Phase	Status	Trial title
NCT05198752	SW1115C3 neoantigen personalized mRNA vaccine	Advanced malignant solid tumors	1	Recruiting	A Study of Neoantigen mRNA Personalized Cancer Vaccine in Patients With Advanced Solid Tumors
NCT05192460	Neoantigen cancer vaccine with or without PD-1/L1	Advanced gastric cancer, esophageal cancer and liver cancer	N/A	Recruiting	Safety and Efficacy of Personalized Neoantigen Vaccine in Advanced Gastric Cancer, Esophageal Cancer and Liver Cancer
NCT03897881	mRNA-4157 + pembro	High-risk melanoma	1	Active, not recruiting	An Efficacy Study of Adjuvant Treatment With the Personalized Cancer Vaccine mRNA-4157 and Pembrolizumab in Participants with High-Risk Melanoma (KEYNOTE-942)
NCT03313778	mRNA-4157 + pembro	Unresectable solid tumors	1	Active, not recruiting	Safety, Tolerability, and Immunogenicity of mRNA-4157 Alone in Participants With Resected Solid Tumors and in Combination With Pembrolizumab in Participants With Unresectable Solid Tumors (KEYNOTE-603)
NCT04382898	BNT112 +/- cemiplimab	Prostate cancer	1/2	Recruiting	PRO-MERIT (Prostate Cancer Messenger RNA Immunotherapy) (PRO-MERIT)
NCT04163094	W_ova1 vaccine + (neo) adjuvant chemo	Ovarian cancer	1	Active, not recruiting	Ovarian Cancer Treatment With a Liposome Formulated mRNA Vaccine in Combination With (Neo-)Adjuvant Chemotherapy (OLIVIA)
NCT01197625	Dendritic cell vaccine	Prostate cancer	1/2	Active, not recruiting	Vaccine Therapy in Curative Resected Prostate Cancer Patients
NCT05714748	EBV mRNA vaccine	Advanced malignant tumors	1	Recruiting	Application of mRNA Immunotherapy Technology in Epstein-Barr Virus-related Refractory Malignant Tumors
NCT05738447	HBV mRNA vaccine	Liver cancer Hepatocellular carcinoma	1	Recruiting	Application of mRNA Immunotherapy Technology in Hepatitis B Virus-related Refractory Hepatocellular Carcinoma
NCT00639639	pp65-LAMP mRNA-loaded dendritic cells +/- autologous lymphocyte transfer	Malignant neoplasms of the brain	1	Active, not recruiting	Vaccine Therapy in Treating Patients With Newly Diagnosed Glioblastoma Multiforme (ATTAC)
NCT01686334	Dendritic cell vaccine	Acute myeloid leukemia	2	Recruiting	Efficacy Study of Dendritic Cell Vaccination in Patients With Acute Myeloid Leukemia in Remission (WIDEA)
NCT04573140	Autologous total tumor RNA and pp65-LAMP mRNA-loaded DOTAP liposome vaccine	Adult glioblastoma	1	Recruiting	A Study of RNA-lipid Particle (RNA-LP) Vaccines for Newly Diagnosed Pediatric High-Grade Gliomas (pHGG) and Adult Glioblastoma (GBM) (PNOC020)
NCT04911621	Dendritic cell vaccine + temozolomide-based chemo or dendritic cell vaccine + conventional therapy	High-grade glioma (phase 1) Diffuse intrinsic pontine glioma (phase 2)	1 & 2	Active, not recruiting	Adjuvant Dendritic Cell Immunotherapy for Pediatric Patients With High-grade Glioma or Diffuse Intrinsic Pontine Glioma (ADDICT-pedGLIO)

Source: ASCO Daily News.

Personalized mRNA Cancer Vaccines for Metastatic Melanoma: Moderna and Merck & Co. versus BioNTech and Genentech

Due in part to the success of mRNA vaccines for COVID-19 by Pfizer, BioNTech, and Moderna, there has been a resurgence of interest in mRNA-based cancer vaccines. Similar to mRNA COVID-19 vaccines, mRNA cancer vaccines introduce mRNA sequences corresponding to antigens expressed by tumor cells, prompting an immune response to target and destroy cancerous cells. These cancer vaccines can be broadly classified as universal or personalized. Personalized mRNA vaccines, tailored to a patient's specific tumor antigens, are considered the most promising by key opinion leaders in oncology.

Merck and Moderna

Merck has been actively involved in developing mRNA vaccines for cancer in collaboration with Moderna, aiming to revolutionize cancer treatment, particularly targeting high-risk melanoma patients. In October 2022, the two companies announced a joint effort to develop a personalized mRNA cancer vaccine called mRNA-4157. This partnership has shown promising results and is a significant step forward in the fight against cancer, affirming Merck's commitment to advancing mRNA-based cancer therapies. Phase II trials in combination with Merck's checkpoint inhibitor, Keytruda, showed a 44% reduction in the risk of recurrence or death in metastatic melanoma patients. Over 12 months of observation, the recurrence-free survival rate was 83.4%, which dropped slightly to 78.6% over 18 months. This promising outcome earned the combination a Breakthrough Therapy designation, expediting its development.

Genentech and BioNTech

Genentech and BioNTech are not far behind with their candidate, autogene cevumeran, which is also in Phase II trials with Keytruda for metastatic melanoma. Notably, there are differences between the two vaccines and approaches, with implications for efficacy and tolerability. This year is a pivotal year for autogene cevumeran with several clinical trials reaching completion. Commercial launch estimates suggest it may be available in the U.S. by 2024.

mRNA Cancer Vaccines for Hepatocellular Carcinoma (HCC) immunotherapy

Neoantigen mRNA vaccines offer a promising avenue for Hepatocellular Carcinoma (HCC) immunotherapy. These innovative vaccines are tailored to target neoantigens, encouraging the patient's immune system to identify and eliminate cancer cells. Neoantigen mRNA vaccines are made using RNA sequences derived from the genetic mutations specific to HCC patients. These sequences are then transformed into a vaccine formulation and administered to the patient, often in conjunction with other cancer treatments, to bolster their anti-cancer efficacy. Both preclinical and clinical investigations have demonstrated encouraging outcomes for neoantigen mRNA vaccines in HCC immunotherapy. Preliminary results suggest that these vaccines could become a valuable addition to the treatment arsenal available to HCC patients. Nevertheless, further research is needed to fully assess the safety and effectiveness of these vaccines.

mRNA vaccine to Treat Pancreatic Ductal Adenocarcinoma (PDAC), a Deadly Form of Pancreatic Cancer

Pancreatic ductal adenocarcinoma (PDAC), a deadly form of pancreatic cancer, has a low survival rate, with only about 12% of patients surviving five years after treatment despite modern therapies. Immunotherapies, which boost the body's immune system to fight cancer, have been successful in treating various cancers but have shown limited effectiveness against PDAC. To address this challenge, a team led by Dr. Vinod Balachandran from Memorial Sloan Kettering Cancer Center (MSKCC) developed a personalized mRNA cancer-treatment vaccine. The vaccine is designed to help the immune system recognize specific neoantigens on the surface of pancreatic cancer cells. In a small clinical trial, tumor samples from 19 PDAC patients were sent to BioNTech, known for its COVID-19 mRNA vaccine, for gene sequencing. This information was used to create personalized mRNA vaccines targeting up to 20 neoantigens for each patient. Customized vaccines were successfully created for 18 of the 19 participants, with the process taking approximately nine weeks from surgery to the first vaccine dose. Patients also received an immune checkpoint inhibitor, called atezolizumab, before vaccination. After eight vaccine doses and standard chemotherapy, a ninth booster dose was administered. Results showed that 16 patients had a strong immune response, with their T cells recognizing the patient-specific neoantigens. In these cases, the cancer did not return within a year and a half after treatment. In contrast, those with weak or no immune responses experienced cancer recurrence within a year. These findings are promising, indicating that personalized vaccines can activate the immune system against PDAC. Researchers are planning a larger clinical trial to further investigate this approach.

