

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2021

or

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

For the transition period from _____ to _____

Commission File Number: 000-55136

Skye Bioscience, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction
of incorporation or organization)

45-0692882

(I.R.S. Employer
Identification No.)

11250 El Camino Real, Suite 100, San Diego, CA 92130

(Address of principal executive offices) (Zip Code)

(858) 410-0266

(Registrant's telephone number, including area code)

5910 Pacific Blvd, San Diego, CA 92121

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<u>None</u>	<u>None</u>	<u>None</u>

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
<u>Common Stock, par value \$0.001</u>	<u>SKYE</u>	<u>OTCQB</u>

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 8, 2021, there were 476,108,455 shares of the issuer's \$0.001 par value common stock issued and outstanding.



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FORWARD-LOOKING STATEMENTS

Statements in this Quarterly Report on Form 10-Q that are not descriptions of historical facts are forward-looking statements that are based on management's current expectations and assumptions and are subject to risks and uncertainties. If such risks or uncertainties materialize or such assumptions prove incorrect, our business, operating results, financial condition and stock price could be materially and negatively affected. In some cases, you can identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," "will," "would" or the negative of these terms or other comparable terminology. Factors that could cause actual results to differ materially from those currently anticipated include those set forth in the section below titled "Risk Factors," including, without limitation, risks relating to:

- the results of our research and development activities, including uncertainties relating to the discovery of potential product candidates and the preclinical and clinical testing of our product candidates;
- the early stage of our product candidates presently under development;
- our need for substantial additional funds in order to continue our operations, and the uncertainty of whether we will be able to obtain the funding we need;
- our ability to obtain and, if obtained, maintain regulatory approval of our current product candidates, and any of our other future product candidates, and any related restrictions, limitations, and/or warnings in the label of any approved product candidate;
- our ability to retain or hire key scientific or management personnel;
- our ability to protect our intellectual property rights that are valuable to our business, including patent and other intellectual property rights;
- our dependence on University of Mississippi, third party manufacturers, suppliers, research organizations, testing laboratories and other potential collaborators;
- our ability to develop successful sales and marketing capabilities in the future as needed;
- the size and growth of the potential markets for any of our approved product candidates, and the rate and degree of market acceptance of any of our approved product candidates;
- competition in our industry;
- the duration and impact of the novel coronavirus ("COVID-19") pandemic; and
- regulatory developments in the United States and foreign countries.

We operate in a rapidly changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, such as the COVID-19 outbreak and associated business disruptions including delayed clinical trials and laboratory resources, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. The forward-looking statements included in this report speak only as of the date hereof, and except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this report to conform these statements to actual results or to changes in our expectations.

PART I - FINANCIAL INFORMATION**Item 1. Financial Statements****SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2021 (Unaudited)	December 31, 2020 (Note 2)
ASSETS		
Current assets		
Cash	\$ 11,089,624	\$ 2,469,410
Restricted cash	4,570	4,566
Prepaid expenses and other current assets	321,497	190,409
Prepaid expenses - related party	18,125	—
Total current assets	<u>11,433,816</u>	<u>2,664,385</u>
Property and equipment, net	80,297	7,341
Operating lease right-of-use asset	164,673	—
Other asset	8,309	—
Total assets	<u>\$ 11,687,095</u>	<u>\$ 2,671,726</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 318,982	\$ 364,340
Accounts payable - related party	20,000	17,032
Accrued interest - related party	130,824	44,087
Accrued payroll liabilities	262,881	61,547
PPP loan current	—	64,062
Other current liabilities	497,390	197,564
Derivative liabilities	207,916	38,567
Operating lease liability, current portion	63,581	—
Total current liabilities	<u>1,501,574</u>	<u>787,199</u>
Non-current liabilities		
PPP loan non-current	—	52,638
Multi-draw credit agreement - related party	450,000	450,000
Convertible multi-draw credit agreement - related party, net of discount	1,370,156	931,103
Operating lease liability, net of current portion	100,583	—
Total liabilities	<u>3,422,313</u>	<u>2,220,940</u>

Commitments and contingencies (Note 9)**Stockholders' equity**

Preferred stock, \$0.001 par value; 50,000,000 and 20,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 5,000,000,000 and 500,000,000 shares authorized at September 30, 2021 and December 31, 2020, respectively; 476,108,455 and 288,074,415 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	476,108	288,074
Additional paid-in-capital	52,532,017	38,896,693
Accumulated deficit	(44,743,343)	(38,733,981)
Total stockholders' equity	<u>8,264,782</u>	<u>450,786</u>
Total liabilities and stockholders' equity	<u>\$ 11,687,095</u>	<u>\$ 2,671,726</u>

See accompanying notes to the condensed consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	\$ 327,731	\$ 346,217	\$ 1,818,059	\$ 1,574,357
General and administrative	1,491,378	1,192,003	3,567,985	3,395,729
Total operating expenses	<u>1,819,109</u>	<u>1,538,220</u>	<u>5,386,044</u>	<u>4,970,086</u>
Operating loss	<u>(1,819,109)</u>	<u>(1,538,220)</u>	<u>(5,386,044)</u>	<u>(4,970,086)</u>
Other expense (income)				
Change in fair value of derivative liabilities	(189,649)	(424,138)	169,349	(433,688)
Interest expense	195,358	182,614	570,322	520,594
Gain on forgiveness of PPP loan	—	—	(117,953)	—
Total other expense, net	<u>5,709</u>	<u>(241,524)</u>	<u>621,718</u>	<u>86,906</u>
Loss before income taxes	<u>(1,824,818)</u>	<u>(1,296,696)</u>	<u>(6,007,762)</u>	<u>(5,056,992)</u>
Provision for income taxes	—	—	1,600	1,600
Net loss and comprehensive loss	<u>\$ (1,824,818)</u>	<u>\$ (1,296,696)</u>	<u>\$ (6,009,362)</u>	<u>\$ (5,058,592)</u>
Loss per common share:				
Basic	\$ —	\$ (0.01)	\$ (0.02)	\$ (0.02)
Diluted	\$ —	\$ (0.01)	\$ (0.02)	\$ (0.03)
Weighted average shares of common stock outstanding used to compute earnings per share:				
Basic	413,489,603	256,758,472	376,547,498	207,536,173
Diluted	<u>414,461,032</u>	<u>257,255,653</u>	<u>376,547,498</u>	<u>208,434,966</u>

See accompanying notes to the condensed consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)

	For the Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (6,009,362)	\$ (5,058,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,412	1,096
Stock-based compensation expense	747,252	241,216
Change in fair value of derivative liabilities	169,349	(433,688)
Amortization of debt discount	439,053	402,624
Gain on forgiveness of PPP loan	(117,953)	—
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(131,088)	40,686
Prepaid expenses - related party	(18,125)	—
Other asset	(8,309)	—
Accounts payable	(72,719)	601,823
Accounts payable - related parties	2,968	11,400
Accrued interest - related party	86,737	81,813
Accrued payroll liabilities	201,334	—
Other current liabilities	201,861	(156,576)
Operating lease liability	(6,442)	—
Net cash used in operating activities	(4,506,032)	(4,268,198)
Cash flows from investing activities:		
Purchase of property and equipment	(36,828)	—
Net cash used in investing activities	(36,828)	—
Cash flows from financing activities:		
Proceeds from multi-draw credit agreement – related party, net of \$0 and \$9,301 issuance costs for the September 30, 2021 and September 30, 2020 periods, respectively	—	450,000
Proceeds from PPP loan	—	116,700
Proceeds from the sale of common stock and warrants – net of \$851,538 and \$854,078 issuance costs for the September 30, 2021 and September 30, 2020 periods, respectively	6,146,496	6,085,589
Proceeds from common stock warrant exercises	6,999,999	—
Proceeds from pre-funded warrant exercises	11,800	10,533
Proceeds from stock option exercises	4,783	—
Net cash provided by financing activities	13,163,078	6,662,822
Net increase in cash and restricted cash	8,620,218	2,394,624
Cash and restricted cash, beginning of period	\$ 2,473,976	\$ 1,834,515
Cash and restricted cash, end of period	\$ 11,094,194	\$ 4,229,139

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Supplemental disclosures of cash-flow information:

Reconciliation of cash and restricted cash:

Cash	\$	11,089,624	\$	4,224,601
Restricted cash		4,570		4,538
Total cash and restricted cash shown in the consolidated statements of cash flows	\$	11,094,194	\$	4,229,139

Cash paid during the period for:

Interest	\$	44,087	\$	35,645
Income taxes		1,600		1,600

Supplemental disclosures of non-cash financing activities:

Purchases of property and equipment in other current liabilities	\$	39,607	\$	—
Establishment of right-of-use asset		170,606		—
Accrued stock issuance costs - September 2021 Financing		83,722		—
Reclassification of warrant liabilities to equity from exercise of warrants		—		26,563

See accompanying notes to the condensed consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(UNAUDITED)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amounts			
Balance, January 1, 2020	<u>182,895,247</u>	<u>\$ 182,895</u>	<u>\$ 32,538,445</u>	<u>\$ (32,173,282)</u>	<u>\$ 548,058</u>
Stock-based compensation expense	—	—	64,142	—	64,142
Series B warrant exercises	312,500	313	26,250	—	26,563
Net loss for the three months ended March 31, 2020	—	—	—	(2,341,660)	(2,341,660)
Balance, March 31, 2020	<u>183,207,747</u>	<u>\$ 183,208</u>	<u>\$ 32,628,837</u>	<u>\$ (34,514,942)</u>	<u>\$ (1,702,897)</u>
Stock-based compensation expense	—	—	28,709	—	28,709
Net loss for the three months ended June 30, 2020	—	—	—	(1,420,236)	(1,420,236)
Balance, June 30, 2020	<u>183,207,747</u>	<u>\$ 183,208</u>	<u>\$ 32,657,546</u>	<u>\$ (35,935,178)</u>	<u>\$ (3,094,424)</u>
Stock-based compensation expense	—	—	148,365	—	148,365
Common stock and warrants issued	56,333,334	56,333	6,029,256	—	6,085,589
Exercise of pre-funded warrants	10,533,334	10,533	—	—	10,533
Net loss for the three months ended September 30, 2020	—	—	—	(1,296,696)	(1,296,696)
Balance, September 30, 2020	<u>250,074,415</u>	<u>\$ 250,074</u>	<u>\$ 38,835,167</u>	<u>\$ (37,231,874)</u>	<u>\$ 1,853,367</u>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amounts			
Balance, January 1, 2021	288,074,415	\$ 288,074	\$ 38,896,693	\$ (38,733,981)	\$ 450,786
Stock-based compensation expense	600,000	600	145,980	—	146,580
Exercise of common stock warrants	67,166,667	67,167	3,962,833	—	4,030,000
Exercise of pre-funded warrants	11,800,000	11,800	—	—	11,800
Net loss for the three months ended March 31, 2021	—	—	—	(2,160,517)	(2,160,517)
Balance, March 31, 2021	367,641,082	\$ 367,641	\$ 43,005,506	\$ (40,894,498)	\$ 2,478,649
Stock-based compensation expense	—	—	111,699	—	111,699
Exercise of common stock options	106,250	107	4,676	—	4,783
Exercise of common stock warrants	28,333,334	28,333	1,671,667	—	1,700,000
Net loss for the three months ended June 30, 2021	—	—	—	(2,024,027)	(2,024,027)
Balance, June 30, 2021	396,080,666	\$ 396,081	\$ 44,793,548	\$ (42,918,525)	\$ 2,271,104
Stock-based compensation expense	750,000	750	484,973	—	485,723
Common stock and warrants issued	58,111,112	58,111	6,004,663	—	6,062,774
Exercise of common stock warrants	21,166,667	21,166	1,248,833	—	1,269,999
Net loss for the three months ended September 30, 2021	—	—	—	(1,824,818)	(1,824,818)
Balance, September 30, 2021	476,108,445	\$ 476,108	\$ 52,532,017	\$ (44,743,343)	\$ 8,264,782

See accompanying notes to the condensed consolidated financial statements.

