

BGC Cannabis Manufacturing and Research Master Project Phase 2

Addendum to EB-5 Business Plan Dated December 2022

March 2024



Sponsored by
Regional Center Bright Green LLC

Prepared by
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Contents Private and Strictly Confidential

1 Overview

This Addendum to the Comprehensive Business Plan (“referred to simply as “the **Addendum**”) for the **BGC Cannabis Manufacturing and Research Master Project Phase 2** (the “**Project**”) outlines updates to the original business plan dated December 2022, which was submitted to USCIS in reference to foreign investors (the “**EB-5 Investors**”) who are applying for immigrant visas through the EB-5 Investor Visa program.

The Job Creating Entity for the Project is **Bright Green Corporation** (“**BGC**”). Bright Green Corporation is also the New Commercial Enterprise and may be referred to as “the **NCE/JCE**” within this Addendum. The NCE/JCE is sponsored by **Regional Center Bright Green LLC** (“**RCBG**” or “the **Regional Center**”).

The purpose of this Addendum is to provide a summary of certain changes to the original business plan, including an update to project details, construction progress/development timeline, development budget, sources of funds, financial projections, and industry performance.

Section 2.0 of this Addendum includes an update to Project details.

Section 3.0 of this Addendum includes a summary of the Project’s investment structure as well as an update to the NCE/JCE’s management team/board of directors.

Section 4.0 of this Addendum includes a summary of the current status of the Project; specifically, activities already completed, development activities in-progress, schedule adjustments for future milestones, etc.

Section 5.0 of this Addendum includes an update to the Uses of Funds.

Section 6.0 of this Addendum includes an update to the Sources of Funds

Section 7.0 of this Addendum presents a summary of updated financial projections.

Section 8.0 of this Addendum presents a summary of updated industry trends and includes a summary of the Project’s new market.

Section 9.0 of this Addendum includes a listing of exhibits.

2 Project Overview

The NCE/JCE was originally established to finance the job-creating **BGC Cannabis Manufacturing and Research Master Project** (the “**Master Project**”), which consisted of the following:

- Renovation of the NCE’s existing 22-acre production facility
- The potential purchase of Alterola Biotech, Inc. (“Alterola”)
- Potential research and development of Alterola assets
- Development of a 118-acre state-of-the-art agricultural manufacturing and research facility
- Future greenhouse developments

Phase 1 of the Master Project consisted of the renovation of the NCE’s existing 22-acre production facility to process medicinal plants, including cannabis and hemp, as well as the purchase of 25% of Alterola Biotech, Inc. stock.

The focus of the business plan dated December 2022 was phase 2 of the Master Project, known officially as the **BGC Cannabis Manufacturing and Research Master Project Phase 2** (the “**Project**”), which consisted of the following:

- Potential completion of Alterola Biotech, Inc.’s acquisition
- Potential research and development of Alterola assets
- Development of a 118-acre state-of-the-art agricultural manufacturing and research facility

Prior to the completion of Phase 1 of the Master Project, however, the NCE/JCE recognized that the primary value, especially in the short term, lay in assets and technology owned by C2 Wellness Corporation. As a result, the NCE/JCE decided to shift its strategy and instead of pursuing complete ownership of Alterola Biotech, Inc., the NCE/JCE opted to purchase assets and technology from C2 Wellness Corporation instead. This decision aligns with the NCE/JCE’s strategic vision of “Drugs Made in America” to address the national security risk/supply chain disruptions encompassing both Schedule I and Schedule II Active Pharmaceutical Ingredients (“API’s”).

The updated Project resulting from this shift in strategy consists of the following:

- C2 Asset and Technology Acquisition
- Research and Development of C2 Wellness Corporation assets
- Development of a 160-acre state-of-the-art agricultural manufacturing and research facility

Acquisition of C2 Wellness Corporation Asset and Technology rights

The NCE/JCE will purchase the following CBD and THC-based molecule assets and platform technology from C2 Wellness Corporation:

- Conjugated CBD and its prodrugs: including gall research, development, and provisional patent applications related to conjugated CBD products with superior pharmacokinetic properties, addressing liabilities associated with Epidiolex.
- Combination drug of CBD and Drug B: Comprising the combination formula, preclinical data, research findings, and all associated intellectual property related to the dual drug product that combines CBD with an off-patent safe drug for the control of seizures.
- Conjugated CBD-THC and its prodrugs: Covering all research and development information, as well as provisional patent applications for a product with superior drug-like properties compared to Sativex for the treatment of multiple sclerosis (MS).
- Self-dissolving, dermal penetrating CBD encapsulated sustained release microneedle patch: This includes the design, prototype, preclinical studies, and all intellectual property related to the microneedle patch technology designed for transdermal delivery of CBD and its prodrugs.

Research and Development of C2 Wellness Corporation Assets

Through research and development, the NCE/JCE expects to advance the programs acquired from C2 Wellness Corporation by establishing translational proof of concepts of its drug candidate for two indications, childhood epilepsy and neuropathic pain. Once complete the NCE/JCE will initiate investigational new drug (“IND”) enabling studies as well as good laboratory practices (“GLP”) and good manufacturing practices (“GMP”) manufacturing and scale-up of drug products. Once IND enabling studies are complete, the NCE/JCE will build a data package for submission of the IND application to the Food and Drug Administration for epilepsy or neuropathic pain. Furthermore, upon approval of the IND application, the NCE/JCE expects to complete Ph 1a/1b safety and preliminary human proof of concept studies.