New mRNA Pancreatic Cancer Vaccine Trial Starts Next Phase After Promising Results

A groundbreaking approach to combat pancreatic cancer is progressing with a Phase 2 clinical trial following promising results from a Phase 1 study. This novel approach involves utilizing mRNA vaccines to target pancreatic cancer, one of the deadliest forms of cancer. The Phase 2 clinical trial aims to determine whether the mRNA vaccine can reduce the risk of pancreatic cancer recurrence following surgery. It will enroll approximately 260 patients at Memorial Sloan Kettering Cancer Center (MSK) and nearly 80 other sites globally. Eligible participants include individuals newly diagnosed with pancreatic cancer who have not undergone prior treatments. The mRNA vaccines used in this trial are customized for each patient. These vaccines leverage proteins, called neoantigens, found in pancreatic tumors to alert the immune system, enabling it to recognize and combat cancer cells effectively. The initiative follows encouraging results from a Phase 1 trial involving 16 MSK patients reported in *Nature* (issue May 10, 2023). In this preliminary study, the mRNA vaccine demonstrated the potential to prevent or delay cancer relapses in about half of the treated patients. The research, spearheaded by Dr. Vinod Balachandran, a pancreatic cancer surgeon-scientist at MSK, in collaboration with Genentech and BioNTech, represents a significant step forward in the pursuit of more effective treatments for pancreatic cancer.

Overall, the development of personalized mRNA cancer vaccines by the above-mentioned companies and technologies represent a significant step forward for precision and personalized medicine, with the potential to revolutionize cancer treatment.

Generic Pharmaceutical Companies in Canada

Nora Pharma Inc. (part of Sunshine Biopharmaceuticals)

Unlike some pharmaceutical sectors, operators within the generic pharmaceutical industry are not heavily involved in the research and development of novel medications. Their primary goal is to manufacture cost-effective alternatives to brand-name drugs, ensuring wider access to essential medications and to provide accessible and affordable pharmaceutical solutions for a variety of medical conditions. The companies below are leading generic pharmaceutical companies marketing products within Canada. Nora Pharma is relatively new in this space but has demonstrated to be one of the fastest year-over-year sales increases amongst its peers.

Apotex Inc.

Apotex Inc. is Canada's largest drug manufacturer with over 300 products selling in over 115 countries and close to 8,000 employees. Through vertical integration, the Apotex Group of Companies is comprised of Apotex Generics, Apotex Active Pharmaceutical Ingredients and Apobiologix. The company manufactures and distributes generic medications for a range of diseases and health conditions, including cancer, diabetes, high cholesterol, glaucoma, infections, and blood pressure. Apotex is a member of the Canadian Generic Pharmaceutical Association (CGPA), the Generic Pharmaceutical Association (GPhA), an associate member of the Canadian Animal Health Institute (CAHI), the Canadian Association for Pharmacy Distribution Management (CAPDM), as well as the Greater Toronto Area's Partners in Project Green. In September 2022, the company was taken over by SK Capital Partners LP. Apotex has headquarters in Toronto, Ontario, Canada.

Novartis AG (Sandoz division)

Novartis AG is a publicly traded Swiss holding company that operates through the Novartis Group. Novartis AG owns, directly or indirectly, all companies worldwide that operate as subsidiaries of the Novartis Group. Sandoz is a division of the Novartis Group and a global leader in generic pharmaceuticals and biosimilars. The division was established in 2003 when Novartis united all of its generics businesses under the name Sandoz. Since then, Sandoz has grown into a leading global generics business with annual sales of approximately $10 billion. Beyond its solid position in the areas of biosimilars and generic antibiotics, Sandoz holds strong global positions in areas ranging from generic cardiovascular, central nervous system (CNS), pain and ophthalmology to oncology and respiratory. The company's portfolio is backed by a range of state-of-the-art technologies, formulations and devices, including prolonged-release and multiple-unit tablets, creams and gels, orodispersible films, transdermal patches, lyophilized products, implants, and inhalers. Sandoz has headquarters in Basel, Switzerland.

Pharmascience Inc.

Founded in 1983, Pharmascience is a leading manufacturer of generic, branded, and over-the-counter (OTC) pharmaceuticals, serving both the Canadian domestic and international markets. The company is a full-service privately-owned company with strong roots in Canada and a growing global reach with product distribution in over 50 countries with its 300-plus product families. Ranked 50th among Canada's top 100 Research & Development (R&D) investors in 2022, with $40 to $50 million invested each year, Pharmascience is among the largest drug manufacturers in Canada. In particular, Pharmascience is the largest pharmaceutical employer in Quebec with 1,500 employees, and has headquarters in Montreal, Quebec, Canada.

Teva Pharmaceutical Industries Ltd.

Teva Pharmaceutical Industries Ltd. is an Israeli multinational pharmaceutical company primarily focused on generic drugs, with other business interests including active pharmaceutical ingredients and proprietary pharmaceuticals. Developing and producing medicines for more than a century, the company is a global leader in generic and innovative medicines with a portfolio of over 3,500 products in nearly every therapeutic area. Approximately 200 million people around the world take a Teva medicine every day and are served by one of the largest and most complex supply chains in the pharmaceutical industry. Along with its established presence in generics, Teva also has significant innovative research and operations supporting its growing portfolio of medicines and biopharmaceutical products. Teva was the largest generic drug manufacturer when it was surpassed briefly by Pfizer. Teva regained its market leader position once Pfizer spun off its generic drug division in a merger with Mylan, forming the new company Viatris at the end of 2020. Overall, Teva is the 18th largest pharmaceutical company in the world. Teva's facilities are located in Israel, North America, Europe, Australia, and South America with its headquarters in Tel Aviv, Israel.

Historical Financial Results

Figures 24, 25, and 26 provide the Company's Consolidated Statements of Operations and Comprehensive Loss, its Consolidated Balance Sheets, and its Consolidated Statements of Cash Flows for the three-month period ended June 30, 2023. The consolidated financial statements contained in this report include the results of operations of Nora Pharma, acquired in October 2022.

In 2022 and YTD, Sunshine Biopharma completed four rounds of financing, generating total net proceeds of $47.7 million, which enabled the Company to expand its proprietary drug development program and complete the acquisition of Nora Pharma. Furthermore, on May 16, 2023, the Company completed a private placement for gross proceeds of $5 million (net proceeds of $4.1 million).

Figure 24
Sunshine Biopharma, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

	3 Months Ended June 30,		6 Months Ended June 30,	
	2023	2022	2023	2022
Sales:	$ 5,560,865	$ 150,307	$ 10,454,918	$ 272,952
Cost of sales	3,608,118	74,683	6,674,049	134,528
Gross profit	1,952,747	75,624	3,780,869	138,424
General and Administrative Expenses:				
Accounting	75,281	41,060	245,031	114,860
Consulting	392,454	101,683	524,069	107,181
Director fees	100,000	50,000	200,000	50,000
Legal	145,815	112,360	259,572	256,919
Marketing	133,177	87,680	261,090	182,720
Office	395,385	90,407	877,843	372,912
R&D	368,565	45,943	801,490	407,595
Salaries	1,200,167	240,000	3,200,424	560,000
Taxes	96,649	–	160,367	–
Depreciation	34,877	2,287	69,587	5,397
Total General and Administrative Expenses	2,942,370	771,420	6,599,473	2,057,584
(Loss) from operations	(989,623)	(695,796)	(2,818,604)	(1,919,160)
Other Income (Expense):				
Foreign exchange	(261)	29	(246)	20
Interest income	203,049	146,043	416,930	146,046
Debt release	–	10,852	–	10,852
Interest expense	(27,596)	–	(68,671)	(12,864)
Total Other Income (Expense)	175,192	156,924	348,013	144,054
Net (loss) before income taxes	(814,431)	(538,872)	(2,470,591)	(1,775,106)
Provision for income taxes	(87,677)	–	(133,947)	–
Net (Loss)	$ (902,108)	$ (538,872)	$ (2,604,538)	$ (1,775,106)
Gain (Loss) from foreign exchange translation	492,049	(12,645)	503,209	(11,638)
Comprehensive (Loss)	$ (410,059)	$ (551,517)	$ (2,101,329)	$ (1,786,744)
Basic (Loss) per common share	$ (0.02)	$ (0.03)	$ (0.09)	$ (0.18)
Weighted average common shares outstanding (Basic and Diluted)	25,350,263	15,849,518	23,827,205	9,691,625

Source: Sunshine Biopharmaceuticals Inc.