SKYE BIOSCIENCE, INC. AND SUBSIDIARIES
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

1. Nature of Operations and Business Activities

Nature of Operations

Skye Bioscience, Inc. (the “Company”) was initially incorporated in Nevada on March 16, 2011 as Load Guard Logistics, Inc. On October 31, 2014, the Company closed a reverse merger transaction (the “Merger”) pursuant to which Nemus, a California corporation (“Nemus Sub”), became the Company’s wholly owned subsidiary, and the Company assumed the operations of Nemus Sub. Nemus Sub was incorporated in the State of California on July 17, 2012. On November 3, 2014, the Company changed its name to Nemus Bioscience, Inc. by merging with Nemus Sub to form a Nevada company.

Effective March 25, 2019, the Company changed its name from Nemus Bioscience, Inc. to Emerald Bioscience, Inc. Effective January 19, 2021, the Company changed its name from Emerald Bioscience, Inc. to Skye Bioscience, Inc.

In August 2019, the Company formed a new subsidiary in Australia, SKYE Bioscience Pty Ltd. (formerly “EMBI Australia Pty Ltd.”), an Australian proprietary limited company (“SKYE Bioscience Australia”), in order to qualify for the Australian government’s research and development tax credit for research and development dollars spent in Australia. The primary purpose of SKYE Bioscience Australia is to conduct clinical trials for the Company’s product candidates.

The Company is a biopharmaceutical company located in San Diego, California that researches and develops and plans to commercialize therapeutics derived from cannabinoids through its own directed research efforts and through several license agreements with the University of Mississippi (“UM”). UM is federally permitted and licensed to cultivate cannabis for research purposes in the United States.

As of September 30, 2021, the Company has devoted substantially all its efforts to securing product licenses, carrying out its own research and development, building infrastructure and raising capital. The Company has not yet realized revenue from its planned principal operations and is a number of years away from potentially being able to do so.

Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows from operations since inception and as of September 30, 2021, had an accumulated deficit of \$44,743,343. As of September 30, 2021, the Company had unrestricted cash in the amount of \$11,089,624. The Company expects to continue to incur significant losses through 2022 and expects to incur significant losses and negative cash flows from operations in the future.

The Company’s continued existence is dependent on its ability to raise sufficient additional funding to cover operating expenses and to carry out its research and development activities. As the Company approaches its first clinical trial, it expects to ramp up research and development spending and to increase cash used in operating activities. However, based on the Company’s expected cash requirements, without obtaining additional funding by September 2022, management believes that the Company will not have enough funds to continue clinical studies and pay down its related party debt. These conditions give rise to substantial doubt as to the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued.

On October 5, 2018, the Company entered into a Multi-Draw Credit Agreement (the “Credit Agreement”) with Emerald Health Sciences (“Sciences”), a related party (Note 8). On April 29, 2020, the Company entered into an Amended and Restated Multi-Draw Credit Agreement (the “Amended Credit Agreement”) with Sciences. As of September 30, 2021, the Company had an outstanding principal balance of \$2,464,500 under the Amended Credit Agreement. Effective September 15, 2021, the disbursement line under the Amended Credit Agreement was closed and it no longer serves as a potential source of liquidity to the Company. The outstanding advances plus accrued interest under the Amended Credit Agreement are due on October 5, 2022 (See Note 4).

On April 22, 2020, the Company entered into a Paycheck Protection Program Promissory Note in the principal amount of \$116,700 (the “PPP Loan”) from City National Bank (the “PPP Loan Lender”). The PPP Loan was obtained pursuant to the Paycheck Protection Program (the “PPP”) of the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) administered by the U.S. Small Business Administration (“SBA”). During the nine months ended September 30, 2021, the full amount of principal and accrued interest was forgiven and the Company realized a gain of \$117,953 (Note 4).

During the nine months ended September 30, 2021, the Company received proceeds of \$7,011,799 from the exercise of warrants (Note 5).

On September 29, 2021, the Company closed the September 2021 Financing (Note 5), pursuant to which the Company sold 58,111,112 shares of common stock, 19,666,667 pre-funded warrants and 77,777,779 common stock warrants in a registered public offering. The net proceeds from the transaction were \$6,062,774. The common stock warrants and pre-funded warrants have an exercise price of \$0.09 and \$0.0001, respectively. The term of the common stock warrants is five years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full. The Company intends to use the net proceeds of the offering for general corporate purposes, including working capital and the repayment of the Amended Credit Agreement, if necessary.

The Company plans to continue to pursue funding through public equity financings, licensing arrangements, government grants or other strategic arrangements. However, the Company cannot provide any assurances that such additional funds will be available on reasonable terms, or at all. If the Company raises additional funds by issuing equity securities, dilution to existing stockholders would result.

In December 2019, a novel strain of coronavirus (“COVID-19”) emerged in Wuhan, China. Since then, it has spread to the United States and infections have been reported around the world. On March 11, 2020, the World Health Organization declared the outbreak of COVID-19 as a global pandemic, which continues to spread around the world and throughout the United States and Australia, where the Company has operations and conducts laboratory research and clinical studies. In response to the outbreak, federal and state authorities in the United States have introduced various recommendations and measures to try to limit the pandemic, including travel restrictions, border closures, nonessential business closures, quarantines, self-isolations, shelters-in-place and social distancing. The COVID-19 outbreak and the response of governmental authorities to try to limit it are having a significant impact on the private sector and individuals, including unprecedented business, employment and significant economic disruptions to the global financial markets. These disruptions could impact the Company’s ability to raise additional capital and obtain the necessary funds.

Notably, the Company relies on third party manufacturers to produce its product candidates. The manufacturing of THC-VHS is conducted in the United States. Formulation of the eye drop for testing is also performed in the United States but can rely on regulatory-accepted excipients that can be sourced from countries outside the United States. In connection with the COVID-19 pandemic, there could possibly be an impact on sourcing materials that are part of the eye drop formulation, as well as impacting volunteer and/or patient recruitment in Australia for clinical studies. The location of the clinical trial are clinical sites in Australia and since the COVID-19 outbreak in that country, the multiple cities have experienced health emergency lockdowns which have had a negative impact on the conduct and timelines of clinical studies. Therefore, the Company has shifted its first-in-human studies of THC-VHS to the second quarter of 2022.

After considering the plans to alleviate substantial doubt, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. The accompanying Condensed Consolidated Financial Statements do not include any adjustments that might result from the outcome of this uncertainty.

2. Summary of Significant Accounting Policies

Basis of Presentation

In the opinion of management, the accompanying Unaudited Condensed Consolidated Financial Statements have been prepared on a consistent basis with the Company’s Audited Consolidated Financial Statements as of and for the year ended December 31, 2020, and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth herein. The Condensed Consolidated Financial Statements have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) and therefore, omit certain information and footnote disclosures necessary to present the financial statements in accordance with generally accepted accounting principles in the United States (“GAAP”).

The results of operations for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or any future periods. The Condensed Consolidated Balance Sheet as of December 31, 2020 was derived from the Company’s audited financial statements as of December 31, 2020, which are included in the Company’s Annual Report on Form 10-K filed with the SEC on March 1, 2021. The unaudited financial statements included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited consolidated financial

statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which includes a broader discussion of the Company's business and the risks inherent therein.

Use of Estimates

The preparation of the Condensed Consolidated Financial Statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Condensed Consolidated Financial Statements and the reported amounts of income and expense during the reporting period. Actual results could differ from those estimates. The most significant accounting estimates inherent in the preparation of the Company's financial statements include estimates and judgements as to the appropriate carrying values of equity instruments, derivative liabilities, debt with embedded features, and the valuation of stock based compensation awards, which are not readily apparent from other sources.

Risks and Uncertainties

The Company's operations are subject to a number of risks and uncertainties, including but not limited to, changes in the general economy, the size and growth of the potential markets for any of the Company's product candidates, uncertainties related to the impact of COVID-19 (Note 1), results of research and development activities, uncertainties surrounding regulatory developments in the United States and Australia, and the Company's ability to attract new funding.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (the "exit price") in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. A fair value hierarchy based on three levels of inputs, of which the first two are considered observable, and the last is considered unobservable, is used to measure fair value:

- Level 1: Valuations for assets and liabilities traded in active markets from readily available pricing sources such as quoted prices in active markets for identical assets or liabilities.
- Level 2: Observable inputs (other than Level 1 quoted prices) such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3: Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of the Company's financial instruments, with the exception of the Amended Credit Agreement and derivative liabilities, including, cash, prepaid expenses, accounts payable and other current liabilities approximate their fair value due to the short maturities of these financial instruments. The derivative liabilities are valued on a recurring basis utilizing Level 3 inputs (Note 3).

As of December 31, 2020, the Company estimated that the fair value of the Amended Credit Agreement was materially consistent with the fair value estimate as of December 31, 2019 of \$1,877,938, plus the non-convertible advances made in 2020. This determination was based on the following considerations: (i) the Company has not experienced any significant change in its credit worthiness or operations year over year, (ii) there have been no repayments or convertible draws, (iii) the facility is closer to maturity, and (iv) the embedded conversion feature on the convertible advances is out-of-the-money at the reporting date. As of September 30, 2021, the Company estimated that the fair value of the Amended Credit Agreement, including the non-convertible advances was \$2,501,632. Information pertinent to estimating the fair value of the Amended Credit Agreement includes valuing the embedded conversion feature using Level 3 inputs and considering the discounted cash flows of the interest and principal payments through maturity (Note 4).

Convertible Instruments

The Company accounts for hybrid contracts with embedded conversion features in accordance with ASC 815, *Derivatives and Hedging Activities* ("ASC 815") which requires companies to bifurcate conversion options from their host instruments and

account for them as free-standing derivative financial instruments according to certain criteria. The criteria includes circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument.

The Company accounts for convertible debt instruments with embedded conversion features in accordance with ASC 470-20, *Debt with Conversion and Other Options* (“ASC 470-20”) if it is determined that the conversion feature should not be bifurcated from their host instruments. Under ASC 470-20, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the difference between the fair value of the underlying common stock at the commitment date and the embedded effective conversion price. When the Company determines that the embedded conversion option should be bifurcated from its host instrument, the embedded feature is accounted for in accordance with ASC 815. Under ASC 815, a portion of the proceeds received upon the issuance of the hybrid contract is allocated to the fair value of the derivative. The derivative is subsequently recorded at fair value at each reporting date based on current fair value, with the changes in fair value reported in the results of operations.