Agricultural Manufacturing and Research Facility

In order to meet the needs of the Project's new strategy the agricultural manufacturing and research facility's design has been updated to accommodate 2 types of crops. The new facility will consist of the following elements:

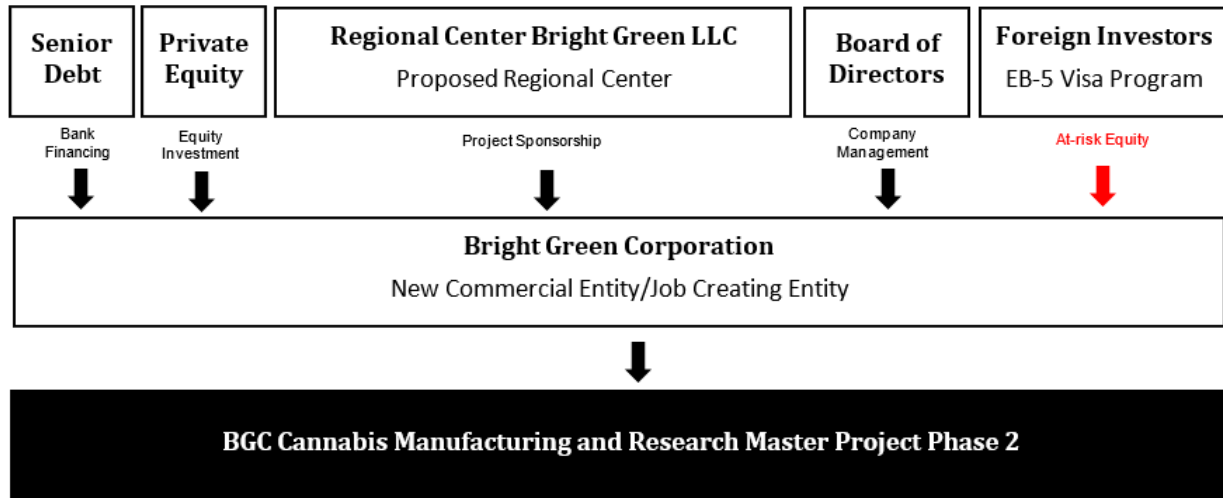
Total area:	160 acres
Area greenhouse blocks No. 1 – No. 3:	288,360 square meters (Poppys)
Area greenhouse blocks No. 4 – No. 5:	192,240 square meters (Cannabis)
Area Handling/Service Building:	67,284 square meters
Energy Building Area:	3,360 square meters
Solar farm:	102 MW

The following is the updated site plan for the agricultural manufacturing and research facility:



3 Investment Structure & Management

The investment structure into the Project was described in the business plan dated December 2022 by the following diagram:



There are no updates to this structure.

The following is a breakdown of the NCE/JCE’s management team/board of directors as outlined in the original business plan dated December 2022:

- Terry Rafih – Chief Executive Officer (“CEO”)
- Lynn Stockwell – Founder and Director
- Dean Valore – Director
- Robert Arnone – Director
- Dr. Alfie Morgan – Director
- Saleem Elmasri – Chief Financial Officer (“CFO”)

This Addendum provides an update to the NCE/JCE’s board of directors. On February 16, 2024, the NCE/JCE announced Gurvinder Singh as the newest member of BGC’s Board of Directors as CEO. Current board member and Co-founder Lynn Stockwell was also announced as the new Chair of the Board. These appointments followed the resignation of the previous CEO, Terry Rafih (Exhibit A). All other members of the board of directors remain unchanged.

Gurvinder Singh, *Chief Executive Officer (“CEO”)*

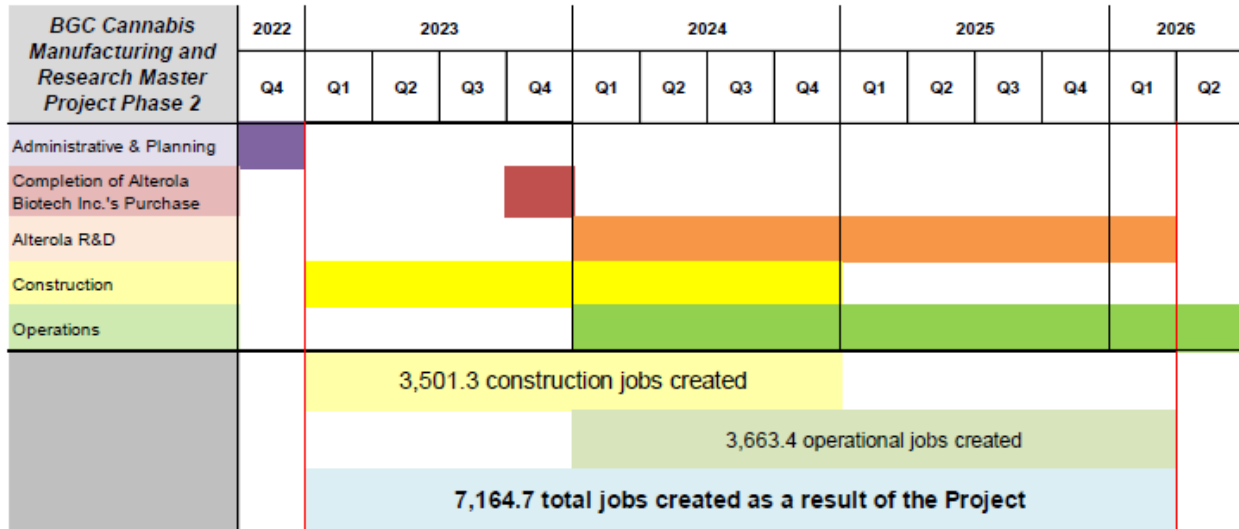
Mr. Singh comes to his role as CEO of Bright Green Corporation with extensive experience in both U.S. and international markets across consumer products, retail, fashion, entertainment, and wellness. Over a 23-year career as co-founder and executive, he has driven the successful growth and expansion of both private brands and public corporations. He brings a penchant for international partnerships as demonstrated at TWC Brands, Inc. where he forged alliances with global active apparel brands Billabong, Reebok, and Disney; and developed significant relations with foreign investors through the management of a real estate fund which will be pivotal to Bright Green’s EB-5 program. Most recently, Mr. Singh co-founded and was the Chief Marketing Officer of Glass House Brands where he was responsible for the formation and growth of the company’s commercial cannabis operations including six million square feet of cultivation and consumer retail business.

Lynn Stockwell, *Chair of the Board*

Lynn Stockwell’s biography is included within the original business plan dated December 2022.