Figure 25
Sunshine Biopharma, Inc.
CONSOLIDATED BALANCE SHEETS

	June 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 19,729,491	$ 21,826,437
Accounts receivable	2,011,308	1,912,153
Inventory	4,250,887	3,289,945
Prepaid expenses	107,023	283,799
Total Current Assets	26,098,709	27,312,334
Property and equipment	366,684	394,249
Intangible assets	1,233,570	776,856
Right-of-use-asset	711,059	760,409
TOTAL ASSETS	$ 28,410,022	$ 29,243,848
LIABILITIES		
Current Liabilities:		
Accounts payable and accrued expenses	$ 1,759,789	$ 2,802,797
Earnout payable	2,547,831	3,632,000
Income tax payable	230,581	373,191
Right-of-use-liability	122,146	123,026
Total Current Liabilities	4,660,347	6,931,014
Long-Term Liabilities:		
Deferred tax liability	43,032	43,032
Right-of-use-liability	596,850	642,232
Total Long-Term Liabilities	639,882	685,264
TOTAL LIABILITIES	5,300,229	7,616,278
SHAREHOLDERS' EQUITY		
Preferred Stock, Series B $0.10 par value per share; 1,000,000 shares authorized; 10,000 shares issued and outstanding	1,000	1,000
Common Stock, $0.001 par value per share; 3,000,000,000 shares authorized; 25,746,302 and 22,585,632 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	25,746	22,585
Capital paid in excess of par value	84,422,143	80,841,752
Accumulated comprehensive income	665,056	161,847
Accumulated (Deficit)	(62,004,152)	(59,399,614)
TOTAL SHAREHOLDERS' EQUITY	23,109,793	21,627,570
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 28,410,022	$ 29,243,848

Source: Sunshine Biopharmaceuticals Inc.

Figure 26
Sunshine Biopharma, Inc.
CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	June 30, 2023	June 30, 2022
Cash Flows From Operating Activities:		
Net (Loss)	$ (2,604,538)	$ (1,775,106)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	69,594	5,397
Foreign exchange	–	(20)
Debt release	–	(10,852)
Accounts receivable	(55,160)	7,774
Inventory	(885,243)	(99,721)
Prepaid expenses	182,852	(18,937)
Accounts payable and accrued expenses	(1,103,502)	61,742
Income tax payable	(147,980)	–
Interest payable	(1,084,169)	(48,287)
Net Cash Flows (Used) in Operations	(5,628,146)	(1,878,010)
Cash Flows From Investing Activities:		
Reduction in Right-of-use asset	66,846	–
Purchase of intangible assets	(17,645)	–
Purchase of equipment	(454,980)	–
Net Cash Flows (Used) in Investing activities	(405,779)	–
Cash Flows From Financing Activities:		
Common stock issued	4,089,208	43,560,363
Exercise of warrants	1,156	–
Purchase of treasury stock	(506,822)	(99,000)
Lease liability	(63,870)	–
Payments of notes payable	–	(1,900,000)
Net Cash Flows Provided by Financing Activities	3,519,672	41,561,363
Cash and Cash Equivalents at Beginning of Period	21,826,437	2,045,167
Net increase (decrease) in cash and cash equivalents	(2,514,253)	39,683,353
Effect of exchange rate changes on cash	9	(12,383)
Foreign currency translation adjustment	417,298	11,638
Cash and Cash Equivalents at End of Period	$ 19,729,491	$ 41,727,775
Supplementary Disclosure Of Cash Flow Information:		
Cash paid for interest	$ –	$ 61,151
Cash paid for income taxes	$ –	$ –

Source: Sunshine Biopharmaceuticals Inc.

Recent Events

September 21, 2023—Sunshine Biopharma announced that it has received a 180-day extension, until March 18, 2024, to achieve compliance with the Nasdaq $1.00 minimum bid price rule. The Nasdaq staff has determined that Sunshine Biopharmaceuticals is eligible, based on the Company meeting the continued listing requirements for market value of publicly held shares and all other applicable requirements for initial listing on the Capital Market with the exception of the bid price requirement, and the Company's written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

August 11, 2023—Announced that it has filed its quarterly report for the 2023 second quarter. The Company reported gross revenues of $5,560,865 for the quarter ended June 30, 2023, an increase of 3,600% over the same period in 2022. The increase was largely due to the prescription drugs sales of Nora Pharma Inc., a generic pharmaceuticals company that Sunshine Biopharma acquired in October 2022. In addition, the Company's second-quarter revenues of $5,560,865 represent a 13.6% increase over first quarter results.

May 16, 2023—Announced that the Company closed its previously announced private placement pursuant to a securities purchase agreement with a single healthcare-focused institutional investor for gross proceeds of approximately $5 million, before deducting fees to the placement agent and other offering expenses payable by the Company. In connection with the private placement, the Company issued 5,952,381 units and pre-funded units at a purchase price of $0.84 per unit (or $0.001 less per pre-funded unit), priced at-the-market under Nasdaq rules. Aegis Capital Corp. acted as the Exclusive Placement Agent in connection with the offering.

May 12, 2023—Announced that it had entered into a securities purchase agreement with a single healthcare-focused institutional investor for aggregate gross proceeds of approximately $5 million, before deducting fees to the placement agent and other offering expenses payable by the Company. In connection with the offering, the Company will issue 5,952,381 units and pre-funded units at a purchase price of $0.84 per unit (or $0.001 less per pre-funded unit), priced at-the-market under Nasdaq rules.

May 11, 2023—Announced that it has filed its 2023 first quarter report. The report shows gross revenues of $4,894,053 as of March 31, 2023, an increase of more than 2,100% over the same period in 2022. The increase was largely due to the prescription drugs sales of Nora Pharma Inc., a generic pharmaceuticals company that Sunshine Biopharma acquired in October 2022.

April 5, 2023—Announced reporting of operating results for the fiscal year ended December 31, 2022, and recent highlights. The Company increased sales from $228,426 in 2021 to $4,345,603 in 2022, largely due to inclusion of the 72 days of Nora Pharma operations, the time since the closing of the acquisition.

February 28, 2023—Announced the signing of an exclusive worldwide license agreement with the University of Arizona. The License Agreement grants Sunshine Biopharma exclusive worldwide rights for all of the University of Arizona and University of Illinois Chicago technology pertaining to PLpro protease inhibitors of SARS-CoV-2, the coronavirus that causes COVID-19. Sunshine Biopharma has been working on this project in collaboration with the University of Arizona since February 2022.

February 10, 2023—Announced the signing of a research agreement with Sir Mortimer B. Davis Jewish General Hospital, a McGill University Health Center hospital located in Montreal, Quebec, Canada. The research effort will be focused on advancing the development of Sunshine Biopharma's Adva-27a anticancer compound through the IND-enabling studies. If at any time, the research results become conclusive, and Sunshine Biopharma wishes to proceed to conducting a Phase I clinical trial, the Jewish General Hospital is prepared to negotiate a new agreement to define the responsibilities and obligations of the parties for such Phase I clinical trial to be performed. Adva-27a had previously been shown to be effective at destroying multidrug resistant cancer cells originating from pancreatic cancer, breast cancer, small-cell lung cancer, and uterine sarcoma.

January 19, 2023—Announced that its board of directors has authorized a share repurchase program to acquire up to $2 million of the Company's common stock. The Company may purchase common stock on the open market, through privately negotiated transactions, or otherwise, in compliance with the rules of the United States Securities and Exchange Commission and other applicable legal requirements.

December 20, 2022—Issued a letter to shareholders from Dr. Steve Slilaty, Chairman and CEO of the Company.