The Company also follows ASC 480-10, *Distinguishing Liabilities from Equity* (“ASC 480-10”) when evaluating the accounting for its hybrid instruments. A financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability (or an asset in some circumstances) if, at inception, the monetary value of the obligation is based solely or predominantly on any one of the following: (a) a fixed monetary amount known at inception (for example, a payable settled with a variable number of the issuer’s equity shares); (b) variations in something other than the fair value of the issuer’s equity shares (for example, a financial instrument indexed to the Standard and Poor’s S&P 500 Index and settled with a variable number of the issuer’s equity shares); or (c) variations inversely related to changes in the fair value of the issuer’s equity shares (for example, a written put option that could be net share settled). Hybrid instruments meeting these criteria are not further evaluated for any embedded derivatives and are carried as a liability at fair value at each balance sheet date with a re-measurement reported in other expense (income), net in the accompanying Condensed Consolidated Statements of Comprehensive Loss.

When determining the short-term vs. long-term classification of derivative liabilities, the Company first evaluates the instruments’ exercise provisions. Generally, if a derivative is a liability and exercisable within one year, it will be classified as short-term. However, because of the unique provisions and circumstances that may impact the accounting for derivative instruments, the Company carefully evaluates all factors that could potentially restrict the instrument from being exercised or create a situation where exercise would be considered remote. The Company re-evaluates its derivative liabilities at each reporting period end and makes updates for any changes in facts and circumstances that may impact classification.

Warrants Issued in Connection with Financings

The Company generally accounts for warrants issued in connection with debt and equity financings as a component of equity, unless the warrants include a conditional obligation to issue a variable number of shares or there is a deemed possibility that the Company may need to settle the warrants in cash. For warrants issued with a conditional obligation to issue a variable number of shares or the deemed possibility of a cash settlement, the Company records the fair value of the warrants as a liability at each balance sheet date and records changes in fair value in other expense (income), net in the Condensed Consolidated Statements of Comprehensive Loss.

Debt Issuance Costs and Interest

Discounts related to bifurcated derivatives, freestanding instruments issued in bundled transactions, and issuance costs are recorded as a reduction to the carrying value of the debt and amortized over the life of the debt using the effective interest method. The Company makes changes to the effective interest rate, as necessary, on a prospective basis. For debt facilities that provide for multiple advances, the Company initially defers any issuance costs until the first advance is made and then amortizes the costs over the life of the facility.

Research and Development Expenses and Licensed Technology

Research and development costs are expensed when incurred. These costs may consist of external research and development expenses incurred under agreements with third party contract research organizations and investigative sites, third party manufacturing organizations and consultants; license fees; employee-related expenses, which include salaries and benefits for

the personnel involved in the Company’s preclinical and clinical drug development activities; facilities expense, and other expenses; and equipment and laboratory supplies. Costs incurred for the rights to use licensed technologies in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred in situations where the Company has not identified an alternative future use for the acquired rights, and are capitalized in situations where there is an identified alternative future use. No cost associated with the use of licensed technologies has been capitalized to date.

Stock-Based Compensation Expense

Stock-based compensation expense is estimated at the grant date based on the fair value of the award, and the fair value is recognized as expense ratably over the vesting period with forfeitures accounted for as they occur. The Company uses the Black Scholes valuation method for estimating the grant date fair value of stock options using the following assumptions:

- Volatility - Expected volatility is estimated using the historical stock price performance over the expected term of the award.
- Expected term - The expected term is based on a simplified method which defines the life as the weighted average of the contractual term of the options and the vesting period for each award.
- Risk-free rate - The risk-free interest rate for the expected term of the option is based on the average market rate on U.S. Treasury securities in effect during the period in which the awards were granted.
- Dividends - The dividend yield assumption is based on the Company’s history and expectation of paying no dividends in the foreseeable future.

Loss Per Common Share

The Company applies ASC No. 260, *Earnings per Share* in calculating its basic and diluted loss per common share. Basic loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of shares of common stock outstanding for the period. The diluted loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, restricted stock subject to vesting, warrants to purchase common stock and common shares underlying convertible debt instruments are considered to be common stock equivalents.

The computations of basic and diluted net loss per common share are as follows:

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2021	2020	2021	2020
Basic net loss per share:				
Net loss	\$ (1,824,818)	\$ (1,296,696)	\$ (6,009,362)	\$ (5,058,592)
Weighted average common shares outstanding – basic	413,489,603	256,758,472	376,547,498	207,536,173
Net loss per share - basic	\$ —	\$ (0.01)	\$ (0.02)	\$ (0.02)
Diluted net loss per share:				
Net loss (as adjusted)	\$ (1,704,980)	\$ (1,720,835)	\$ (6,009,362)	\$ (5,401,484)
Weighted average common shares outstanding – diluted	414,461,032	257,255,653	376,547,498	208,434,966
Net loss per share - diluted	\$ —	\$ (0.01)	\$ (0.02)	\$ (0.03)

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been anti-dilutive:

	Three Months Ended September 30, (Unaudited)		Nine Months Ended September 30, (Unaudited)	
	2021	2020	2021	2020
Stock options	23,490,000	25,000,678	23,490,000	25,000,678
Common shares underlying convertible debt	5,303,591	5,215,457	5,303,591	5,215,457
Warrants	133,945,796	145,336,155	134,917,225	22,304,750

Leases

In February 2016, the FASB issued Accounting Standards Update, or ASU, No. 2016-02, *Leases* (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019.

At the inception of an arrangement, the Company determines whether the arrangement is, or contains, a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contract is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the Condensed Consolidated Balance Sheets as operating lease right-of-use assets, operating lease liability, current portion and operating lease liability, net of current portion.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options* (Subtopic 470-20) and *Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*. This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in fiscal periods ending after December 15, 2020. Upon implementation, the Company may use either a modified retrospective or full retrospective method of adoption. The adoption of ASU 2020-06 will impact the way the Company calculates its loss per common share, result in expanded disclosures around convertible instruments and remove the requirement to assess and record beneficial conversion features. The impact from adoption will depend on whether the Company elects to early adopt this ASU. The Company currently plans to adopt the provisions of this ASU on the effective date. However, it reserves the right to early adopt these provisions.

Recently Adopted Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share* (Topic 260), *Debt—Modifications and Extinguishments* (Subtopic 470-50), *Compensation—Stock Compensation* (Topic 718), and *Derivatives and Hedging—Contracts in Entity's Own Equity* (Subtopic 815-40): *Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. The aim of ASU 2021-04 is to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after modification or exchange. The Company has elected to early adopt this guidance as of July 1, 2021 and has applied the guidance as of January 1, 2021, in accordance with the ASU. The adoption of this guidance had no impact on the interim periods in 2021 prior to the date of adoption. Upon implementation, the new guidance was applied to the July 2021 Inducement (Note 5), which resulted in recording the value attributable to the Inducement Warrants as an equity issuance cost. Because this amendment provided clarification where there was a lack of GAAP, management has determined that there was no resulting impact from the adoption of this standard to the financial statements.

3. Warrants and Derivative Liabilities

There are significant judgements and estimates inherent in the determination of the fair value of the Company's warrants and derivative liabilities. These judgements and estimates include assumptions regarding the Company's future operating performance, the time to completing a liquidity event, if applicable, and the determination of the appropriate valuation methods.

If the Company had made different assumptions, the fair value of the warrants and derivative liabilities could have been significantly different (See Note 2).

Warrants

Warrants vested and outstanding as of September 30, 2021 are summarized as follows:

Source	Exercise Price	Term (Years)	Number of Warrants Vested and Outstanding
Pre 2015 Common Stock Warrants	\$ 1.00	10	1,110,000
2015 Common Stock Warrants	5.00	10	100,000
2016 Common Stock Warrants to Service Providers	1.15	10	40,000
2016 Series C Common Stock Warrants to Placement Agent	0.40	5	125,000
2017 Series D Common Stock Warrants to Placement Agent	0.25	5	480,000
2017 Common Stock Warrants to Service Provider	0.41	5	125,000
2018 Emerald Financing Warrants	0.10	5	3,400,000
Emerald Multi-Draw Credit Agreement Warrants	0.50	5	7,500,000
2019 Common Stock Warrants	0.35	5	8,000,000
2020 Common Stock Warrants to Placement Agent	0.08	4.99	8,166,667
2021 Inducement Warrants	0.15	5	21,166,667
2021 Inducement Warrants to Placement Agent	0.19	5	1,481,667
2021 Common Stock Warrants	0.09	5	77,777,779
2021 Pre-Funded Warrants	—	Indefinite	19,666,667
2021 Common Stock Warrants to Placement Agent	0.11	5	5,444,445
Total warrants vested and outstanding as of September 30, 2021			154,583,892

July 2021 Inducement Warrants and September 2021 Financing Warrants

In connection with the July 2021 Inducement (Note 5), the Company issued 21,166,667 common stock warrants and 1,481,667 warrants to the placement agent. The warrants were equity classified at issuance and the Company recorded the fair value of the common stock warrants and placement agent warrants of \$2,790,884 and \$192,224, respectively, as equity issuance costs related to the September 2021 Financing within equity. The warrants were vested at issuance and were valued utilizing the Black-Scholes Merton option pricing model with the following assumptions:

	Common Stock Warrants	Placement Agent Warrants
Dividend yield	0.00 %	0.00 %
Volatility factor	137.87 %	137.87 %
Risk-free interest rate	0.73 %	0.73 %
Expected term (years)	5	5
Underlying common stock price	\$ 0.15	\$ 0.15

In connection with the September 2021 Financing (Note 5), the Company issued 77,777,779 common stock warrants, 19,666,667 pre-funded warrants, and 5,444,445 common stock warrants to the placement agent. The warrants were equity classified at issuance and the Company allocated \$3,265,676 and \$943,489 of the gross proceeds to the common stock warrants and pre-funded warrants on a relative fair value basis, respectively. The common stock warrants issued to the placement agent were valued at \$421,522 and recorded as equity issuance costs within equity. The warrants vested immediately and were valued utilizing the Black-Scholes Merton option pricing model with the following assumptions:

	Common Stock Warrants	Pre-funded Warrants	Placement Agent Warrants
Dividend yield	0.00 %	0.00 %	0.00 %
Volatility factor	136.02 %	135.06 %	136.02 %
Risk-free interest rate	1.01 %	1.55 %	1.01 %
Expected term (years)	5	10	5
Underlying common stock price	\$ 0.09	\$ 0.09	\$ 0.09

Derivative Liabilities

The following tables summarize the activity of derivative liabilities for the periods indicated:

	Nine Months Ended September 30, 2021				
	December 31, 2020 Fair Value of Derivative Liabilities	Fair Value of Derivative Liabilities Issued	Change in Fair Value of Derivative Liabilities	Reclassification of Derivatives to Equity	September 30, 2021 Fair Value of Derivative Liabilities
Emerald Financing - warrant liability ⁽¹⁾	\$ 38,567	\$ —	\$ 169,349	\$ —	\$ 207,916
Current balance of derivative liabilities	\$ 38,567	\$ —	\$ 169,349	\$ —	\$ 207,916

	Nine Months Ended September 30, 2020				
	December 31, 2019 Fair Value of Derivative Liabilities	Fair Value of Derivative Liabilities Issued	Change in Fair Value of Derivative Liabilities	Reclassification of Derivatives to Equity	September 30, 2020 Fair Value of Derivative Liabilities
Emerald Multi Draw Credit Agreement - compound derivative liability ⁽²⁾	\$ 90,797	\$ —	\$ (90,797)	\$ —	\$ —
Emerald Financing - warrant liability ⁽¹⁾	276,024	—	(234,875)	—	41,149
Series B - warrant liability ⁽³⁾	134,579	—	(108,016)	(26,563)	—
Total derivative liabilities	\$ 501,400	\$ —	\$ (433,688)	\$ (26,563)	\$ 41,149
Less, noncurrent portion of derivative liabilities	(90,797)	—	—	—	—
Current balance of derivative liabilities	\$ 410,603	\$ —	\$ —	\$ —	\$ 41,149

Emerald Financing Warrant Liability (1)

In connection with the August 2020 Financing, the exercise price of the warrants was permanently set to \$0.10. The warrants contain a contingent put option if the Company undergoes a subsequent financing that results in a change in control. The warrant holder also has the right to participate in subsequent financing transactions on an as-if converted basis.