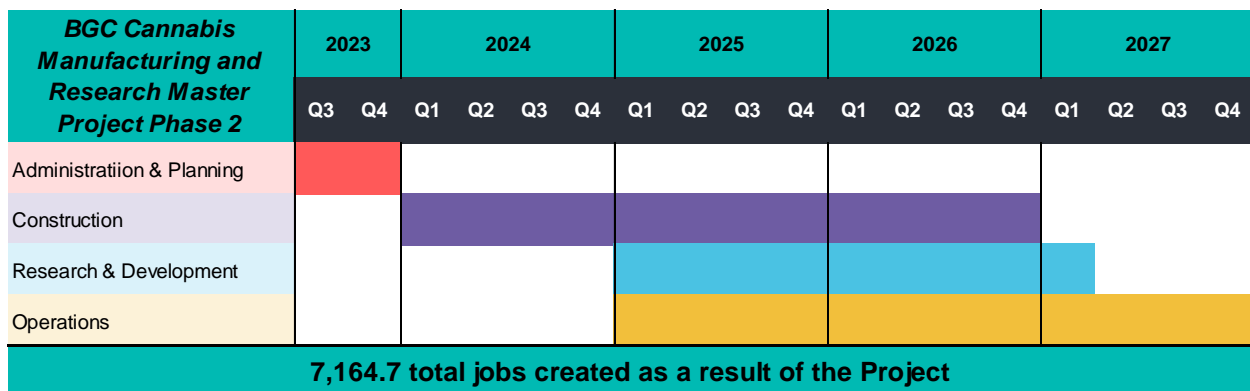
4 Current Status of Development

The following table presents the development timeline within the business plan dated December 2022:



This Addendum provides details of development activities already completed and in-progress at the time of this business plan addendum as well as anticipated changes to the development schedule required in order to complete the Project's development.

Project construction is currently underway having commenced in January 2024 with site work activities. The following chart illustrates the updated Project development timeline:



As can be seen, Project development was pushed back 12 months. This shift was due to delays in the completion of Phase 1 of the Master Project resulting from the NCE/JCE's shift in strategy, which required the Phase 1 facility to be retooled to expand production for all plant-based APIs. This required the separation of growing areas, installation of humidity and temperature capabilities, and creation of new standard operating procedures, as outlined in the New Mexico Regulation and Licensing Department Board of Pharmacy pre-licensing inspection report (Exhibit B).

As of the date of this Addendum, **Phase 1 of the Master Project has been completed** which is evidenced by follow-up inspection notes which show completion of all additional facility requirements (Exhibit B).

Note: The NCE/JCE has received its DEA Registration for the Bulk Manufacturing of Schedule 1 Controlled Substances (DEA Reg. No. RB0649383) on <Date of Receipt>, which was necessary to commence Phase 1 operations (Exhibit C).

The only other update to the development timeline is an extension to the Project's construction timeline, which extends the construction period out to 30 months due to changes in the sourcing of the solar farm components to ensure they are all made in America.

In an article published February 1, 2023 on Nasdaq.com, the New Mexico Governor, Michelle Lujan Grisham, showed her support for the Project by congratulating the NCE/JCE's team on the launch of its EB-5 program as well as going on further to explain that, "Bright Green's plans to develop facilities using only renewable energy further fosters both the State of New Mexico and the Federal view of the benefits of clean air and clean energy". Afterwards she acknowledges that the NCE/JCE adds to the types of companies and their technologies the state looks for to make New Mexico a great place to live and do business (Exhibit D).

The following Project activities have been completed as of March 2024:

- The NCE/JCE and C2 Wellness Corporation executed a term sheet for the proposed sale and purchase of C2 Wellness Corporation assets and technology (Exhibit E).
- Facility site work commenced January 2024
- The Controlled Substance Facility License No. CS02324187 for both Schedule I and II drugs was issued February 14, 2024 (Exhibit F)
- The Controlled Substance Manufacturer License No. WD00012763 was issued February 14, 2024 (Exhibit G)
- The NCE/JCE has submitted DEA registration application W24025292E for the bulk manufacturing of Schedule I and II Controlled Substances (Exhibit H).

On January 25, 2024, the NCE/JCE announced the agreement to purchase assets and technology of C2 Wellness corporation (Exhibit I)

On February 22, 2024, the NCE/JCE announced that final approval has been received from the New Mexico Board of Pharmacy and the DEA for unique licensing that allows the BGC to register, license, and authorize Schedule I and II plant-based drugs and Active Pharmaceutical Ingredients ("API's") for the research, production, and manufacturing purposes (Exhibit J).

The NCE/JCE announced the submission of its DEA registration for the production of Schedule I and Schedule II controlled substances on March 7, 2024 (Exhibit K).

The following are planned milestones required to complete the Project in its entirety:

- <insert permits/licenses/approvals to be obtained and anticipated receipt dates>
- Completion of construction is anticipated in December 2026.
- Commencement of R&D activities are anticipated in January 2025.
- Commencement of operations is anticipated in January 2025.

5 Use of Funds

The following table presents Project costs within the business plan dated December 2022:

Development Cost	
Property Acquisition	2,725,000
Potential Alterola Acquisition	46,000,000
Total Potential Acquisition Costs	\$ 48,725,000
Construction	295,531,719
Water infrastructure improvements	10,473,000
Total Construction Hard Costs	306,004,719
Solar Farm	83,000,000
Total FF&E Costs	83,000,000
Potential Alterola R&D	50,000,000
delivery, transportation, building site, preparation, taxes	20,782,250
Permits	105,320
Total Soft Costs	70,887,570
Working Capital	29,982,711
Total Pre-Opening Costs	29,982,711
TOTAL DEVELOPMENT COST	\$ 538,600,000

The following table summarizes updated Project costs resulting from the NCE/JCE's shift in strategy:

PROJECT DEVELOPMENT COSTS	
Cost Item	Budget
Property Acquisition	\$ 2,725,000
C2 Asset and Technology Acquisition	850,000
Total Acquisition Costs	\$ 3,575,000
Construction	267,822,660
Construction Contingency	27,709,059
Water infrastructure improvements	10,473,000
Total Construction Costs	306,004,719
Solar Farm	83,000,000
Solar Farm Contingency	17,000,000
Total FF&E Costs	100,000,000
Design & Construction Management	32,138,719
C2 Asset Research and Development	50,000,000
Delivery, transportation, building site, preparation, taxes	15,336,000
Permits	105,320
Total Soft Costs	97,580,039
Working Capital	1,457,531
Total Pre-Opening Costs	31,440,242
TOTAL DEVELOPMENT COST	\$ 538,600,000

The main change to development costs resulting from the NCE/JCE's shift in strategy is the removal of the Potential Alterola Acquisition cost and the addition of the C2 Asset and Technology Acquisition cost. Furthermore, the \$50M Potential Alterola R&D has been reallocated to C2 Asset R&D. All other changes to development cost items are a result of updated quotes and contracts caused by Phase 2 Project delays but simply result in a reallocation of funds. As can be seen, the updated development cost total is the same as the original.

Updated costs are based on the following:

Property Acquisition cost has not changed from the original budget.