November 16, 2022—Announced that it had entered into a collaboration agreement with one of North America's leading lipid nanoparticle ("LNP") companies. The purpose of the collaboration is to advance the development of Sunshine Biopharma's mRNA-based anticancer macromolecule, K1.1. The Company's collaboration partner will prepare two LNP formulations (K1.1a and K1.1b) of Sunshine Biopharma's in-house developed antineoplastic mRNA, K1.1.

October 20, 2022—Announced that it has completed the acquisition of all the outstanding shares of Nora Pharma Inc. As such, Nora Pharma Inc. is now a wholly-owned subsidiary of Sunshine Biopharma Inc. Nora Pharma is one of North America's fastest growing generic pharmaceuticals companies. The addition of Nora Pharma allows Sunshine Biopharma to expand its operations into the area of generic prescription drugs and biosimilars. The purchase price of $30,000,000 Canadian (approximately $21,900,000 US) was paid by cash, Sunshine Biopharma common stock, and an earn-out amount.

July 28, 2022—Announced that it has agreed to provide additional resources to the University of Arizona R. Ken Coit College of Pharmacy for the purposes of accelerating the development of novel PLpro inhibitors currently underway. The development of the Company's lead PLpro inhibitor, SBFM-PL4, is continuing in parallel.

April 28, 2022—Closed its previously announced private placement pursuant to a securities purchase agreement entered into on April 25, 2022, with certain institutional and accredited investors for aggregate gross proceeds of approximately $19.5 million, before deducting fees to the placement agent and other offering expenses payable by the Company. In connection with the offering, the Company issued 4,862,845 units and pre-funded units at a purchase price of $4.01 per unit (or $4.009 per pre-funded unit), priced at-the-market under Nasdaq rules. Each unit and pre-funded unit consist of 1 share of common stock or common stock equivalent, and 2 non-tradable warrants, each warrant exercisable for one share of common stock for $3.76 (for a total of 9,725,690 shares underlying the warrants). Aegis Capital Corp. acted as the Exclusive Placement Agent in connection with the offering.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Sunshine Biopharma Inc. ("Sunshine Biopharma" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this Executive Informational Overview (EIO) relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Sunshine Biopharma's statements on forms filed from time to time.

The content of this report with respect to Sunshine Biopharma has been compiled primarily from information available to the public released by the Company through news releases and other filings. Sunshine Biopharma is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Sunshine Biopharma or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of fifty thousand dollars for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about Sunshine Biopharma's business, as described below. Investors should not interpret the order in which considerations are presented in this document or other filings as an indication of their relative importance. In addition, the risks and uncertainties covered in the accompanying sections are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Sunshine Biopharma or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, Sunshine Biopharma's business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved of investing in the Company, as well as for copies of this report, please contact Sunshine Biopharma by calling (514) 426-6161.

RISK FACTORS

Investing in the Company's securities includes a high degree of risk. Prior to making a decision about investing in Sunshine Biopharma's securities, you should carefully consider the specific factors discussed below, together with all of the other information contained in this report. The Company's business, financial condition, results of operations, and prospects could be materially and adversely affected by these risks.

RISKS RELATED TO THE COMPANY'S BUSINESS

Sunshine Biopharma has incurred losses and may never achieve profitability.

The Company has an accumulated deficit of $59,399,614 as of December 31, 2022. Sunshine Biopharma incurred a net loss of $26,744,440 for the year ended December 31, 2022, and a net loss of $12,436,447 for the year ended December 31, 2021. It may never achieve profitability.

Sunshine Biopharma is subject to the significant risks associated with the generic pharmaceutical business.

Since its acquisition of Nora Pharma in October 2022, the Company has generated revenues primarily through sales of generic pharmaceutical products in Canada, and it expects this to remain the case for the foreseeable future. Generic pharmaceuticals are, as a general matter, significantly less profitable than innovative medicines.

In recent years, the generic pharmaceutical business has experienced increased volatility in volumes due in large part to global supply chain issues and the COVID-19 pandemic. In 2022, the global economy was continuing to recover from the impacts of the COVID-19 pandemic and also began experiencing additional macroeconomic pressures, such as rising inflation and disruptions to the global supply chain, in part resulting from the ongoing conflict between Russia and Ukraine. Sunshine Biopharma may experience supply discontinuities due to macroeconomic issues, regulatory actions, including sanctions and trade restrictions, labor disturbances and approval delays, which may impact the Company's ability to timely meet demand in certain instances. These adverse market forces have a direct impact on Sunshine Biopharma's overall performance. Any such disruptions could have a material adverse impact on its business, results of operation, and financial condition.

Sales of the Company's generic products may be adversely affected by the drug regulatory environment in Canada.

Currently, Sunshine Biopharma sells its generic drugs only in Canada. The Company's net sales may be affected by fluctuations in the buying patterns of its customers resulting from government lead pricing pressures and other factors. Sunshine Biopharma's generic sales in Canada are done via retail pharmacies, pharmacy channels, distributors, and wholesalers. Pricing pressures in Canada represent the highest risk due to ongoing and unresolved negotiations between the pharmaceutical industry and the federal government. These, together with the fact that a significant portion of the Company's revenues is derived from relatively few key customers, any financial difficulties experienced by a single key customer, or any delay in receiving payments from such a customer, could have a material adverse effect on its business, financial condition, and results of operations.

Sunshine Biopharma's revenues and profits from generic products may decline as a result of competition from other pharmaceutical companies and changes in regulatory policy.

The Company's generic drugs face intense competition. Prices of generic drugs may, and often do, decline, sometimes dramatically, especially as additional generic pharmaceutical companies receive approvals and enter the market for a given product and competition intensifies. Consequently, Sunshine Biopharma's ability to sustain sales and profitability on any given product over time is affected by the number of companies selling such product, including new market entrants, and the timing of their approvals.

Furthermore, brand pharmaceutical companies continue to manage products in a challenging environment through marketing agreements with payers, pharmacy benefits managers, and generic manufacturers. For example, brand companies often sell or license their own generic versions of their products, either directly or through other generic pharmaceutical companies (so-called "authorized generics"). No significant regulatory approvals are required for authorized generics, and brand companies do not face any other significant barriers to entry into such market. Brand companies may seek to delay introductions of generic equivalents through a variety of commercial and regulatory tactics. These actions may increase the costs and risks of the Company's efforts to introduce generic products and may delay or prevent such introduction altogether.

Sunshine Biopharma may experience delays in launches of its new generic products.

If the Company cannot execute timely launches of new products, it may not be able to offset the increasing price erosion on existing products resulting from pricing pressures and accelerated generics approvals for competing products. Such unsuccessful launches can be caused by many factors, including delays in regulatory approvals, lack of operational or clinical readiness, or patent litigation. Failure or delays to execute launches of new generic products could have a material adverse effect on Sunshine Biopharma's business, financial condition, and results of operations.

The Company may not receive the required regulatory approval for any of its non-generic pharmaceutical product candidates.

Sunshine Biopharma has not received approval for any of its proprietary (non-generic) drug development operations product candidates from the FDA. Any compounds that it discovers, or in-licenses will require extensive and costly development, preclinical testing, and clinical trials prior to seeking regulatory approval for commercial sales. The Company's most advanced product candidate, Adva-27a, and its potential COVID-19 treatments in development, may never be approved for commercial sale. Sunshine Biopharma has not made any filings to date with the FDA or other regulatory bodies in other jurisdictions. The time required to attain product sales and profitability is lengthy and highly uncertain. If the Company fails to obtain required regulatory approvals for its pharmaceutical product candidates, its business will be materially harmed.

As Sunshine Biopharma has no approved non-generic pharmaceutical products on the market, it does not expect to generate significant revenues from non-generic pharmaceutical product sales in the foreseeable future, if at all.