The Company reviewed the warrants for liability or equity classification under the guidance of ASC 480-10, *Distinguishing Liabilities from Equity*, and concluded that the warrants should be classified as a liability and re-measured to fair value at the end of each reporting period. The Company also reviewed the warrants under ASC 815, *Derivatives and Hedging/Contracts in Entity's Own Equity*, and determined that the warrants also meet the definition of a derivative. With the assistance of a third party valuation specialist, the Company valued the warrant liabilities utilizing the Monte Carlo valuation method pursuant to the accounting guidance of ASC 820-10, *Fair Value Measurements*. Beginning March 31 2021, the Company changed its valuation approach for the Emerald Financing Warrant Liability to a Black Scholes valuation method, as it was determined that a more simplistic model such as the Black Scholes valuation method yields a substantially similar result as a Monte Carlo simulation due to the Company's current assumptions.

The warrant liability is valued at the balance sheet dates using the following assumptions:

	September 30, 2021	December 31, 2020
Dividend yield	0.00%	0.00%
Volatility factor	134.8%	90.9%
Risk-free interest rate	0.16%	0.14%
Expected term (years)	1.38	2.13
Underlying common stock price	\$ 0.11	\$ 0.04

Emerald Multi-Draw Credit Agreement Compound Derivative Liability (2)

On April 29, 2020, the Company entered into the Amended Credit Agreement which removed the change in control provision as an event of default for advances before and after the amendment. As a result of the modification, the contingent interest feature component of the compound derivative is no longer required to be bifurcated as a derivative liability.

Series B Warrant Liability (3)

During the nine months ended September 30, 2020, 312,500 Series B Common Stock Warrants with an intrinsic value of \$26,563 were exercised for no consideration per share, which resulted in the issuance of 312,500 shares of common stock. Prior to exercise, these Series B Warrants were adjusted to fair value using a Black Scholes valuation method which considered the closing trading price on the exercise dates. Because the exercise price of these options had been reset to \$0.00, the fair value derived from the valuation model approximated the market value of the Company's common stock on the exercise dates.

4. Debt

Multi-Draw Credit Agreement- Related Party

The Company's Debt with Sciences consists of the following:

	Conversion Price	As of September 30, 2021	As of December 31, 2020
Total principal value of convertible debt—related party	\$ 0.40	\$ 2,014,500	\$ 2,014,500
Unamortized debt discount		(641,987)	(1,079,821)
Unamortized debt issuance costs		(2,357)	(3,576)
Carrying value of total convertible debt - related party		1,370,156	931,103
Total principal value of non-convertible debt—related party	n/a	450,000	450,000
Total carrying value of advances under the multi-draw credit agreement		\$ 1,820,156	\$ 1,381,103

On October 5, 2018, the Company entered into the Credit Agreement with Sciences, a related party (See Note 8). On April 29, 2020, the Company entered into the Amended Credit Agreement with Sciences, which amends and restates the Credit Agreement. For all pre-existing and new advances, the Amended Credit Agreement removed the change in control as an event of default. The amendments to the pre-existing advances were accounted for as a modification. For all advances made after the Credit Agreement was amended, advances will be convertible at a reduced conversion price of \$0.25 per share of Common Stock, unless Sciences provides notice that the advance will not be convertible.

On March 29, 2021, the Company amended the Amended Credit Agreement to defer interest payments through the earlier of maturity or prepayment of the principal balance. On September 15, 2021, the Company further amended the Amended Credit Agreement to close the disbursement line. The amendments were considered a modification for accounting purposes.

Advances under the Amended Credit Agreement are unsecured, and bear interest at an annual rate of 7% and mature on October 5, 2022. At Sciences' election, convertible advances and unpaid interest may be converted into common stock at the applicable fixed conversion price of the underlying advance, subject to customary adjustments for stock splits, stock dividends, recapitalizations, etc.

The Amended Credit Agreement provides for customary events of default which may result in the acceleration of the maturity of the advances in addition to, but not limited to, cross acceleration to certain other indebtedness of the Company. In the case of an event of default arising from specified events of bankruptcy or insolvency or reorganization, all outstanding advances will become due and payable immediately without further action or notice. If any other event of default under the Amended Credit Agreement occurs or is continuing, Sciences may, by written notice, terminate its commitment to make any advances and/or declare all the advances, including accrued interest, payable due immediately. If any amount under the Amended Credit Agreement is not paid when due, such overdue amount shall bear interest at an annual default interest rate of the applicable rate plus 10%, until such amount is paid in full.

In connection with each advance under the Amended Credit Agreement, the Company has agreed to issue to Sciences warrants to purchase shares of common stock in an amount equal to 50% of the number of shares of common stock that each advance may be converted into. The warrants have a term of five years and are immediately exercisable upon issuance. Under the Amended Credit Agreement, Sciences may issue notice that no warrants will be granted at the time of the advance request. The warrants issued under the Credit Agreement have an exercise price of \$0.50 per share and any future warrants issued under the Amended Credit Agreement will have a reduced exercise price of \$0.35 per share. The exercise prices are subject to adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events or upon any distributions of assets, including cash, stock or other property to the Company's stockholders (See Note 3).

As of September 30, 2021, the unamortized debt discount on the convertible advances will be amortized over a remaining period of approximately 1.01 years. As of September 30, 2021, the fair value of the shares underlying the convertible advances under the Amended Credit Agreement was \$528,806. As of September 30, 2021, the if-converted value did not exceed the principal balance.

PPP Loan

On April 24, 2020, the Company received funding from the PPP Loan Lender pursuant to the PPP of the CARES Act administered by the SBA for a principal amount of \$116,700. The PPP Loan had an interest rate of 1.00% per year and funds from the PPP Loan could only be used by the Company for payroll costs, costs for continuing group healthcare benefits, mortgage interest payments, rent, utility and interest on any other debt obligations that were incurred before October 9, 2020.

On April 5, 2021, the Company submitted an application for the full forgiveness of the PPP Loan to the PPP Loan Lender for the full amount of the loan. On May 20, 2021, the Company received notification that the application was accepted and that the full amount of the PPP Loan including accrued interest was forgiven. During the nine months ended September 30, 2021, the Company has recorded a gain on forgiveness of the PPP loan in an amount of \$117,953.

Interest Expense

The Company's interest expense consists of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Related party interest expense – stated rate	\$ 44,086	\$ 44,087	\$ 130,824	\$ 117,459
PPP loan interest expense – stated rate	—	294	445	511
Non-cash interest expense:				
Amortization of debt discount	150,852	137,849	437,834	401,507
Amortization of transaction costs	420	384	1,219	1,117
	\$ 195,358	\$ 182,614	\$ 570,322	\$ 520,594

5. Stockholders' Equity and Capitalization

Increase to Authorized Shares of Capital Stock

On February 5, 2021, the Company increased its authorized shares of common and preferred stock to 5,000,000,000 and 50,000,000, respectively.

Warrant Exercises

During the nine months ended September 30, 2021, 11,800,000 pre-funded warrants with an intrinsic value of \$460,200 were exercised in exchange for 11,800,000 shares of common stock for gross proceeds of \$11,800. As of September 30, 2021 all of the pre-funded warrants have been exercised.

During the nine months ended September 30, 2021, 116,666,668 of the 2020 common stock warrants, including the warrants that were exercised in connection with the July 2021 Inducement discussed below, with an intrinsic value of \$8,764,967 were exercised in exchange for 116,666,668 shares of common stock for gross proceeds of \$6,999,999.

July 2021 Inducement and September 2021 Financing

On July 21, 2021, the Company entered into an Inducement Offer to Exercise Common Stock Purchase Warrants (the "July 2021 Inducement") with certain institutional investors and H.C. Wainwright & Co., LLC ("Wainwright") acting as the placement agent. As a result, on July 26, 2021, the investors exercised 21,166,667 warrants at their original exercise price of \$0.06, for gross proceeds of \$1,270,000. In exchange, the Company granted 21,166,667 new warrants with substantially the same terms and an exercise price of \$0.15 per share (Notes 2 & 3).

On September 27, 2021, the Company entered into a Securities Purchase Agreement with certain institutional investors for the issuance and sale of securities, with Wainwright acting as the placement agent, pursuant to which the Company sold 58,111,112 shares of common stock and 19,666,667 pre-funded warrants, and issued 77,777,779 common stock warrants, in a registered public offering which closed on September 29, 2021 (the "September 2021 Financing"). The common stock and pre-funded warrants were sold at a price per share of \$0.09 and \$0.0899, respectively, for gross aggregate proceeds of \$6,998,034. The common stock warrants and pre-funded warrants have an exercise price of \$0.09 and \$0.0001, respectively. The common stock warrants have a term of five years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full (Note 3).

In connection with the July 2021 Inducement and September 2021 Financing, the Company incurred cash issuance costs of \$935,260, for net proceeds of \$6,062,774.

Additionally, the Company issued warrants to purchase 6,926,112 shares of common stock to the placement agent, which represent 7% of the total shares of common stock and pre-funded warrants sold in the offering and 7% of the Inducement Warrants issued (Note 3).

6. Stock-Based Compensation

Stock Incentive Plan

On October 31, 2014, after the closing of the Merger, the Board of Directors approved the Company's 2014 Omnibus Incentive Plan (the "2014 Plan"). The share reserve under the 2014 Plan equals 10% of the number of issued and outstanding shares of common stock of the Company. In August 2020, the Company approved Amendment No. 2 to the 2014 Plan, which increased the share reserve by an additional 7,876,835 shares over the 10% of the number of issued and outstanding shares of common stock, and removed certain restrictions on the number of shares of common stock and the amount of cash-based awards up to which participants of the 2014 Plan can receive in a calendar year. The 2014 Plan authorizes the issuance of awards including stock options, stock appreciation rights, restricted stock, stock units and performance units to employees, directors, and consultants of the Company. As of September 30, 2021, the Company had 30,047,929 shares available for future grant under the 2014 Plan.