C2 Asset and Technology Acquisition Cost refers to the cost incurred to acquire assets and technology from C2 Wellness Corporation for a total of 5 million shares of BGC stock, which is currently estimated to be approximately \$850,000 (Exhibit E).

Construction has been updated to reflect the new quote received from Dalsem (Exhibit L). On March 6, 2024, the NCE/JCE announced the execution of the contract with Dalsem to develop the Project facility (Exhibit M).

Construction Contingency is estimated at a rate of approximately 10% of the construction cost. This estimate is reasonable as it falls within the typical contingency rate of 5-10% for most construction projects.

Water infrastructure improvements cost has not changed from the original budget.

Solar Farm cost has not changed from the original budget.

Solar Farm Contingency is a reserve of funds set aside to cover any additional solar farm costs that may exceed the budgeted total.

The NCE/JCE currently has an LOI with Gridworks outlining a solar farm cost of \$60 million (**Exhibit N**); however, the specific scope of services is still being agreed upon and updates to the solar farm estimate are in progress. Continued discussions between the two entities indicate an estimated solar farm cost closer to \$100 million (**Exhibit O**). Therefore, the budgeted solar farm cost is reasonable as it falls within the \$60-\$100 million range. Furthermore, the development budget includes sufficient solar farm contingency to cover the solar farm cost at the \$100 million threshold.

Design & Construction Management cost: Costs have been reallocated to account for design & construction management costs necessary to develop the Project. The total for this cost is based on a proposal provided by Scott C. Anderson & Associates Architects (**Exhibit O**).

C2 Asset Research & Development: With this commitment of funds the NCE/JCE will progress CBD and THC-based molecules through preclinical and clinical development to develop CBD and THC-based medicines for multiple unmet needs with significant addressable market.

Delivery, transportation, building site, preparation, taxes cost has been updated to reflect the new quote received from Dalsem (**Exhibit L**).

Permits cost has not changed from the original budget.

Working Capital has been reduced due to the reallocation of funds to other development costs.

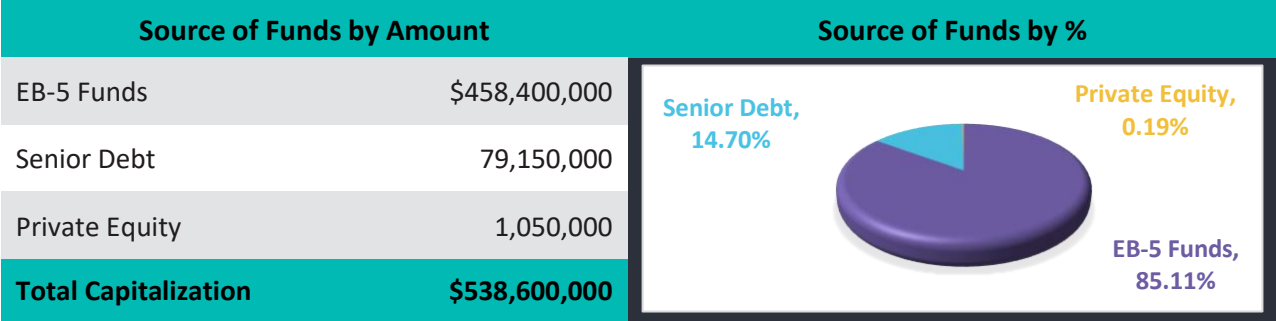
6 Source of Funds

The following table presents the sources of funding as outlined within the business plan dated December 2022:



This addendum provides an update to the Project’s source of funds resulting from the NCE/JCE’s shift in strategy.

The updated sources of funding for the Project are summarized and illustrated as follows:



EB-5 Funds in the amount of \$458.4 million will be provided by 573 EB-5 investors that will be sponsored by the Regional Center, with each investing \$800,000.

Senior Debt: A loan will be obtained as necessary to fully capitalize the Project. With the Project costs of 538.6 million, \$79.2 million is a 14.7% Loan-to-Cost (“LTC”). A credit agreement dated March 6, 2024 between the NCE/JCE and JVR Holdings shows the availability of a \$60,000,000 credit facility (Exhibit Q).

As of February 26, 2024, the NCE/JCE has announced collaboration with its strategic partner, Asia Capital Pioneer Group (“ACPG”), an Asia-based investment firm with global investments within high growth industries. The NCE/JCE will offer up to \$100 million of Convertible Secured Notes, which will be marketed to qualified investors, that will close in 4 tranches

taking security on the existing Phase 1 facility. The first tranche of \$20 million has already been committed as of the date of this Addendum (Exhibit R).

Private Equity Approximately \$5 million in equivalent BGC stock will be paid to C2 Wellness Corporation or its designees as outlined in the executed asset purchase agreement term sheet (Exhibit E). The estimated value of these shares is approximately \$850,000.

In exchange for 9,500 shares of restricted BGC stock, Lynn Stockwell has contributed a 40-acre parcel of land, with an estimated value of \$200,000.

7 Financial Performance

The following table presents the financial projections for the first four years of business operations specific to Phase 2 manufacturing and research facility acreage as outlined in the within the business plan dated December 2022:

Phase 2 Operations - Four Year Financial Projections				
REVENUES	2024	2025	2026	2027
Wholesale Revenue	186,839,730	339,384,128	418,992,750	475,789,545
Retail Revenue	564,864,300	1,089,381,150	1,452,508,200	1,767,218,310
Potential Alterola Profit before taxes	78,000,000	101,400,000	131,820,000	17,166,000
Total Revenue	\$ 829,704,030	\$ 1,530,165,278	\$ 2,003,320,950	\$ 2,260,173,855
EXPENSES				
Cost of Goods Sold				
Plants	12,414,600	12,414,600	12,414,600	12,414,600
Utilities	24,829,200	24,829,200	24,829,200	24,829,200
Distribution Overhead	16,945,929	32,681,435	43,575,246	53,016,549
Labor	14,300,000	39,325,000	64,886,250	71,374,875
Total Cost of Goods Sold	68,489,729	109,250,235	145,705,296	161,635,224
GROSS MARGIN	\$ 761,214,301	\$ 1,420,915,043	\$ 1,857,615,654	\$ 2,098,538,631
Operating Expenses				
Sales & Marketing expense	13,752,899	100,875,005	139,800,720	140,347,961
General & Administrative expense	10,293,100	11,247,410	12,297,151	13,451,866
Total Operating Expenses	24,045,999	112,122,415	152,097,871	153,799,827
EBITDA	\$ 737,168,302	\$ 1,308,792,628	\$ 1,705,517,783	\$ 1,944,738,804