To date, the Company has no approved non-generic pharmaceutical products on the market and has generated product revenues solely from its OTC supplements operations and generic pharmaceutical product sales. Sunshine Biopharma has funded its operations primarily from sales of its securities. The Company has not received and does not expect to receive for at least the next three to four years, if at all, any revenues from the commercialization of its non-generic pharmaceutical product candidates. To obtain revenues from sales of such pharmaceutical product candidates, Sunshine Biopharma must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing, marketing, and distributing drugs with commercial potential. Sunshine Biopharma may never succeed in these activities, and it may not generate sufficient revenues to continue its business operations or achieve profitability.

Sunshine Biopharma will require additional funding to satisfy its future capital needs, which may not be available.

The Company may require significant additional funding in large part due to its research and development expenses, future preclinical and clinical testing costs, and the absence of significant revenues in the near future. Sunshine Biopharma does not know whether additional financing will be available on favorable terms or at all. If the Company cannot raise additional funds, it may be required to reduce its capital expenditures, scale back product development programs, reduce its workforce, and license to other products or technologies that Sunshine Biopharma may otherwise be able to commercialize. The Company is currently unable to project when or whether its operations will generate positive cash flows from operations.

Any additional equity securities Sunshine Biopharma issues or issuances of debt it may enter into or undertake may have rights, preferences, or privileges senior to those of existing holders of common stock. To the extent that it raises additional funds through collaboration and licensing arrangements, the Company may be required to relinquish some rights to its technologies or product candidates or grant licenses on terms that are not favorable to Sunshine Biopharma.

The FDA may change its approval policies or requirements, or apply interpretations to its policies or requirements, in a manner that could delay or prevent commercialization of Adva-27a or the Company's potential COVID-19 treatment in development.

Regulatory requirements may change in a manner that requires Sunshine Biopharma to conduct additional clinical trials, which may delay or prevent commercialization of its Adva-27a and potential COVID-19 treatment in development. Sunshine Biopharma cannot provide any assurance that the FDA will not require it to repeat existing studies or conduct new or unforeseen experiments in order to demonstrate the safety and efficacy of any product candidate before considering the approval of such product candidate.

The product candidate Sunshine Biopharma is developing for the treatment of COVID-19 may not be granted an emergency use authorization by the FDA. If the Company does not receive such authorization, or if, once granted, it is terminated, it will be required to pursue the drug approval process, which is lengthy and expensive.

Subject to completing and receiving favorable results for clinical trials, Sunshine Biopharma intends to seek emergency use authorization, or EUA, for a potential COVID-19 treatment, which would allow it to market and sell such product candidate without the need to pursue the lengthy and expensive drug approval process. The FDA may issue an EUA during a public health emergency if it determines that the potential benefits of a product outweigh the potential risks and if other regulatory criteria are met. In addition, the FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization. Sunshine Biopharma may not receive EUA for any COVID-19 treatment product candidate. In addition, even if it does receive EUA for any product candidate, Sunshine Biopharma cannot predict how long such EUA will remain in place. If the Company fails to receive an EUA for any COVID-19 product candidate, or such EUA is granted but subsequently terminated, its business, financial condition, and results of operations could be adversely affected.

Sunshine Biopharma's business would be materially harmed if it fails to obtain FDA approval for its pharmaceutical product candidates.

Sunshine Biopharma anticipates that its ability to generate significant product revenues from its drug development business will depend on the successful development and commercialization of Adva-27a or its potential COVID-19 treatment in development. The FDA may not approve in a timely manner, or at all, any of the Company's drug candidates. If Sunshine Biopharma is unable to submit a new drug application, or NDA for its product candidates, it will be unable to commercialize such products and its business will be materially harmed. The FDA can and does reject NDAs, and often requires additional clinical trials, even when product candidates performed well or achieved favorable results in large-scale Phase III clinical trials. The FDA imposes substantial requirements on the introduction of pharmaceutical products through lengthy and detailed laboratory and clinical testing procedures, sampling activities, and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years and may vary substantially based upon the type and complexity of the pharmaceutical product. Sunshine Biopharma's product candidates are novel compounds or new chemical entities, which may further increase the time required for satisfactory testing procedures.

Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which could delay, limit, or prevent regulatory approval. In addition, delays or rejections may be encountered based on changes in, or additions to, regulatory policies for drug approval during product development and regulatory review. Government regulation may delay or prevent the commencement of clinical trials or marketing of the Company's product candidates, impose costly procedures upon its activities, and provide an advantage to its competitors with greater financial resources or more experience in regulatory affairs. The FDA may not approve Sunshine Biopharma's product candidates for clinical trials or marketing on a timely basis or at all. Delayed or failed approvals would adversely affect the marketing of its product candidates and its liquidity and capital resources.

Drug products and their manufacturers are subject to continual regulatory review after the product receives FDA approval. Later discovery of previously unknown problems with a product or manufacturer may result in additional clinical testing requirements or restrictions on such product or manufacturer, including withdrawal of the product from the market. Failure to comply with applicable regulatory requirements can, among other things, result in fines, injunctions and civil penalties, suspensions or withdrawals of regulatory approvals, product recalls, operating restrictions or shutdown and criminal prosecution. Sunshine Biopharma may lack sufficient resources and expertise to address these and other regulatory issues as they arise.

The Company may be sued or become a party to litigation, which could require significant management time and attention and result in significant legal expenses and may result in an unfavorable outcome, which could have a material adverse effect on its business, financial condition, results of operations, and cash flows.

Sunshine Biopharma may be forced to incur costs and expenses in connection with defending itself with respect to litigation and the payment of any settlement or judgment in connection therewith if there is an unfavorable outcome. The expense of defending litigation may be significant. The amount of time to resolve lawsuits is unpredictable and defending itself may divert management's attention from the day-to-day operations, which could adversely affect the Company's business, results of operations, and cash flows. In addition, an unfavorable outcome in any such litigation could have a material adverse effect on its business, results of operations, and cash flows.

If Sunshine Biopharma is unable to attract and retain qualified scientific, technical, and key management personnel, or if its key executive, Dr. Steve N. Slilaty, discontinues his employment, it may delay the Company's research and development efforts.

Sunshine Biopharma relies on the services of Dr. Slilaty for strategic and operational management, as well as for scientific and/or medical expertise in the development of its products. The loss of Dr. Slilaty would result in a significant negative impact on the Company's ability to implement its business plan. Sunshine Biopharma has not entered into an employment agreement with any member of its management, including Dr. Slilaty. The loss of Dr. Slilaty will also significantly delay or prevent the achievement of the Company's business objectives.

Sunshine Biopharma's business exposes it to potential product liability risks, and it may be unable to acquire and maintain sufficient insurance to provide adequate coverage against potential liabilities.

The Company's business exposes it to potential product liability risks that are inherent in the testing, manufacturing, and marketing of pharmaceutical products and OTC supplements. The use of its product candidates in clinical trials also exposes Sunshine Biopharma to the possibility of product liability claims and possible adverse publicity. These risks will increase to the extent the Company's pharmaceutical product candidates receive regulatory approval and are commercialized. Sunshine Biopharma currently has product liability insurance for its generic drugs and it plans to obtain product liability insurance in connection with its OTC supplements and future clinical trials of its pharmaceutical product candidates in the near future. However, current and future product liability insurance, once obtained, may not provide adequate coverage against potential liabilities. On occasion, juries have awarded large judgments in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against Sunshine Biopharma would decrease its cash reserves and could cause its stock price to fall significantly.

Sunshine Biopharma faces regulation and risks related to hazardous materials and environmental laws, violations of which may subject it to claims for damages or fines that could materially affect its business, cash flows, financial condition, and results of operations.

The Company's research and development activities involve the use of controlled and/or hazardous materials and chemicals. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of an accident, Sunshine Biopharma could be held liable for any damages or fines that result and the liability could have a material adverse effect on its business, financial condition, and results of operations. Sunshine Biopharma is also subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of hazardous materials and waste products. If the Company fails to comply with these laws and regulations or with the conditions attached to its operating licenses, the licenses could be revoked, and it could be subjected to criminal sanctions and substantial liability or be required to suspend or modify its operations. In addition, the Company may have to incur significant costs to comply with future environmental laws and regulations. Sunshine Biopharma does not currently have a pollution and remediation insurance policy.