Stock Options

The following is a summary of option activities under the Company's 2014 Plan for the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding, December 31, 2020	22,050,000	\$ 0.06	9.52
Granted	2,475,000	0.14	
Exercised	(106,250)	0.05	
Cancelled	(40,000)	0.05	
Forfeited	(888,750)	0.05	
Outstanding, September 30, 2021	23,490,000	\$ 0.07	8.88
Exercisable, September 30, 2021	8,690,000	\$ 0.09	8.61

During the nine months ended September 30, 2021, 106,250 stock options with an intrinsic value of \$13,281 were exercised for gross proceeds of \$4,783.

The fair value of each stock option grant was estimated on the date of grant using the Black-Scholes option-pricing model using the following assumptions:

	For the Nine Months Ended September 30, 2021
Dividend yield	0.00%
Volatility factor	119.1 - 124.2%
Risk-free interest rate	0.82 - 1.11%
Expected term (years)	5.27 - 6.13

For the nine months ended September 30, 2021, the weighted average grant date fair value of options granted was \$0.14 per share.

In connection with the termination of Dr. Avtar Dhillon's Independent Contractor Agreement on October 14, 2021 (Note 8), the Company modified Dr. Dhillon's option awards to accelerate the vesting of 1,650,000 unvested stock options and, extend the post-termination exercise period from 30 days to five years for all of his outstanding awards. The approval of the modification and receipt of notice to terminate the Independent Contractor Agreement on September 14, 2021, resulted in the recognition of \$309,487 in stock compensation expense for the three and nine months ended September 30, 2021.

Awards Granted Outside the 2014 Plan

During the nine months ended September 30, 2021, the Company granted 1,200,000 and 300,000 restricted shares of common stock to a non-employee consultant for investor relations services under two successive six month service contracts. Half of the shares will be issued within the first month of entering each service contract and the remaining half will be issued within thirty days from contract completion.

The following is a summary of restricted stock activity outside of the Company’s 2014 Plan during the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, December 31, 2020	—	\$ —
Granted	1,500,000	0.12
Released	(1,350,000)	0.12
Unvested, September 30, 2021	150,000	\$ 0.13

Stock-Based Compensation Expense

The Company recognizes compensation expense using the straight-line method over the requisite service period. Stock-based compensation is included in the Condensed Consolidated Statements of Comprehensive Loss in general and administrative or research and development, depending upon the nature of services provided. Stock-based compensation expense (including compensation expense for restricted stock awards discussed above) was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 17,986	\$ 44,010	\$ 37,350	\$ 82,463
General and administrative	470,987	104,355	709,902	158,753
	\$ 488,973	\$ 148,365	\$ 747,252	\$ 241,216

The total amount of unrecognized compensation cost was \$860,985 as of September 30, 2021. This amount will be recognized over a weighted average period of 2.76 years.

7. Significant Contracts - University of Mississippi

UM 5050 and UM 8930 License Agreements

In July 2018, the Company renewed its ocular licenses for UM 5050, a prodrug of tetrahydrocannabinol (“THC”), and UM 8930, an analog of cannabidiol (“CBD”). On May 24, 2019, the ocular delivery licenses were replaced by “all fields of use” licenses for both UM 5050 and UM 8930 (collectively, the “License Agreements”). Pursuant to the License Agreements, UM granted the Company an exclusive, perpetual license, including, with the prior written consent of UM, not to be unreasonably withheld, the right to sublicense, the intellectual property related to UM 5050 and UM 8930 for all fields of use.

The License Agreements contain certain milestone payments, royalty and sublicensing fees payable by the Company, as defined therein. Each License Agreement provides for an annual maintenance fee of \$75,000 payable on the anniversary of the effective date. The Company made upfront payments for UM 5050 and UM 8930 of \$100,000 and \$200,000, respectively. In addition, in March 2020, the Company was notified by the United States Patent and Trademark Office, that a notice of allowance was issued for the proprietary analog of cannabidiol, CBDVHS, under the UM 8930 License Agreement. As a result, the Company paid UM a fee of \$200,000. The milestone payments payable for each license are as follows:

- i) \$100,000 paid within 30 days following the submission of the first Investigational New Drug (“IND”) application to the Food and Drug Administration or an equivalent application to a regulatory agency anywhere in the world, for a product;
- ii) \$200,000 paid within 30 days following the first submission of a New Drug Application (“NDA”), or an equivalent application to a regulatory agency anywhere in the world, for each product that is administered in a different route of administration from that of the earlier submitted product(s); and
- iii) \$400,000 paid within 30 days following the approval of an NDA, or an equivalent application to a regulatory agency anywhere in the world, for each product that is administered in a different route of administration from that of the early approved product(s).

The royalty percentage due on net sales under each License Agreement is in the mid-single digits. The Company must also pay to UM a portion of all licensing fees received from any sublicensees, subject to a minimum royalty on net sales, and the Company is required to reimburse patent costs incurred by UM related to the licensed products. The royalty obligations apply by country and by licensed product, and end upon the later of the date that no valid claim of a licensed patent covers a licensed product in a given country, or ten years after the first commercial sale of such licensed product in such country.

Each License Agreement continues, unless terminated, until the later of the expiration of the last to expire of the patents or patent applications within the licensed technology, and the expiration of the Company's payment obligations under such License Agreement. UM may terminate each License Agreement, by giving written notice of termination, upon the Company's material breach of such License Agreement, including failure to make payments or satisfy covenants, representations or warranties without cure, noncompliance, a bankruptcy event, the Company's dissolution or cessation of operations, the Company's failure to make reasonable efforts to commercialize at least one product or failure to keep at least one product on the market after the first commercial sale for a continuous period of one year, other than for reasons outside the Company's control, or the Company's failure to meet certain pre-established development milestones. The Company may terminate each License Agreement upon 60 days' written notice to UM.

As of September 30, 2021, with the exception of the fee due for the notice of patent allowance for CBDVHS, none of the other milestones under these license agreements have been met.

UM 5070 License Agreement

In January 2017, the Company entered into a license agreement with UM pursuant to which UM granted the Company an exclusive, perpetual license, including the right to sublicense, to intellectual property related to a platform of cannabinoid-based molecules ("UM 5070"), to research, develop and commercialize products for the treatment of infectious diseases.

The Company paid UM an upfront license fee of \$65,000 under the license agreement. Under the license agreement, the Company is also responsible for annual maintenance fees of \$25,000 that will be credited against any royalties incurred, contingent milestone payments upon achievement of development and regulatory milestones, and royalties on net sales of licensed products sold for commercial use. The aggregate milestone payments due under the license agreement if all the milestones are achieved is \$700,000 and the royalty percentage due on net sales is in the mid-single digits. The Company must also pay to UM a percentage of all licensing fees it receives from any sublicensees, subject to a minimum royalty on net sales by such sublicensees. The Company's royalty obligations apply on a country by country and licensed product by licensed product basis, and end upon the later of the date that no valid claim of a licensed patent covers a licensed product in a given country, and ten years after first commercial sale of such licensed product in such country.

The license agreement continues, unless terminated, until the later of the expiration of the last to expire of the patents or patent applications within the licensed technology, and expiration of the Company's payment obligations under the license. UM may terminate the license agreement, effective with the giving of notice, if: (a) the Company fails to pay any material amount payable to UM under the license agreement and does not cure such failure within 60 days after UM notifies the Company of such failure, (b) the Company materially breaches any covenant, representation or warranty in the license agreement and does not cure such breach within 60 days after UM notifies us of such failure, (b) the Company materially breaches any covenant, representation or warranty in the license agreement and does not cure such breach within 60 days after UM notifies the Company of such breach, (c) the Company fails to comply in any material respect with the terms of the license and do not cure such noncompliance within 60 days after UM notifies the Company of such failure, (d) the Company is subject to a bankruptcy event, (e) the Company dissolves or ceases operations or (f) if after the first commercial sale of a product during the term of the license agreement, the Company materially fails to make reasonable efforts to commercialize at least one product or fails to keep at least one product on the market after the first commercial sale for a continuous period of one year, other than for reasons outside of the Company's control. The Company may terminate the license agreement upon 60 days' written notice to UM.

As of September 30, 2021, none of the milestones under this license agreement have been met (Note 10).

8. Related Party Matters

Emerald Health Sciences

In January 2018, the Company entered into a securities purchase agreement with Sciences pursuant to which Sciences purchased a majority of the equity interest in the Company, resulting in a change in control transaction. While Sciences no

longer maintains a controlling interest in the Company, it holds a significant equity interest and has provided the Company with financing under the Amended Credit Agreement (Note 4).

On December 19, 2019, the Company entered into an Independent Contractor Services Agreement with Dr. Avtar Dhillon, a member of Sciences Board of Directors and its CEO, pursuant to which Dr. Dhillon provides ongoing corporate finance and strategic business advisory services to the Company. In exchange for his services, Dr. Dhillon received a monthly fee of \$10,000, per month for his services.

Under the Independent Contractor Agreement, for the three and nine months ended September 30, 2021, the Company incurred fees of \$30,000 and \$90,000, respectively. For the three and nine months ended September 30, 2020, the Company incurred fees of \$31,000 and \$97,387, respectively. As of September 30, 2021 and December 31, 2020, the Company has accrued \$20,000 of consulting fees and \$7,032 in expense related to the Independent Contractor Services Agreement, respectively. On September 14, 2021, Dr. Dhillon provided his notice to terminate the Independent Contractor Services Agreement, with an effective termination date of October 14, 2021. As of October 14, 2021, the Company no longer has any obligations or business relationship with Dr. Dhillon (Note 6).

In addition, the Board Observer Agreement in place with Sciences was amended in September 2021 to allow any board member or officer of Sciences to act as a representative of Sciences on a non-voting observer basis in meetings of the Board.

Emerald Health Pharmaceuticals, Inc.

On April 30, 2021, the Company entered into a month-to-month lease agreement with Emerald Health Pharmaceuticals, an affiliate of the Company with a significant common shareholder, as the sublessor and the Company as the sublessee. The Company shared the same office location as Emerald Health Pharmaceuticals in San Diego, California until the termination of the sublease on August 31, 2021. Under the sublease agreement, the Company paid monthly base rent of \$4,000 in addition to its share of common area expenses and utilities. For the three and nine months ended September 30, 2021, the Company recognized \$8,830 and \$15,453, respectively, in expense under the sublease.

Emerald Health Biotechnology España, S.L.U.