The following table summarizes updated revenue and expense projections for the first four years of business operations specific to Phase 2 greenhouse acreage resulting from the NCE/JCE's shift in strategy:

Phase 2 Operations - Four-Year Financial Projections				
REVENUES	2025	2026	2027	2028
Wholesale Revenue	186,839,730	339,384,128	418,992,750	475,789,545
Retail Revenue	564,864,300	1,089,381,150	1,452,508,200	1,767,218,310
C2 Asset & Technology Revenue			65,910,000	8,583,000
Total Revenue	\$ 751,704,030	\$ 1,428,765,278	\$ 1,937,410,950	\$ 2,251,590,855
EXPENSES				
Cost of Goods Sold				
Plants	12,414,600	12,414,600	12,414,600	12,414,600
Utilities	24,829,200	24,829,200	24,829,200	24,829,200
Distribution Overhead	16,945,929	32,681,435	43,575,246	53,016,549
Labor	14,300,000	39,325,000	64,886,250	71,374,875
Total Cost of Goods Sold	68,489,729	109,250,235	145,705,296	161,635,224
Gross Margin	683,214,301	1,319,515,043	1,791,705,654	2,089,955,631
Operating Expenses				
Sales & Marketing Expense	13,752,899	100,875,005	139,800,720	140,347,961
General & Administrative Expense	10,293,100	11,247,410	12,297,151	13,451,866
Total Operating Expenses	24,045,999	112,122,415	152,097,871	153,799,827
EBITDA	\$ 659,168,302	\$ 1,207,392,628	\$ 1,639,607,783	\$ 1,936,155,804

The following table outlines assumptions made by the NCE in determining anticipated sales revenue:

ASSUMPTIONS	2025	2026	2027	2028
Facility Capacity	57	114	114	114
Plants Harvested for Wholesale	2,482,920	2,482,920	2,482,920	2,482,920
Plants Harvested for Retail	2,482,920	7,448,760	7,448,760	7,448,760
Product Yield (grams/plant)	35	45	60	73
Percentage of Yield for Wholesale Revenue	50%	75%	75%	75%
Percentage of Yield for Retail Revenue	50%	25%	25%	25%
Wholesale Price per gram (\$)	\$4.30	\$4.05	\$3.75	\$3.50
Retail Price per gram (\$)	\$13.00	\$13.00	\$13.00	\$13.00

Updates to revenue and expense projections include the commencement of Project operations being delayed by 12 months and the replacement of Potential Alterola Profit before taxes with C2 Asset & Technology Revenue. This change is a direct result of the NCE/JCE's shift in strategy. As can be seen in the table, all wholesale and retail revenue and assumptions as well as all expense estimations remain unchanged.

C2 Asset & Technology Revenue is derived from the sale of CBD and THC-based pharmaceutical products developed from the research and development of C2 assets and technology acquired as part of the Project’s development.

Note: Deliverables from asset & technology R&D are not expected for 18-24 months; therefore, there is no estimate of C2 Asset & Technology Revenue for 2025 and 2026.

Revenue across all four years is reasonable and conservative in comparison to the calculated 6-year-average annual revenue for the Pharmaceutical & Medicine manufacturing industry across the entire US Sales Class: > \$500m, as reported by Bizminer (Exhibit S):

NAICS 3254 All US	
Year	Average Annual Revenue
2018	\$2,715,067,672
2019	\$3,152,606,911
2020	\$2,512,331,029
2021	\$2,470,240,593
2022	\$2,273,210,681
<u>2023 Q2</u>	<u>\$2,021,265,815</u>
Average	\$2,524,120,450

8 Market Analysis

Market trends have changed from the original business plan. The following sub-sections present updated summaries of trends in the industries in which the JCE is operating, specifically the Other Food Crops Grown Under Cover and Pharmaceutical and Medicine Manufacturing industries.

INDUSTRY ANALYSIS: OTHER FOOD CROPS GROWN UNDER COVER

This market analysis update focuses on the ***Other Food Crops Grown Under Cover (NAICS 111419)*** sub-sector of the *Greenhouse, Nursery, and Floriculture Production (NAICS 1114)* parent industry. Discussions of this industry as they apply to the Project are outlined in the IBISWorld *Industry Report OD4141 Medical and Recreational Marijuana Growing in the US* and the IBISWorld *Industry Report OD3315 Industrial Hemp Production in the US*.

Medical and Recreational Marijuana Growing

The IBISWorld *January 2024 Industry Report OD4141 Medical and Recreational Marijuana Growing in the U.S.* reports the following key trends:

- Increasing legalization benefits growers as more consumers can legally purchase products from dispensaries. However, since marijuana is still illegal at the federal level, growth is limited.
- Recreational marijuana has driven recent growth. In states where the use of both recreational and medical marijuana is legal, demand for recreational marijuana has outpaced medical.

The industry, which includes establishments that grow marijuana for medical and recreational use, flourished over the past five years. Legislative victories over recent years provided that the cannabis industry is one of the fastest-growing industries in the US. Consumer attitudes are also accelerating legalization efforts at the state level. A recent Pew Research Center survey finds that 88.0% of US adults approve of legal access to medical marijuana, while 59.0% approve of full adult use legalization. The growing acceptance of medical marijuana is providing growers and investors with unprecedented opportunities. As a result, industry revenue increased at a CAGR of 20.4% to \$23.8 billion over the five years to 2024, including an increase of 93.7% in 2024 alone.

In 2016 and 2020 elections, many states passed legalization laws. These legislative victories fueled strong growth for industry operations and provided opportunities for growth. The licensing of commercial marijuana growers for recreational purposes in these states drove revenue 39.6% higher in 2020 alone as new entrants flooded the market. Medical marijuana growers have also continued to benefit from the steadily aging population. Chronic illnesses and cancer become more prevalent as individuals age, which drives demand for medical marijuana products. As recreational marijuana continues to be legalized and accepted by different states, profit for industry operators will increase.

Over the five years to 2029, revenue is expected to increase at a CAGR of 15.1% to \$48.2 billion. The future of the industry remains uncertain until the federal government definitively rules to legalize marijuana. Until then, a growing number of medical marijuana patients and the recreational cannabis legalization movement will generate an expanding consumer base for growers. As surrounding nations, including Canada and Mexico, legalize the drug, the US government will likely be pressured to follow suit.