Third party manufacturers may not be able to manufacture Sunshine Biopharma's pharmaceutical product candidates, which would prevent the Company from commercializing its product candidates.

If any of the Company's pharmaceutical product candidates is approved by the FDA or other regulatory agencies for commercial sale, Sunshine Biopharma will need third parties to manufacture the product in larger quantities. If the Company is able to reach an agreement with any collaborator or third-party manufacturer in the future, of which there can be no assurance due to factors beyond its control, these collaborators and/or third-party manufacturers may not be able to increase their manufacturing capacity for any of Sunshine Biopharma's product candidates in a timely or economic manner, or at all. A significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If Sunshine Biopharma is unable to increase the manufacturing capacity for a product candidate successfully, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. The Company's product candidates require precise, high-quality manufacturing. The failure of collaborators or third-party manufacturers to achieve and maintain these high manufacturing standards, including the incidence of manufacturing errors, could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns, or other problems that could seriously harm Sunshine Biopharma's business.

If the Company is unable to establish sales and marketing capabilities for its pharmaceutical product candidates or enter into agreements with third parties to sell and market any such products Sunshine Biopharma may develop, it may be unable to generate revenues from its pharmaceutical business.

Sunshine Biopharma does not currently have product sales and marketing capabilities for its pharmaceutical operations. If the Company receives regulatory approval to commence commercial sales of any of its pharmaceutical product candidates, it will have to establish a sales and marketing organization with appropriate technical expertise and distribution capabilities or make arrangements with third parties to perform these services in other jurisdictions. If Sunshine Biopharma receives approval in applicable jurisdictions to commercialize Adva-27a for the treatment of breast cancer, it intends to engage additional pharmaceutical or healthcare companies with existing distribution systems and direct sales organizations to assist in North America and throughout the world. Sunshine Biopharma may not be able to negotiate favorable distribution partnering arrangements, if at all. To the extent the Company enters into co-promotion or other licensing arrangements, any revenues it receives will depend on the efforts of third parties and will not be under its control. If Sunshine Biopharma is unable to establish adequate sales, marketing, and distribution capabilities, whether independently or with third parties, its ability to generate product revenues and become profitable would be severely limited.

Even if Sunshine Biopharma obtains the required U.S. and foreign regulatory approvals, as applicable, factors that may inhibit its efforts to commercialize its pharmaceutical product candidates without strategic partners or licensees include:

- difficulty recruiting and retaining adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to, or persuade adequate numbers of, physicians to prescribe the Company's products;
- the lack of complementary products to be offered by sales personnel, which may put Sunshine Biopharma at a competitive disadvantage against companies with broader product lines; and
- unforeseen costs associated with creating an independent sales and marketing organization.

Even if Sunshine Biopharma successfully develops and obtains approval for its proprietary drug product candidates, its business will not be profitable if such products do not achieve and maintain market acceptance.

Even if the Company's proprietary drug product candidates are approved for commercial sale by the FDA or other regulatory authorities, the degree of market acceptance of its approved product candidates by physicians, healthcare professionals, patients, and third-party payors, and the Company's resulting profitability and growth, will depend on a number of factors, including:

- Sunshine Biopharma's ability to provide acceptable evidence of safety and efficacy;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- the availability of alternative treatments;
- the details of FDA labeling requirements, including the scope of approved indications and any safety warnings;
- pricing and cost effectiveness;
- the effectiveness of the Company's or its collaborators' sales and marketing strategy;
- Sunshine Biopharma's ability to obtain sufficient third-party insurance coverage or reimbursement; and
- the Company's ability to have the product listed on insurance company formularies.

If Sunshine Biopharma's proprietary drug product candidates achieve market acceptance, it may not maintain that market acceptance over time if new products or technologies are introduced that are received more favorably or are more cost effective. Complications may also arise, such as development of new know-how or new medical or therapeutic capabilities by other parties that render the Company's product obsolete.

Because the results of preclinical studies for Sunshine Biopharma's preclinical product candidates are not necessarily predictive of future results, its pharmaceutical product candidates may not have favorable results in later clinical trials or ultimately receive regulatory approval.

The Company's proprietary drug product candidates have not been tested in clinical trials. Positive results from preclinical studies are no assurance that later clinical trials will succeed. Preclinical studies are not designed to establish the clinical efficacy of preclinical product candidates. Sunshine Biopharma will be required to demonstrate through clinical trials that its product candidates are safe and effective for use before it can seek regulatory approvals for commercial sale. There is typically an extremely high rate of failure as product candidates proceed through clinical trials. If Sunshine Biopharma's product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, it would experience potentially significant delays in, or be required to abandon, development of that product candidate. This would adversely affect the Company's ability to generate revenues and may damage its reputation in the industry and in the investment community.

The future clinical testing of Sunshine Biopharma's proprietary drug product candidates could be delayed, resulting in increased costs and a delay in its ability to generate revenues.

The Company's proprietary drug product candidates will require additional preclinical testing and extensive clinical trials prior to submitting a regulatory application for commercial sales. Sunshine Biopharma does not know whether clinical trials will begin on time, if at all. Delays in the commencement of clinical testing could significantly increase the Company's product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial

of regulatory approval of a product candidate. Each of these results would adversely affect the Company's ability to generate revenues.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate;
- obtaining institutional review board approvals to conduct clinical trials at prospective sites; and
- procuring adequate financing to fund the work.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial. If Sunshine Biopharma is unable to enroll a sufficient number of evaluable patients, the clinical trials for its product candidates could be delayed until sufficient numbers are achieved.

The Company faces or will face significant competition from other biotechnology, pharmaceutical, and OTC supplement companies, and its operating results will suffer if it fails to compete effectively.

Most of Sunshine Biopharma's pharmaceutical company competitors, such as Merck, Bristol-Myers Squibb, Pfizer, Amgen, and others, are large pharmaceutical companies with substantially greater financial, technical, and human resources. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The drugs that the Company is attempting to develop will compete with existing therapies if it receives marketing approval. Because of their significant resources, the Company's competitors may be able to use discovery technologies and techniques, or partnerships with collaborators, to develop competing products that are more effective or less costly than the product candidate it is developing. This may render Sunshine Biopharma's technology or product candidate obsolete and noncompetitive. Academic institutions, government agencies, and other public and private research organizations may seek patent protection with respect to potentially competitive products or technologies and may establish exclusive collaborative or licensing relationships with its competitors.

The Company's competitors may succeed in obtaining FDA or other regulatory approvals for product candidates more rapidly than Sunshine Biopharma. Companies that complete clinical trials, obtain required regulatory agency approvals, and commence commercial sale of their drugs before the Company does may achieve a significant competitive advantage, including certain FDA marketing exclusivity rights that would delay or prevent Sunshine Biopharma's ability to market certain products. Any approved drugs resulting from its research and development efforts, or from its joint efforts with its existing or future collaborative partners, might not be able to compete successfully with Sunshine Biopharma's competitors' existing or future products.

The Company also faces competition in its OTC supplements business. The business of marketing OTC supplements is highly competitive. This market segment includes numerous manufacturers, marketers, and retailers that actively compete for the business of consumers both in the U.S. and abroad. The market is highly sensitive to the introduction of new products, which may rapidly capture a significant share of the market. Sales of similar products by competitors may materially and adversely affect Sunshine Biopharma's business, financial condition, and results of operations.

The market for the Company's potential COVID-19 treatment in development could be adversely affected if the COVID-19 disease outbreak subsides.

Disease outbreaks are unpredictable. In the event that the COVID-19 outbreak subsides, or COVID-19 is substantially eradicated, there may be reduced demand or need for Sunshine Biopharma's potential COVID-19 treatment in development, which may have a negative effect on the market for such treatment, even if it is approved.

The COVID-19 pandemic has significantly impacted worldwide economic conditions and could have a material adverse effect on the Company's operations and business.

While Sunshine Biopharma has been able to continue to operate, the global COVID-19 pandemic has caused disruptions in supply chains, affecting production and sales across a range of industries. While the disruptions are currently expected to be temporary, there is considerable uncertainty around the duration and the impact of these disruptions.