In January 2021 and April 2021, the Company entered into two separate Collaborative Research Agreements pursuant to a Master Services Agreement with Emerald Health Biotechnology España, S.L.U. ("EHBE"), a research and development entity with substantial expertise in cannabinoid science and a subsidiary of Emerald Health Research, Inc. which is 100% owned by Sciences. Under the agreements, Emerald Health Biotechnology España, S.L.U. will provide research and development services pursuant to agreed upon project plans for the research and development of CBDVHS and the preclinical development services for novel analogues. The term of each agreement is initially for a one-year period. The agreements will terminate upon delivery and acceptance of the final deliverables under the project plans or if either party is in breach of the terms of the contract and such breach remains uncured for 45 days. Payment for services are based on the negotiated amounts for the completion of agreed upon objectives as provided in the Collaborative Research Agreements. For the three and nine months ended September 30, 2021, the Company incurred \$62,940 and \$206,218, respectively, in expenses under the Collaborative Research Agreements. As of September 30, 2021, the Company has recognized prepaid asset in the amount of \$18,125 to be offset against future research and development costs under the Collaborative Research Agreements (Note 10).

Board Members

As of September 30, 2021, Jim Heppell and Punit Dhillon are board members of the Company and Emerald Health Pharmaceuticals, a subsidiary of Sciences. As of September 30, 2021, Jim Heppell is also a board member of Sciences and Emerald Health Biotechnology España, S.L.U. The Company's CEO, Punit Dhillon also served as a board member of Sciences and Emerald Health Biotechnology España, S.L.U. until he tendered his resignation from such boards on August 10, 2020 and September 22, 2021, respectively.

9. Commitments and Contingencies

Office Lease

The Company leases office space for its corporate headquarters, located at 1250 El Camino Real, San Diego, California 92130. The lease is effective from September 1, 2021 through October 31, 2022 and contains a renewal option for a two-year extension after the current expiration date. The Company does not expect that the renewal option will be exercised, and has therefore excluded the option from the calculation of the right of use asset and lease liability. The lease provides for two months of rent

abatement and the initial monthly rent is \$8,067 per month with annual increases of 3% commencing on November 1, 2022. The lease includes non-lease components (i.e., property management costs) that are paid separately from rent, based on actual costs incurred, and therefore were not included in the right-of-use asset and lease liability but are reflected as an expense in the period incurred. In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the lease term.

For the three and nine months ended September 30, 2021, lease expense comprised of \$7,558 in lease cost from the Company's non-cancellable operating lease.

The remaining lease term and discount rate related to the operating lease are presented in the following table:

	September 30, 2021
Weighted-average remaining term – operating lease (in years)	2.08
Weighted-average discount rate – operating lease	12 %

Future minimum lease payments as of September 30, 2021 are presented in the following table:

Year:		
2021 (remaining three months)	\$	8,067
2022		97,291
2023		83,093
Total future minimum lease payments:		188,451
Less imputed interest		(24,287)
Total	\$	164,164

Reported as:

Operating lease liability	\$	63,581
Operating lease liability, net of current portion		100,583
Total lease liability	\$	164,164

General Litigation and Disputes

From time to time, in the normal course of operations, the Company may be a party to litigation and other dispute matters and claims. Litigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict. An unfavorable outcome to any legal matter, if material, could have a materially adverse effect on the Company's operations or financial position, liquidity or results of operations. As of September 30, 2021, there were no pending or threatened lawsuits or claims that could reasonably be expected to have a material effect on the Company's financial position or results of operations.

10. Subsequent Events

Stock option grant

On October 4, 2021, the Company granted 1,600,000 stock options to the Company's Chief Financial Officer. The options have an exercise price of \$0.09 per share and 10% of the options vest on the grant date with the remainder vesting in semi-annual installments over four years. In the event of a change of control of the Company (as defined in the award documents), the options shall become vested in full.

Exclusive Sponsored Research Agreement

On October 11, 2021, the Company entered into an Exclusive Sponsored Research Agreement (the "ESRA") with EHBE to fund certain research and development programs which are of mutual interest to both the Company and EHBE. The Company

will have the right to use all data, products, and information, including intellectual property which are generated in the performance of the research under each and all projects funded by the Company pursuant to the ESRA, and EHBE assigns and agrees to assign, to the Company all rights to any intellectual property created or reduced-to-practice under, or as a part of, a project funded by the Company pursuant to the ESRA.

The Company has agreed to pay to EHBE a royalty based on any and all licensing revenue or other consideration paid to the Company by a third-party licensee, assignee or purchaser of intellectual property rights created under the ESRA. In addition, upon a change of control transaction the Company has agreed to pay an amount equal to the royalty percentage multiplied by the fair value of the intellectual property created under the ESRA. Pursuant to the ESRA, EHBE will provide a budget to be approved by the Company for each project, and the Company will make payments in accordance with the approved budget and pay an annual retainer to EHBE of \$200,000 per year.

The initial term of the agreement is one year, with automatic renewal for successive one-year terms unless either party terminates upon 60 days' prior written notice to the other party pursuant to the ESRA.

Termination of UM 5070 License Agreement

On November 9, 2021, the Company provided its 60 day notice of termination to UM to terminate the UM 5070 license agreement effective January 8, 2022.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements for the three and nine months ended September 30, 2021 and 2020 (unaudited) and the year ended December 31, 2020 together with the notes thereto. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including, but not limited, to those set forth under “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q.

Unless otherwise provided in this Quarterly Report, references to “we,” “us,” “our” and “Skye Bioscience” in this discussion and analysis refer to Skye Bioscience, Inc., a Nevada corporation formerly known as Emerald Bioscience, Inc., together with its wholly owned subsidiaries, Nemus, a California corporation, and SKYE Bioscience Pty Ltd. (formerly known as “EMBI Australia Pty Ltd.”), an Australian proprietary limited company.

About Skye Bioscience, Inc.

We are a biopharmaceutical company targeting the discovery, development and commercialization of a novel class of therapeutics that modulate the endocannabinoid system (ECS) which has shown to play a vital role in overall human health and specifically, ECS mediated signaling plays a role in multiple ocular indications. We are also developing novel cannabinoid-based therapeutics through our own directed research efforts and through a number of license agreements with the University of Mississippi (“UM”). We continue to be a development and commercialization partner of UM working to bring UM’s proprietary cannabinoid molecules through the development process.

Effective March 25, 2019, we changed our name from Nemus Bioscience, Inc. to Emerald Bioscience, Inc. and effective January 19, 2021, we changed our name to Skye Bioscience, Inc. Our common stock is quoted on the OTCQB, under the symbol “SKYE”. Previously, it traded under the symbol “EMBI”.

In August 2019, we formed a new subsidiary in Australia, SKYE Bioscience Australia, in order to qualify for the Australian government’s research and development tax credit for research and development dollars spent in Australia. The primary purpose of SKYE Bioscience Australia is to conduct clinical trials for our product candidates.

Our Product Candidates and Significant Contracts.

UM 5050 and UM 8930 License Agreements

In July 2018, we renewed our ocular licenses for UM 5050, a prodrug of THC, and UM 8930, an analog of CBD. In May 2019, the ocular licenses were replaced by “all fields of use” licenses for both UM 5050 and UM 8930 (collectively, the “License Agreements”). Pursuant to the License Agreements, UM granted us an exclusive, perpetual license, including, with the prior written consent of UM, the right to sublicense, the intellectual property related to UM 5050 and UM 8930 for all fields of use. All fields of use means that we may develop UM 5050 and UM 8930 to treat any disease through any form of delivery.

The exclusive license for THC-VHS, a proprietary prodrug of THC, is expected to allow us to explore related uses for the active moiety of the prodrug, namely THC. Independent in vitro and in vivo studies have demonstrated the potential use of THC in a variety of potential indications based on the ability of the cannabinoid to act as an anti-inflammatory, anti-fibrotic, and/or inhibitor of neovascularization. The Company has generated data related to these effects using an ex vivo human tissue model of the eye. The prodrug approach employed in THC-VHS is designed to enhance the pharmacokinetic and pharmacodynamics of the active part of the molecule, once introduced into the body through various routes of administration being considered by the development team.

The exclusive license of CBD-VHS, an analog of CBD, is expected to permit us to expand research and development into organ systems outside of the ocular space. CBD-VHS has demonstrated pharmacology different than CBD, while also exhibiting improved pharmacokinetics and bioavailability. As a result, CBD-VHS will allow us to broaden our target diseases. Potential therapeutic areas for CBD-VHS may include, the central nervous system, the gastrointestinal tract, the endocrine/metabolic system, reproductive system diseases, or as yet unrecognized opportunities. Moreover, the determination by the DEA that CBD-VHS is not a controlled substance permits us to avoid additional regulatory scrutiny from the DEA throughout the development of the drug. We have developed strategic collaborations to identify and advance these applications.

UM 5070 License Agreement

In January 2017, we entered into a license agreement with UM pursuant to which UM granted us an exclusive, perpetual license, including the right to sublicense, the intellectual property related to a combination of cannabinoid molecules (i.e. "cannabinoid cocktail"), to research, develop and commercialize products for the treatment of infectious diseases. On November 9, 2021, we provided our notice of termination to UM to terminate the UM 5070 license agreement effective January 8, 2022.

Our Product Candidates

Cannabinoids are a class of chemically diverse compounds that are mainly found in extracts from the cannabis plant. The human body also produces cannabinoids, called endocannabinoids, to regulate a number of biological pathways. These compounds express their physiological response by binding to cannabinoid receptors (CB1 and CB2) and certain other receptors found throughout the human body. Some cannabinoids have been observed to exert multiple effects on the human body, including, but not limited to impacting the immune response, nervous system function and repair, gastrointestinal maintenance and motility, motor function in muscles, pancreatic functionality, tissue repair, blood sugar regulation, and integrity of function in the eye (including the optic nerve). Cannabis and specific cannabinoids have been studied widely and the results suggest that there is potential for these compounds to prevent, treat and/or alleviate symptoms of multiple diseases and disorders.

We are focused on the development of proprietary, synthetic cannabinoid-derived molecules that have been bioengineered to improve the solubility, bioavailability and pharmacology of natural cannabinoids, while also providing the Company with strong intellectual property protection. The following table summarizes certain information regarding our cannabinoid product candidates, along with a proprietary cannabinoid cocktail:

Product Candidate	Indication	Development Status
THCVHS	Glaucoma	Preclinical
CBDVHS	Multiple Targets	Preclinical
Cannabinoid Cocktail	Anti-infective	Research

THCVHS

Our lead compound, THCVHS, is initially being developed to treat ocular disease. The first-in-human Phase 1 trials are expected to be conducted in healthy volunteers in Australia (the "Clinical Trial") to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of THCVHS. We are eligible under the AusIndustry research and development tax incentive program to obtain a cash incentive from the Australian Taxation Office. The tax incentive is available to us based on specific criteria with which we must comply and is based on our eligible research and development spend in Australia. The Company may be eligible for either a 43.5% refundable tax offset if it has aggregate turnover of less than \$20 million per annum or a 38.5% non-refundable tax offset. Prior to August 2020, we executed several agreements, and the work underlying those agreements was subsequently delayed to the second quarter of 2022. Since August 2020, we have been focused on clinical enabling activities, notably:

- formulation and manufacturing of drug product to supply our GLP toxicology studies and first-in-human Phase 1 clinical trial;
- initiating and completing GLP toxicology studies to support our first-in-human Phase 1 clinical trial;
- initiating and completing validation of a pharmacokinetic assay for both animal and human samples to support our pre-clinical and clinical studies; and
- engaging our vendors and contractors to support the finalization of study-related materials for our Phase 1 study, including the finalization of the clinical study protocol.