Industrial Hemp Production

The IBISWorld *January 2024 Industry Report OD3315 Industrial Hemp Production in the U.S.* reports the following key trends:

- Hemp legalization led to massive growth. The market for hemp has already been established during trials, so the new industry had minimal growing pains.
- Association with marijuana limits growth. In pushing for legalization, farms and industry groups have educated the public on the difference between hemp and marijuana.

As an almost brand-new industry, industrial hemp production is currently in a period of explosive growth. Industrial hemp, which has become synonymous with the simplified term hemp, is a variety of cannabis with only trace amounts of tetrahydrocannabinol (THC).

With very few exceptions, hemp production was illegal in the US until 2018. The 2018 Farm Bill legalized hemp growing because the hemp growth has a THC content of less than 0.3% by weight. Upon legalization, industrial hemp production boomed as companies rapidly entered the industry to take advantage of the high demand for hemp-based products. Over the five years to 2023, revenue grew at a CAGR of 12.7% to \$253.5 million.

The sudden surge of companies producing hemp has illustrated some potential problems for the industry. Industrial hemp producers must have their crops tested in a Drug Enforcement Agency-approved laboratory before bringing them to market. This has made it difficult and costly for growers to sell their hemp, resulting in relatively subdued profit quickly. Demand for cannabidiol (CBD) and other hemp-based products has been strong, but the industry's rapid expansion has contributed to oversupply and falling hemp prices. With relatively low profits and high regulation, growers struggled significantly during the pandemic. As the outbreak of

COVID-19 disrupted the economy, many companies that were new to the industry were forced to shutter operations. Now that the pandemic has passed, revenue has returned to growth, demonstrated by a 2.2% rise in 2023.

Over the years to 2028, revenue is anticipated to grow steadily despite a highly volatile start to the industry. Following the boom in industrial hemp production over the last five years, companies are likely to settle into a more stable position. Hemp growers expecting to turn a fast profit will eventually leave the industry, allowing hemp prices to begin stabilizing. Over the years to 2028, revenue is expected to grow at a CAGR of 5.3% to \$327.6 million.

INDUSTRY ANALYSIS: PHARMACEUTICAL AND MEDICINE MANUFACTURING

This market analysis update focuses on the **Pharmaceutical and Medicine Manufacturing (NAICS 32541)** sub-sector of the *Pharmaceutical and Medicine Manufacturing (NAICS 3254)* parent industry. Discussions of this industry as they apply to the Project are outlined in the *IBISWorld Industry Report 32541A Brand Name Pharmaceutical Manufacturing in the US*, *IBISWorld Industry Report 32541B Generic Pharmaceutical Manufacturing in the US*, and the *IBISWorld Industry Report 32541D Vitamin Supplement Manufacturing in the US*.

Brand Name Pharmaceutical Manufacturing

The *IBISWorld November 2023 Industry Report 32541A Brand Name Pharmaceutical Manufacturing in the U.S.* reports the following key trends:

- Drug expirations have had the largest effect on industry performance, with some major drugs set to expire in 2023.
- Growth in the US dollar has contributed to rising import penetration, which has increasingly threatened domestic drug manufacturers.
- Oncology, diabetes, and Alzheimer's disease have been the major areas of industry research.

Over the past five years, the Brand Name Pharmaceutical Manufacturing industry has experienced several new drug launches, with over 28 novel drugs approved in 2022. Given increasing price scrutiny, competition from generics, intensifying market competition among brand-name producers, and rising research and development expenses, many manufacturers have shifted their strategic focus to more lucrative therapy areas, such as rare diseases and oncology. Many companies pivoted their pipelines to rare diseases, in which low prescription volumes can be offset by high per-unit costs and benefit from orphan drug exclusivity, which grants longer patent exclusivity in the United States and the European Union. Over the past five years, revenue has grown at a CAGR of 3.1% to \$237.8 billion, including an expected 2.9% increase in 2023 alone. Profit is expected to lag to 7.8% of revenue in 2023 from 7.9% in 2018.

The role of international trade has increased in the past five years due to the development of COVID-19 vaccines. While the COVID-19 vaccine is just one of many products included in this industry, having a relatively small overall effect on the industry domestically, demand for US-manufactured vaccines skyrocketed abroad in 2021. As a result, the share of exports increased to 38.5% of industry revenue in 2021, up from 31.2% in 2020. In addition, an expected decline in the value of the US dollar over the next five years will likely have a positive effect on exports, making US manufactured drugs more attractive abroad.

Over the next five years, patents will expire for major brand names like Revlimid, Keytruda and Eliquis. As some major industry patents expire, drug manufacturers are expected to focus more on niche diseases that have better exclusivity terms and greater profit potential. So many companies are expected to drive sales volumes from biologic drugs, while also raising prices on widely used specialty drugs. Overall, revenue is forecast to grow at a CAGR of 2.0% to \$262.5 billion over the five years to 2028.

Generic Pharmaceutical Manufacturing

The IBISWorld *September 2023 Industry Report 32541B Generic Pharmaceutical Manufacturing in the U.S.* reports the following key trends:

- Generic drug manufacturers have faced intense price competition, which is why many companies have invested in value-added generics and biosimilar drugs.
- Import penetration has been rising, driven mainly by flexible regulatory frameworks and low production costs in India and China.

The Generic Pharmaceutical Manufacturing industry is a globalized industry that manufactures drugs protected initially by patents. Revenue growth depends on patent expirations, FDA approvals of new drug applications, and competition from foreign companies. Over the past five years, revenue has grown at a CAGR of 0.9% to \$53.8 billion, which includes a 14.2% increase in 2023 alone. Unlike brand-name drug manufacturers, companies in this industry have not benefited much from the COVID-19 pandemic. The main challenge for the industry has been to retain prices at acceptable levels. While prices for branded drugs have risen, prices for generic drugs have declined, contributing to a decline in profit.

The industry has also witnessed rising import penetration and a growing focus on biosimilar drugs and value-added generics. Over the past five years, imports' share of domestic demand has increased to 47.9% in 2023, indicating rising competition from foreign markets, primarily from India and China. The inability to set prices at levels sufficient to offset rising costs has led some major companies to divest their generic drug units, which include a spinoff of Pfizer Inc.'s Upjohn business in 2020. Meanwhile, more companies have invested in biosimilar drugs, which have rapidly gained market share, driven by rising demand for biologic drugs. Specialty generics and value-added generics have also become more widespread, driven by their higher return on investment.