The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on the on-going and future impact on its customers, vendors, service providers, and availability of labor as well as the potential impact of future expanded local, state, or federal restrictions—all of which are uncertain and are difficult to predict.

Because Sunshine Biopharma proprietary drug product candidates and its development and collaboration efforts depend on the Company's intellectual property rights, adverse events affecting its intellectual property rights will harm Sunshine Biopharma's ability to commercialize products.

The Company's success will depend, to a large degree, on its own and its licensors' ability to obtain and defend patents for each party's respective technologies and the compounds and other products, if any, resulting from the application of such technologies. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and technical questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, Sunshine Biopharma cannot predict the breadth of claims that will be allowed or maintained, after challenge, in the Company's or other companies' patents.

The degree of future protection for Sunshine Biopharma's proprietary rights is uncertain and it cannot ensure that:

- the Company was the first to make the inventions covered by each of its pending patent applications;
- the Company was the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of Sunshine Biopharma's technologies;
- any patents issued to the Company or its collaborators will provide a basis for commercially viable products, will provide Sunshine Biopharma with any competitive advantages, or will not be challenged by third parties;
- the Company's pending patent applications will result in issued patents;
- the Company will develop additional proprietary technologies that are patentable;
- the patents of others will not have a negative effect on Sunshine Biopharma's ability to do business; or
- the Company's issued patents will have sufficient useful life remaining for commercial viability of its product candidate.

If Sunshine Biopharma cannot maintain the confidentiality of its technology and other confidential information in connection with its collaborations, then the Company's ability to receive patent protection or protect its proprietary information will be impaired. In addition, some of the technology Sunshine Biopharma has developed or licensed relies on inventions developed using U.S. and other governments' resources. Under applicable law, the U.S. government has the right to require the Company to grant a nonexclusive, partially exclusive, or exclusive license for such technology to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, if the government determines that such action is necessary.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect Sunshine Biopharma's intellectual property.

The Company relies on trade secrets to protect its technology, particularly when it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. In order to protect its proprietary technology and processes, Sunshine Biopharma relies, in part, on confidentiality and intellectual property assignment agreements with its employees, consultants, outside scientific collaborators, and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of confidential information nor result in the effective assignment to the Company of intellectual property and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or other breaches of the agreements. In addition, others may independently discover Sunshine Biopharma's trade secrets and proprietary information, and in such case the Company could not assert any trade secret rights against such party. Enforcing a claim that a party illegally obtained and is using trade secrets is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Costly and time-consuming litigation could be necessary to seek to enforce and determine the scope of Sunshine Biopharma's proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect its competitive business position.

The implementation of the Company's business plan may result in a period of rapid growth that will impose a significant burden on its current administrative and operational resources.

Sunshine Biopharma's ability to effectively manage its growth will require it to substantially expand the capabilities of its administrative and operational resources by attracting, training, managing, and retaining additional qualified personnel, including additional members of management, technicians, and others. To successfully develop Sunshine Biopharma's products, it will need to manage operating, producing, marketing, and selling its products. There can be no assurances that the Company will be able to do so. Sunshine Biopharma's failure to successfully manage its growth will have a negative impact on its anticipated results of operations.

A significant or prolonged economic downturn could have a material adverse effect on Sunshine Biopharma's results of operations.

A significant or prolonged economic downturn may adversely affect the disposable income of many consumers and may lower demand for the Company's OTC supplement products. Any decline in economic conditions could negatively impact Sunshine Biopharma's business. A significant decline in consumer demand, even if only due in part to general economic conditions, could have a material adverse effect on the Company's revenues and profit margins.

The failure of Sunshine Biopharma's service providers and suppliers to supply quality services and materials in sufficient quantities, at a favorable price, and in a timely fashion could adversely affect the results of its operations.

The Company's outside manufacturer buys raw materials for its OTC supplements business from a limited number of suppliers. The loss of any of Sunshine Biopharma's major suppliers or of any supplier who, through the Company's contract manufacturer, provides it materials that are hard to obtain elsewhere at the same quality could adversely affect the Company's business operations. Although Sunshine Biopharma believes it could establish alternate manufacturers and sources for most of its raw materials, any delay in locating and establishing

relationships with other sources could result in shortages of products it manufactures from such raw materials, with a resulting loss of sales and customers. In certain situations, Sunshine Biopharma may need to alter its products or, with its customer's consent, to substitute different materials from alternative sources.

A shortage of raw materials or an unexpected interruption of supply could also result in higher prices for those materials. Sunshine Biopharma has experienced increases in various raw material costs, transportation costs, and the cost of petroleum-based raw materials and packaging supplies used in its business. Increasing cost pricing pressures on raw materials and other products have continued throughout fiscal 2020 as a result of limited supplies of various ingredients, the effects of higher labor and transportation costs, and impact of COVID-19. Sunshine Biopharma expects these upward pressures to continue through fiscal 2021. Although the Company may be able to raise its prices in response to significant increases in the cost of raw materials, it may not be able to raise prices sufficiently or quickly enough to offset the negative effects such cost increases could have on its results of operations or financial condition.

There can be no assurance suppliers will provide the quality raw materials Sunshine Biopharma needs in the quantities requested or at a price it is willing to pay. Because the Company does not control the actual production of these raw materials, it is also subject to delays caused by interruption in production of materials including but not limited to those resulting from conditions outside of its control, such as pandemics, weather, transportation interruptions, strikes, terrorism, natural disasters, wars, and other catastrophic events.

Sunshine Biopharma's OTC supplements business is subject to the effects of adverse publicity, which could negatively affect its sales and revenues.

The Company's business can be affected by adverse publicity or negative public perception about it, its competitors, its products, or its industry or competitors generally. Adverse publicity may include publicity about the OTC supplements industry generally, the efficacy, safety and quality of OTC supplements and other healthcare products or ingredients in general, or Sunshine Biopharma's products or ingredients specifically, and regulatory investigations, regardless of whether these investigations involve the Company or the business practices or products of its competitors, or its customers. Any adverse publicity or negative public perception could have a material adverse effect on Sunshine Biopharma's business, financial condition and results of operations. The Company's business, financial condition, and results of operations could be adversely affected if any of its products or any similar products distributed by other companies are alleged to be or are proved to be harmful to consumers or to have unanticipated and unwanted health consequences.

Sunshine Biopharma's manufacturing and third-party fulfillment activities are subject to certain risks.

The Company's OTC supplement products are manufactured at third party manufacturing facilities in Canada. As a result, Sunshine Biopharma is dependent on the uninterrupted and efficient operation of these facilities. Such manufacturing operations, and those of their suppliers, are subject to power failures, blackouts, border shutdowns, telecommunications failures, computer viruses, cybersecurity vulnerabilities, human error, breakdown, failure or substandard performance of facilities, equipment, the improper installation or operation of equipment, terrorism, pandemics (including COVID-19), natural or other disasters, intentional acts of violence, and the need to comply with the requirements or directives of governmental agencies, including the FDA. The occurrence of these or any other operational problems at such facilities may have a material adverse effect on the Company's business, financial condition, and results of operations.

RISKS RELATED TO THE COMPANY'S COMMON STOCK

There is a limited market for Sunshine Biopharma's common stock and investors may find it difficult to buy and sell its shares.

Prior to February 15, 2022, the Company's common stock was quoted on the OTC Pink Sheets, which is an unorganized, inter-dealer, over-the-counter market, which provides significantly less liquidity than the Nasdaq Capital Market or other national securities exchanges.

Sunshine Biopharma's common stock has been listed on the Nasdaq Capital Market since February 15, 2022. Currently, its common stock is thinly traded and there is no assurance any significant trading volume will develop or be sustained or that the Company will remain eligible for continued listing on the Nasdaq Capital Market.

Sunshine Biopharma's common stock has in the past been, and may in the future be considered, a "penny stock" and thus be subject to additional sale and trading regulations that may make it more difficult to buy or sell.