The manufacturing of THCVHS is conducted in the United States. Formulation of the eye drop for testing is also performed in the United States but we rely on regulatory-accepted excipients that can be sourced from countries outside the United States, such as China. In connection with the recent pandemic of COVID-19 there could possibly be an impact on sourcing materials that are part of the eye drop formulation, as well as impacts to our volunteer and/or patient recruitment in Australia for clinical studies.

CBDVHS

We have initiated research activities to explore the utility of different formulations of CBDVHS, our proprietary CBD analog. Early studies of CBDVHS demonstrated analgesic, anti-inflammation, anti-fibrotic, anti-seizure properties, including the potential treatment and management of several eye diseases, such as uveitis, dry eye syndrome, macular degeneration and diabetic retinopathy. Data we presented at the American Association of Pharmaceutical Scientists (“AAPS”) meeting held in November 2017, revealed that an ocular formulation of CBDVHS was able to penetrate multiple compartments of the eye, including reaching the retina and the optic nerve. Further testing will need to be conducted to further evaluate the possible utility of this compound as a therapeutic agent and we continue to advance our research studies related to CBDVHS to explore different therapeutic applications.

Cannabinoid Cocktail

Cannabinoid molecules have previously been shown through in vitro studies conducted by third parties to possess anti-infective activity against a variety of bacterial strains. We entered into a research agreement with UM to explore this area in 2015 and have tested a variety of cannabinoids in various strengths, combinations, and delivery systems against a variety of bacterial species found in community, healthcare, and institutional settings such as nursing homes, correctional facilities, and military quarters.

General Trends and Outlook

COVID-19 related

The COVID-19 pandemic has prompted governments and businesses to take unprecedented measures, such as restrictions on travel and business operations, temporary closures of business, quarantines, and shelter-in-place orders. The COVID-19 pandemic has significantly curtailed global economic activity and caused significant volatility and disruption in global financial markets. The COVID-19 pandemic and the measures taken by many countries in response have affected, and could in the future, materially impact the Company's business, results of operations, financial condition and stock price.

The full extent of the future impact of the COVID-19 pandemic on the Company's operational and financial performance is currently uncertain and will depend on many factors outside of our control, including, without limitation, the timing, extent, trajectory, and the duration of the pandemic; the availability, distribution, and effectiveness of vaccines; the imposition of protecting public safety measures, and the impact of the pandemic on any local operations across the United States and Australia, where we have operations and conduct laboratory research and clinical studies.

The ultimate impact on us and overall delay in our drug product research and development is unknown, but our operations and financial condition will suffer in the event of business interruptions, delayed clinical trials, production or a lack of laboratory resources due to the pandemic. As of the date of this filing, we are aware of the impact on our business as a result of COVID-19 but uncertain as to the extent of this impact on our Condensed Consolidated Financial Statements. There is uncertainty as to the duration and hence the potential impact. As a result, we are unable to estimate the potential impact on our business as of the date of this filing.

Financial Overview

We have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue development activities to support our product candidates through clinical trials. As a result, we expect to continue to incur operating losses and negative cash flows until our product candidates gain market acceptance and generate significant revenues.

Our net losses for the three and nine months ended September 30, 2021 were \$1,824,818 and \$6,009,362, respectively, as compared to net losses of \$1,296,696 and \$5,058,592, respectively, for the three and nine months ended September 30, 2020. As of September 30, 2021, we had an accumulated deficit of \$44,743,343 and negative cash flows from operations of \$4,506,032. As of September 30, 2021, we had unrestricted cash of \$11,089,624 as compared to \$2,469,410 December 31, 2020.

On February 5, 2021, we increased our authorized shares of common and preferred stock to 5,000,000,000 and 50,000,000, respectively.

Critical Accounting Policies and Estimates

Our Management's Discussion and Analysis of Financial Condition and Results of Operations section discusses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of income and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgements, including those related to accrued expenses, financing operations, and contingencies and litigation. Management bases its estimates and judgements on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The most significant accounting estimates inherent in the preparation of our financial statements include estimates and judgements as to the appropriate carrying values of our equity instruments, derivative liabilities, debt with embedded features and the valuation of our stock based compensation awards, which are not readily apparent from other sources. We consider certain accounting policies related to fair value measurements, convertible instruments, warrants issued in connection with financings, stock-based compensation expense, and earnings per share to be critical accounting policies that require the use of significant judgements and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions.

Management assessed the critical accounting policies as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020 and determined that there were no changes to our critical accounting policies and estimates during the three and nine months ended September 30, 2021.

Recently Issued and Adopted Accounting Pronouncements

See Note 2 to the accompanying Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information on recently issued accounting pronouncements and recently adopted accounting pronouncements. While we expect certain recently adopted accounting pronouncements to impact our estimates in future periods, the impact upon adoption was not significant to our current estimates and operations.

Results of Operations

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our clinical trials, our research and development efforts, variations in the level of expenditures related to investor relations and seeking new sources of capital, debt service obligations during any given period, and the uncertainty as to the extent and magnitude of the impact from the COVID-19 pandemic. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. In particular, to the extent our medical affairs personnel and clinical trial subjects are subject to varying levels of restriction on accessing hospitals due to COVID-19, and to the extent government authorities and healthcare providers are continuing to limit elective surgeries, we expect our progress towards executing our clinical trials to be adversely affected.

Three months ended September 30, 2021 and 2020

Research and Development Expenses

Research and development expenses included the following:

- license fees;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party contract research organizations and investigative sites; and
- payments to third party manufacturing organizations and consultants.

We expect to incur future research and development expenditures to support our preclinical and clinical studies. Preclinical activities include, laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies to assess safety and efficacy. Subject to the submission and approval by the FDA of our IND, clinical trials may commence and will involve the administration of the investigational new drug candidate to human subjects.

Below is a summary of our research and development expenses during the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,			
	2021	2020	\$ Change 2021 vs. 2020	% Change 2021 vs. 2020
Research and development expenses	\$ 327,731	\$ 346,217	\$ (18,486)	(5)%

Research and development expenses for the three months ended September 30, 2021 remained relatively consistent as compared to the three months ended September 30, 2020. During both periods research and development costs included manufacturing, employee related expenses, formulation and product costs and our use of consultants.

General and Administrative Expenses

General and administrative expenses consisted primarily of salaries, benefits, stock compensation expense, general legal, and patent related fees. Other significant expenses included investor relations, professional and consulting fees related to the Company's fundraising efforts and regulatory filings.

Total general and administrative expenses for the three months ended September 30, 2021 and 2020, were as follows:

	Three Months Ended September 30,			
	2021	2020	\$ Change 2021 vs. 2020	% Change 2021 vs. 2020
General and administrative expenses	\$ 1,491,378	\$ 1,192,003	\$ 299,375	25 %

General and administrative expenses for the three months ended September 30, 2021 increased as compared to the three months ended September 30, 2020. Within general and administrative expenses there were increases in investor and public relations expenses, an increase in stock compensation expense due to the modification of stock options, and payments to recruiters. These increases were offset by decreases in costs related to finance and accounting services, severance, consulting, insurance, and marketing.

Other Expense (Income)

Total other expense (income) for the three months ended September 30, 2021 and 2020, was as follows:

	Three Months Ended September 30,			
	2021	2020	\$ Change 2021 vs. 2020	% Change 2021 vs. 2020
Change in fair value of derivative liabilities	\$ (189,649)	\$ (424,138)	\$ 234,489	(55) %
Interest expense	195,358	182,614	12,744	7 %
Total other expense (income)	\$ 5,709	\$ (241,524)	\$ 247,233	(102)%

For the three months ended September 30, 2021, we had net other expense of \$5,709 related to interest expense and a gain from the change in fair value of derivative liabilities. The primary reason for the increase in other expense was the decrease in the gain from the change in fair value of our derivative liabilities during the period. Gains from the change in fair value of our derivative liabilities are due primarily to decreases in our stock price and fluctuations in our volatility during each period. The increase in interest expense was due to a higher average outstanding principal balance on our Amended Credit Agreement for the period ended September 30, 2021, as compared to the period ended September 30, 2020.

For the three months ended September 30, 2020, we had other income of \$241,524 related primarily to interest expense of \$182,614 and a decrease in the fair value of our derivative liabilities of \$424,138.

Nine months ended September 30, 2021 and 2020

Below is a summary of our research and development expenses during the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,			
	2021	2020	\$ Change 2021 vs. 2020	% Change 2021 vs. 2020
Research and development expenses	\$ 1,818,059	\$ 1,574,357	\$ 243,702	15 %

Research and development expenses for the nine months ended September 30, 2021 increased as compared to the nine months ended September 30, 2020. The increase in research and development expenses was primarily due to increases in contract research and development activities and our use of specialized consultants. These increases were offset by reduced license fees due to the milestone payment related to the notice of patent allowance for CBDVHS, which was paid to UM in the prior period.

General and Administrative Expenses

Total general and administrative expenses for the nine months ended September 30, 2021 and 2020, were as follows:

	Nine Months Ended September 30,			
	2021	2020	\$ Change 2021 vs. 2020	% Change 2021 vs. 2020
General and administrative expenses	\$ 3,567,985	\$ 3,395,729	\$ 172,256	5 %

General and administrative expenses for the nine months ended September 30, 2021 increased as compared to the nine months ended September 30, 2020. The increase in general and administrative expenses was primarily due to increases in consulting, recruiting, stock compensation from the modification of option awards, and investor relations expenses. The increase was partially offset by lower legal and accounting fees incurred during the period.

Other Expense (Income)

Total other expense (income) for the nine months ended September 30, 2021 and 2020, was as follows:

	Nine Months Ended September 30,			
	2021	2020	\$ Change 2021 vs. 2020	% Change 2021 vs. 2020
Change in fair value of derivative liabilities	\$ 169,349	\$ (433,688)	\$ 603,037	(139) %
Interest expense	570,322	520,594	49,728	10 %
Gain on forgiveness of PPP loan	(117,953)	—	(117,953)	100 %
Total other expense (income)	\$ 621,718	\$ 86,906	\$ 534,812	615 %

For the nine months ended September 30, 2021, we had net other expense of \$621,718 related to interest expense and a loss from the change in fair value of derivative liabilities. The primary reason for the increase in the loss on the change in fair value of our derivative liabilities was due to the increase in our stock price and volatility, for the period ended September 30, 2021 as compared to the period ended September 30, 2020. In addition, the Credit Agreement was amended in the prior period which resulted in the extinguishment of the compound derivative liability. The increase in interest expense was due to a higher average outstanding principal balance from non-convertible advances on the Credit Agreement for the period ended September 30, 2021, as compared to the period ended September 30, 2020. Other expenses during the period were offset by the gain on debt forgiveness realized from the PPP Loan.

For the nine months ended September 30, 2020, the Company had other expense of \$86,906 related primarily to interest expense under the Credit Agreement, which was offset by a gain from the decrease in the fair value of our derivative liabilities.