Over the next five years, revenue is estimated to grow at a CAGR of 6.0% to \$71.9 billion. The industry will benefit from the expiration of several blockbuster drugs, including Humira, enabling generic drug manufacturers to capture previously unavailable demand for some major drugs. The FDA's initiatives aimed at improving the review process for new drug applications will make it easier to release new products in a timely manner while intensifying price competition. To avoid heavy competition, generic drug manufacturers will increasingly focus on value-added generics and biosimilar drugs.

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Vitamin & Supplement Manufacturing

The IBISWorld *February 2024 Industry Report 32541D Vitamin Supplement Manufacturing in the U.S.* reports the following key trends:

- An aging domestic population bolsters demand for anti-aging antioxidant supplements. Immune-boosting supplements, especially vitamin C, benefit from more people taking preventative care after the pandemic.
- The US-China trade war has an adverse consequence on industry trade volumes. However, trade accounts for a minimal share of industry revenue.

US consumers have been buying vitamins and supplements for decades, but the growing popularity of health and wellness trends have pushed interest in dietary supplements to a record level. Now, more people are turning to supplements to improve things like their mental health, physical appearance, and stamina. The pandemic also reinvigorated the dietary supplement category, as concerned consumers sought vitamins to boost their and their family's immunities. While a combination of easing pandemic anxieties and inflation has slowed spending since, vitamin and supplement manufacturers are still benefiting from the heightened interest in health products. In all, revenue has been expanding at a CAGR of 1.0% to an estimated \$41.2 billion over the past five years, including expected growth of 0.8% in 2024.

A booming health and wellness market has widened the scale and scope of vitamin and supplement production in the US. Big-box retailers like Target and Walmart are introducing more varieties of vitamins and nutritional aids to shelves, with newer markets like beauty stores also offering larger assortments of vitamins than ever before. Social media is partially responsible for driving this interest by exposing new customers to trending health fads or exciting ingredients, although longer-term trends in longevity and overall well-being are also supporting the industry's growth.

The rising interest in vitamins and supplements in recent years won't settle moving forward, but some shifts in the industry's landscape are expected. Consumers will continue becoming more critical of what they buy and put in their bodies, supporting manufacturers that connect with their buyers or offer personalized options. More standard offerings, like from major brands such as Nature's Bounty, will remain a mainstay, especially for a growing number of adults aged 65 and over looking to maintain their health and wellness. In all, industry-wide revenue is forecast to expand at a CAGR of 1.0% over the next five years to total \$45.3 billion.

U.S. Opium and Cannabis API Market

The following section summarizes discussions of the U.S. Opium and Cannabis API market as reported by Coherent Market Insights (Exhibit T).

The following slide provides an overview of the U.S. Opium and Cannabis API Market (Exhibit T):

U.S. OPIUM AND CANNABIS API MARKET

Market

- Market Value (2023): US\$ 4,609.2 Mn
- CAGR, By Value (2023-2030): 12.3%
- Major API Type, By Value: Opium
- Major End User, By Value: Biopharmaceutical Companies

Drivers and Opportunities

DRIVERS

- Growing Demand for Pain Management Medications in the U.S.
- Rising Incidence of Chronic Diseases in the U.S.

OPPORTUNITY

- Rising Demand for Medication-assisted Treatment ("MAT") for Opioid Use Disorder
- Increasing Product Launch and Product Availability by the Key Players

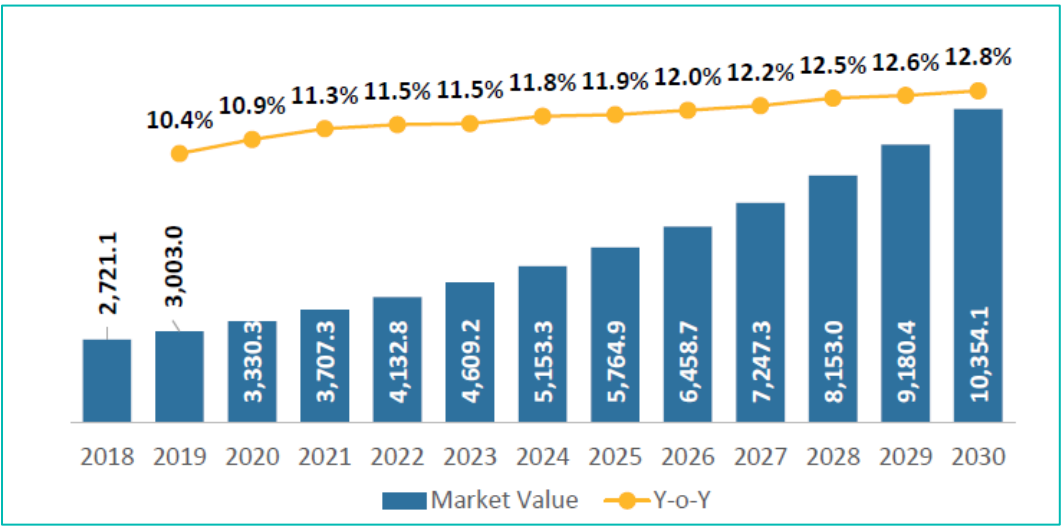
Restraints

RESTRAINT

- Opioid Epidemic and Regulatory Scrutiny
- Quality Control and Manufacturing Challenges for Opium API in the U.S.

Source: CMI Analysis, Primary Research, Secondary Research
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The following chart illustrates historical, current, and future forecasted value for the U.S. Opium and Cannabis API market (Exhibit T):



The following tables provide further breakdown of the current estimated and future forecasted market value of the U.S. Opium and Cannabis API market by API type and end user (Exhibit T):

API TYPE	2023 E	2026 F	2030 F
Opium	2,995.3	4,032.2	6,086.2
Oxycodone	1,164.6	1,578.6	2,405.4
Hydrocodone	840.0	1,132.4	1,712.6
Hydromorphone	274.6	364.0	537.5
Morphine	322.6	429.7	639.1
Codeine	393.5	527.5	791.6
Cannabis	1,613.9	2,426.6	4,267.9
Tetrahydrocannabinol (THC)	841.8	1,272.0	2,252.2
Cannabidiol (CBD)	628.5	942.0	1,649.5
Others	143.6	212.6	366.2

END USER	2023 E	2026 F	2030 F
Biopharmaceutical Companies	3,702.9	5,246.3	8,540.7
Research Institutes	906.3	1,212.4	1,813.4

The following is a P.E.S.T. analysis for the Project as it applies to the U.S. Opium and Cannabis API market (Exhibit T).