The Company's common stock may in the future (if it is not then listed on a national securities exchange) be considered a "penny stock." Securities broker-dealers participating in sales of "penny stocks" are subject to the "penny stock" regulations set forth in Rules 15g-2 through 15g-9 promulgated under the Exchange Act. Generally, brokers may be less willing to execute transactions in securities subject to the "penny stock" rules. This may make it more difficult for investors to dispose of the Company's common stock and cause a decline in the market value.

Sunshine Biopharma does not intend to pay dividends on its common stock for the foreseeable future.

The Company has paid no dividends on its common stock to date and it does not anticipate paying any dividends to holders of its common stock in the foreseeable future. While Sunshine Biopharma's future dividend policy will be based on the operating results and capital needs of the business, the Company currently anticipates that it will retain any earnings to finance its future expansion and for the implementation of its business plan. Investors should take note of the fact that a lack of a dividend can further affect the market value of the common stock and could significantly affect the value of any investment in the Company.

Sunshine Biopharma's articles of incorporation allow for its board to create a new series of preferred stock without further approval by stockholders, which could adversely affect the rights of the holders of the Company's common stock.

Sunshine Biopharma's board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. The Company's board of directors has the authority to issue up to 30,000,000 shares of Sunshine Biopharma's preferred stock without further stockholder approval. 1,000,000 shares of preferred stock are designated Series B Preferred Stock and 10,000 of such shares are outstanding and held by the Company's chief executive officer. Sunshine Biopharma's board of directors could authorize the creation of additional series of preferred stock that would grant to holders of preferred stock the right to the Company's assets upon liquidation, or the right to receive dividend payments before dividends are distributed to the holders of common stock. In addition, subject to the rules of any securities exchange on which Sunshine Biopharma's stock is then listed, the board of directors could authorize the creation of additional series of preferred stock that has greater voting power than the common stock or that is convertible into the Company's common stock, which could decrease the relative voting power of the common stock or result in dilution to Sunshine Biopharma's existing stockholders.

Additional stock offerings in the future or the issuance of stock upon exercise of outstanding warrants may dilute then-existing shareholders' percentage ownership of the Company.

Given Sunshine Biopharma's plans and expectations that it will need additional capital and personnel, the Company anticipates that it will need to issue additional shares of common stock or securities convertible or exercisable for shares of common stock, including convertible preferred stock, convertible notes, stock options, or warrants. In addition, as of March 31, 2023, Sunshine Biopharma has 1,764,594 and 9,725,690 shares of common issuable upon exercise of outstanding warrants with an exercise price of $2.22, and $3.76, respectively. The issuance of additional securities in the future will dilute the percentage ownership of then current stockholders.

Glossary

Cancer Cell Lines—Cancer cell lines are cell lines that consist of cancer cells that continually divide and grow over time under laboratory conditions. Human cancer cell lines are commonly used to study cancer biology, identify new treatments, and improve the efficacy of existing cancer treatments.

Coronaviruses—A large family of respiratory viruses that cause diseases in mammals and birds, and are named for the crown-like spikes on their surface. In humans, the viruses can cause respiratory tract infections that can range from mild to lethal. Mild illnesses include some cases of the common cold, while more serious varieties include viruses that cause Severe acute respiratory syndrome (SARS), Middle East respiratory syndrome (MERS), and Coronavirus Disease 2019 (COVID-19).

Cytotoxic—Toxic to living cells.

Endocytosis—A cellular process by which cells absorb external material by engulfing it with the cell membrane.

Etoposide—A semisynthetic derivative of podophyllotoxin that exhibits antitumor activity. Etoposide is widely used as a chemotherapy agent in the management and treatment of various cancers, such as testicular, prostate, bladder, stomach, and lung cancer. It is in the topoisomerase II inhibitor class of medications.

Generic Prescription Drugs—A pharmaceutical product that is bioequivalent to a brand-name drug in terms of dosage, strength, safety, efficacy, route of administration, and intended use. Generic drugs are produced and marketed after the patent protection of the original brand-name drug expires and are typically sold at substantial discounts from the branded price.

IC50—Commonly used as a measure of drug potency, it measures the concentration of a drug or inhibitor needed to inhibit a biological process or response by 50%.

IND (Investigational New Drug)—A program by which a pharmaceutical company obtains authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans, in order to start human clinical trials.

Lipid Nanoparticle (LNP)—A novel pharmaceutical drug delivery system that encapsulates biological molecules, such as nucleic acids and proteins, within a lipid nanoparticle vesicle. LNPs can be used to deliver a wide range of therapeutic agents, including nucleic acids such as DNA and mRNA, overcoming a major barrier preventing the development and use of genetic medicines.

MERS-CoV (Middle East respiratory syndrome-related coronavirus)—The virus that causes MERS, a disease first reported in 2012 in Saudi Arabia and spread to more than 25 other countries. Symptoms include fever, cough, and shortness of breath, and often progress to pneumonia. About 3 or 4 out of every 10 patients reported with MERS have died.

mRNA—A molecule of RNA that contains a genetic sequence template involved in protein synthesis. The role of mRNA is to carry protein information from the DNA in a cell's nucleus to the cytoplasm, where is it read by a ribosome in the process of synthesizing a protein.

Multidrug Resistant (MDR) Cancer—The ability of cancer cells to survive treatment with a variety of anticancer drugs, limiting the efficacy of chemotherapy. MDR represents a major obstacle to effective therapeutic interventions against cancer and is responsible for over 90% of deaths in cancer patients receiving traditional chemotherapeutics or novel targeted drugs.

Nrf-2 (nuclear factor erythroid 2-related factor 2)—A transcription factor (i.e., a protein that regulates the transcription of genes) that plays a critical roles in various cellular processes, including cell proliferation and cell defense mechanisms, as well as regulation of antioxidant, anti-inflammatory, drug metabolizing, and other homeostatic functions.

OTC (Over the Counter)—Pharmaceutical drugs that individuals can buy without a prescription.

Pharmacokinetic—The study of how the body interacts with administered substances, such as drugs, over a period of time, including the processes of absorption, distribution, localization in tissues, biotransformation, and excretion.

PLpro (papain-like protease)—A large protein family found in all domains of life. In coronaviruses, PLpro is one of the viral enzymes encoded in the genome that plays an essential role in both viral replication, as well the inhibition of the immune response to the virus.

Podophyllotoxin—A plant derived natural product and the main cytotoxic ingredient of podophyllin, a resin used for many years for topical treatment of warts. Synthetic forms of podophyllotoxin (e.g., etoposide) are used as chemotherapy agents in the treatment of many forms of cancers.

Polyproteins—Chains of conjoined smaller proteins that, after synthesis, are cleaved to produce several functionally distinct polypeptides. Polyprotein processing is an essential mechanism for the generation of major components of the virus particle needed for virus replication.

Proteases—An enzyme which breaks down proteins and peptides.

Ribosome—Macromolecular machines, found within all cells, that perform biological protein synthesis.

Small Molecules—Drugs or organic compounds with low molecular weight that regulate a biological process. Many current drugs are small molecules.

Topoisomerase II—Topoisomerases are nuclear enzymes that catalyze the introduction of topological changes to the DNA molecule. Replication and transcription of DNA require the unwinding (or flattening) of the DNA helix, a process carried out by topoisomerases. Type II topoisomerases cut both strands of the DNA helix simultaneously in order to manage DNA tangles and supercoils, unlike Type I topoisomerase which cuts only one strand.

Translation—The process in living cells in which proteins are produced using RNA molecules as templates.

SARS-CoV2 (Severe acute respiratory syndrome coronavirus 2)—The virus that causes COVID-19. The outbreak of COVID-19 has been declared a global pandemic by the World Health Organization. As of October 2023, more than 770 million cases had been reported worldwide, resulting in over 6.9 million deaths.

SARS-CoV (Severe acute respiratory syndrome coronavirus)—The virus that causes SARS, a disease first reported in Southern China in 2002, spreading to more than two dozen countries. Infection with the SARS virus causes acute respiratory distress (severe breathing difficulty), with a mortality rate of about 10%.

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