Our results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon the progress of our clinical trials, our research and development efforts, variations in the level of expenditures related to investor relations and seeking new sources of capital, debt service obligations during any given period, and the uncertainty as to the extent and magnitude of the impact from the COVID-19 pandemic. Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results. In particular, to the extent our medical affairs personnel and clinical trial subjects are subject to varying levels of restriction on accessing clinical trial sites due to COVID-19, we expect our progress towards executing our clinical trials to be adversely affected.

Liquidity, Going Concern and Capital Resources

Liquidity and Going Concern

We have incurred operating losses and negative cash flows from operations since our inception. We expect to continue to incur significant losses through 2022 and expect to incur significant losses and negative cash flows from operations in the future. We anticipate that we will continue to incur net losses into the foreseeable future in order to advance and develop potential drug candidates into preclinical and clinical development activities and support our corporate infrastructure, which includes the costs associated with being a public company. We have funded our operations primarily through issuance of equity securities and borrowings from a related party.

On October 5, 2018, we secured a Credit Agreement with Sciences, that provided us with a credit facility of up to \$20,000,000. On April 29, 2020, we entered into the first amendment to the Credit Agreement with Sciences, which amended and restated the Credit Agreement. On March 29, 2021, we entered the second amendment to the Amended Credit Agreement to defer interest payments until the earlier of maturity or prepayment of the principal balance. Effective September 15, 2021, the disbursement line under the credit facility was closed and the Amended Credit Agreement no longer serves as a potential source of liquidity to the Company. The outstanding principal advances of \$2,464,500 under the Amended Credit Agreement bear interest at 7% per annum and mature on October 5, 2022.

On April 22, 2020, we received a principal amount of \$116,700 from City National Bank under the Paycheck Protection Program of the Coronavirus Aid, Relief, and Economic Security Act administered by the U.S. Small Business Administration. We used the proceeds of the PPP loan for the payment of payroll and rent for our office space. On May 20, 2021, the principal amount plus interest was forgiven in full and we recognized a gain of \$117,953 for the nine months ended September 30, 2021.

On July 21, 2021, we entered into the July 2021 Inducement with certain institutional investors to exercise 21,166,667 existing warrants in exchange for the issuance of 21,166,667 new warrants with an exercise price of \$0.15 per share. The existing warrants had an exercise price of \$0.06 and we received gross proceeds of \$1,270,000 from the exercise. Wainwright acted as the placement agent in the transaction and upon the issuance of the Inducement Warrants, we issued 1,481,667 placement agent warrants with an exercise price of \$0.19 and paid \$132,950 in fees to Wainwright.

On September 27, 2021, we entered into a Securities Purchase Agreement with certain institutional investors for the issuance and sale of securities, with Wainwright acting as the placement agent, pursuant to which we sold 58,111,112 shares of common stock and 19,666,667 pre-funded warrants, and issued 77,777,779 common stock warrants, in a registered direct public offering which closed on September 29, 2021. The common stock and pre-funded warrants were sold at a price per share of \$0.09 and \$0.0899, respectively, for gross aggregate proceeds of \$6,998,034. The common stock warrants and pre-funded warrants have an exercise price of \$0.09 and \$0.0001, respectively. The common stock warrants have a term of five years, and the pre-funded warrants are exercisable until all the pre-funded warrants have been exercised in full.

As of September 30, 2021, we had an accumulated deficit of \$44,743,343, stockholders' equity of \$8,264,782 and working capital of \$9,932,242. We had unrestricted cash of \$11,089,624 as of September 30, 2021, as compared to \$2,469,410 as of December 31, 2020. The net increase was primarily attributable to the exercise of 116,666,668 common stock warrants and 11,800,000 pre-funded warrants for cash proceeds of \$6,999,999 and \$11,800, respectively, net cash proceeds of \$6,146,496 from the sale of our common stock, pre-funded warrants, and common stock warrants, as described above, offset by operating cash burn during the nine months ended September 30, 2021. Without additional funding, management believes that we will not have enough funds to meet our obligations and continue our pre-clinical and clinical studies beyond one year after the date the Condensed Consolidated Financial Statements are issued. These conditions indicate it is probable that there is substantial doubt as to our ability to continue as a going concern, unless we are able to raise sufficient capital to continue our operations.

Our independent registered public accounting firm has issued a report on our audited consolidated financial statements as of and for the year ended December 31, 2020 that included an explanatory paragraph referring to our recurring operating losses and expressing substantial doubt in our ability to continue as a going concern. Our Condensed Consolidated Financial Statements have been prepared on a going concern basis, which assumes the realization of assets and settlement of liabilities in the normal course of business. Our ability to continue as a going concern is dependent upon our ability to generate profitable operations in the future and/or to obtain the necessary financing to meet our obligations and repay our liabilities arising from normal business operations when they become due. The outcome of these matters cannot be predicted with any certainty at this time and raise substantial doubt that we will be able to continue as a going concern. Our Condensed Consolidated Financial Statements do not include any adjustments to the amount and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern.

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our Condensed Consolidated Financial Statements which are included elsewhere in this Form 10-Q:

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	\$ (4,506,032)	\$ (4,268,198)
Net cash used in investing activities	(36,828)	—
Net cash provided by financing activities	13,163,078	6,662,822

Cash Flows from Operating Activities

The primary use of cash for our operating activities during these periods was to fund research development activities for our pre-clinical product candidates and general and administrative activities. Our cash used in operating activities also reflected changes in our working capital, net of adjustments for non-cash charges, such as stock-based compensation, non-cash interest expense related to the amortization of the debt discount on our related party Amended Credit Agreement, fair value adjustments related to our warrant liability and the gain realized from the forgiveness of the PPP Loan.

Cash used in operating activities of \$4,506,032 during the nine months ended September 30, 2021, reflected a net loss of \$6,009,362, partially offset by aggregate non-cash charges of \$1,247,113 and included a \$256,217 net change in our operating assets and liabilities. Non-cash charges included \$747,252 for stock-based compensation expense, \$439,053 non-cash interest expense from the amortization of the debt discount on the multi-draw credit facility – related party, a \$169,349 loss from the increase in fair value of our warrant liability and a \$117,953 gain from the forgiveness of the PPP Loan. The net change in our operating assets and liabilities included a \$131,088 increase in our prepaid expense and other current assets, and a \$489,932 increase in our accrued expense and other current liabilities.

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures in relation to the purchase of property plant and equipment. During the nine months ended September 30, 2021, the Company purchased \$36,828 in machinery and office equipment. During the nine months ended September 30, 2020, there were no cash flows from investing activities.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities and debt financings.

During the nine months ended September 30, 2021, cash provided by financing activities included \$7,011,799 in proceeds received in connection with the exercise of warrants, \$6,146,496 in net proceeds from the issuance of common stock, pre-funded warrants and common stock warrants, and \$4,783 received from employee stock option exercises.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Not applicable.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures. We maintain controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that any control and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily is required to apply its judgement in evaluating the cost-benefit relationship of possible controls and procedures.

We conducted an evaluation, under the supervision and with the participation of our principal executive and financial officers, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2021. Based upon their evaluation and subject to the foregoing, the principal executive and financial officers have concluded that, as of the end of the period covered by this report, the disclosure controls and procedures were effective at a reasonable assurance level.

Changes in internal controls. Management determined there were no changes in internal control over financial reporting that occurred during the fiscal quarter covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

There have been no other material developments with respect to previously reported legal proceedings discussed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Our Annual Report on Form 10-K for the year ended December 31, 2020 includes a detailed discussion of our risk factors under the heading “Part I, Item 1A-Risk Factors.” There are no changes from the risk factors previously disclosed in our Annual Report on Form 10-K. You should carefully consider the risk factors discussed in our Annual Report on Form 10-K, as well as the other information in this report before deciding whether to invest in shares of our common stock. The occurrence of any of the risks discussed in the Annual Report on Form 10-K could harm our business, financial condition, results of operations or growth prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On August 16, 2021 and September 29, 2021, we issued 600,000 and 150,000 shares of restricted common stock to a consultant for investor relations services. The issuance of the shares of common stock was exempt from the registration requirements of the Securities Act, pursuant to the exemption for transactions by an issuer not involved in any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder and corresponding state securities laws.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

3.1 ⁽¹⁾	Articles of Incorporation of Registrant, as amended
3.2 ⁽²⁾	Amended and Restated Bylaws of Registrant
4.1 ⁽³⁾	Form of Series A Warrant
4.2 ⁽³⁾	Form of Pre-Funded Warrant
4.3 ⁽³⁾	Form of Placement Agent Warrant
10.1 ⁽⁴⁾	Form of Letter Agreement
10.2 ⁽⁴⁾	Form of New Warrant
10.3 ⁽³⁾	Form of Securities Purchase Agreement
10.4 ⁽³⁾	Form of Lock-up Agreement
31.1*	Certification of Principal Executive Officer, pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934
31.2*	Certification of Principal Financial Officer, pursuant to Rule 13a-14 and 15d-14 of the Securities Exchange Act of 1934
32.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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- (1) Included as exhibit to our Annual Report on Form 10-K filed on March 1, 2021.
- (2) Included as exhibit to our Current Report on Form 8-K filed August 20, 2015.
- (3) Included as exhibit to our Current Report on Form 8-K filed September 28, 2021.
- (4) Included as exhibit to our Current Report on Form 8-K filed July 22, 2021.

(*) Filed herewith.

SIGNATURES

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

**Skye Bioscience, Inc.,
a Nevada corporation**

November 10, 2021

By: /s/ Punit Dhillon

Punit Dhillon

Its: Chief Executive Officer, Secretary, Chairman of the Board, and Director
(Principal Executive Officer)

November 10, 2021

By: /s/ Kaitlyn Arsenault

Kaitlyn Arsenault

Its: Chief Financial Officer
(Principal Financial and Accounting Officer)

**Certification of Principal Executive Officer,
Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as Amended,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Punit Dhillon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Skye Bioscience, Inc. for the quarter ended September 30, 2021;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting, which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Punit Dhillon

Punit Dhillon

Chief Executive Officer, Chairman of the Board, and Director

Date: November 10, 2021

**Certification of Principal Financial Officer,
Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as Amended,
as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, *Kaitlyn Arsenault*, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Skye Bioscience, Inc. for the quarter ended September 30, 2021;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Kaitlyn Arsenault

Kaitlyn Arsenault

Chief Financial Officer

(Principal Accounting Officer)

Date: November 10, 2021

**Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350,
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Skye Bioscience, Inc. a Nevada corporation (the "Company") on Form 10-Q for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Punit Dhillon, Chief Executive Officer, Chairman of the Board, and Director of the Company, certifies to the best of his knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Punit Dhillon

Punit Dhillon

Chief Executive Officer, Chairman of the Board, and Director

Date: November 10, 2021

**Certification of Principal Financial Officer, pursuant to 18 U.S.C. Section 1350,
as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

In connection with the Quarterly Report of Skye Bioscience, Inc. a Nevada corporation (the "Company") on Form 10-Q for the quarter ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Kaitlyn Arsenault, Chief Financial Officer of the Company, certifies to the best of his knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Kaitlyn Arsenault

Kaitlyn Arsenault

Chief Financial Officer

(Principal Accounting Officer)

Date: November 10, 2021