Political Factors:

- The U.S. government has implemented various steps to increase the production of controlled substances used in coronavirus (“COVID-19”). For instance, in April 2020, the Drug Enforcement Administration announced that it had increased production quotas available to pharmaceutical manufacturers for the production of controlled substance medications that have huge demand due to the COVID-19 pandemic.
- DEA has issued a final order to increase the 2020 APQ by 15% for certain substances needed for the treatment of COVID-19 including fentanyl, morphine, hydromorphone, codeine, ephedrine, and others.

Economic Factors:

- Opioid overdose, abuse, and dependency impacts demand for opioid API's and prescription medications, and thus, directly affects the cost of healthcare and the expense of the criminal justice system. For instance, according to the data published by The Pew Charitable Trusts, U.S. hospital expenses related to patients who overdosed on opioids total US\$1.94 billion annually. The expenses of criminal justice, larceny, and drug-related crimes are reduced by US\$4-US\$7 for every dollar spent on addiction treatment.

Social Factors:

- The social stigma associated with opioid use may influence patient preferences and healthcare provider prescribing practices. For instance, in January 2022, according to the data published by the National Center for Biotechnology Information, opioid use disorder is heavily stigmatized and legislation regulating the prescribing opioids, treatment delivery methods, and organizational and social norms all contribute to this stigma in the healthcare system and in general society.

Technological Factors:

- Technological innovations in electronic prescribing systems can influence the monitoring and control of opioid prescriptions. For instance, on November 19, 2021, the Drug Enforcement Agency published a notice of proposed rulemaking proposing to permit the transfer of electronic prescriptions for controlled substances in schedules II-V between registered retail pharmacies for initial filling on a onetime basis only.

Competitors

The following outlines Project competitors specific to the U.S. Opium and Cannabis API market, as outlined by Coherent Market Insights (Exhibit T):

Mallinckrodt Pharmaceuticals

Mallinckrodt Pharmaceuticals is a multinational company that comprises several fully owned subsidiaries that develop, manufacture, market, and distribute specialty pharmaceutical products and therapies.

The company operations two reportable segments: Specialty Brands (specialty pharmaceutical brands) and Specialty Generics (niche specialty generic drugs and active pharmaceutical ingredients).

Teva Pharmaceutical Industries Ltd.

Teva Pharmaceutical Industries Ltd. is a multinational pharmaceutical company. The company focuses on developing, manufacturing, distributing, and selling generic medicines, specialty products, and Active Pharmaceutical Ingredients (“API”). The company’s product portfolio includes generic drugs, specialty drugs, therapeutic areas including neurodegenerative conditions and movement disorders, migraines, etc.

Sun Pharmaceutical Industries Ltd.

Sun Pharmaceutical Industries Ltd. is a global generic pharmaceutical company. The company has a wide product portfolio that includes generics, branded generics, specialty, over-the-count (OTC), anti-retrovirals (ARVs), and others. The company offers formulations in various therapeutic areas such as psychiatry, neurology, cardiology, orthopedic, diabetes, gastroenterology, ophthalmology, nephrology, urology, dermatology, gynecology, respiratory, oncology, dental, and nutritionals.

Aspen Holdings

Aspen Holdings is a global specialty and branded pharmaceutical company that improves the health of patients across the world through its high-quality and affordable medicines.

The company has 23 manufacturing units in 15 different countries worldwide. The company focuses on manufacturing and marketing a diverse range of post-patent, branded pharmaceuticals, and domestic brands for both hospital and consumer markets.

Collegium Pharmaceutical

Collegium Pharmaceuticals is a pharmaceutical company focused on delivering medicines for serious medical conditions, currently including moderate-to-severe pain. The company’s product portfolio includes internally developed and more recently acquired products for pain management.

Trulieve

Trulieve is a medical cannabis manufacturing company. The company operates in cultivation, manufacturing, retail, and logistics markets and focuses on cannabis research, technology, and product development.

Cresco Labs

Cresco Labs is a vertically integrated multi-state cannabis operator in the U.S. that cultivates, manufactures, and sells retail and medical cannabis products through Sunnyside, Cresco Labs' national dispensary brand and third-party retail stores. The company operates through one segment that engages in the cultivation, manufacturing, distribution, and sale of cannabis.

Curaleaf

Curaleaf is a holdings company that engages in medical and wellness cannabis operations. The company operates through the Cannabis Operations and Non-Cannabis Operations segments. The Cannabis Operations segment includes the production and sale of cannabis via retail and wholesale channels. The Non-Cannabis Operations segment provides professional services such as lending facilities to medical and adult-use cannabis licensees and others.

Green Thumb Industries

Green Thumb Industries is a company that produces and sells medicinal and recreational cannabis through wholesale and retail channels in the U.S. The company has presence in 15 states and operations 84 cannabis stores under the brand Rise in the U.S. The company offers multiple products under a portfolio of cannabis consumer packaged goods brands including &Shine, Beboe, Dogwalkers, Doctor Solomon's, Good Green, incredible, and RYTHM.

9 Exhibits

Exhibit A – Change to Board of Directors Announcement

Exhibit B – Phase 1 Pre-Licensing Inspection Reports

Exhibit C – DEA Registration

Exhibit D – Launch of the EB-5 Program Announcement

Exhibit E – Executed Term Sheet

Exhibit F – Controlled Substance Facility Application and License

Exhibit G – Controlled Substance Manufacturer Application and License

Exhibit H – Schedule I and II DEA Registration Application

Exhibit I – C2 Asset and Technology Acquisition Announcement

Exhibit J – Final Approval Announcement

Exhibit K – Submission of DEA Registration Application Announcement

Exhibit L – Dalsem Quote

Exhibit M – Dalsem Contract Announcement

Exhibit N – Solar Farm LOI

Exhibit O – Solar Farm Announcement

Exhibit P – Architect Proposal

Exhibit Q – Credit Agreement

Exhibit R – Secured Convertible Note Offering Announcement

Exhibit S – Bizminer 3254 IFP All US

Exhibit T – U.S. Opium and Cannabis API Market Report