

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

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2021

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: 001-36338

**22nd Century Group, Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or other jurisdiction  
of incorporation)

**98-0468420**  
(IRS Employer  
Identification No.)

**500 Seneca Street, Suite 507, Buffalo, New York 14204**  
(Address of principal executive offices)

**(716) 270-1523**  
(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Title of each class	Ticker symbol	Name of Exchange on Which Registered
Common Stock, \$0.00001 par value	XXII	NASDAQ Capital Market

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, 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 3, 2021, there were 162,748,483 shares of common stock issued and outstanding.

22nd CENTURY GROUP, INC.

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**22nd CENTURY GROUP, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(Unaudited)  
(\$ in thousands, except per-share data)

	September 30, 2021	December 31, 2020
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 1,629	\$ 1,029
Short-term investment securities	53,532	21,313
Accounts receivable, net	1,179	2,159
Inventory, net	2,703	2,034
Prepaid expenses and other assets	3,131	1,806
<b>Total current assets</b>	<u>62,174</u>	<u>28,341</u>
Property, plant and equipment, net	4,754	2,483
Operating leases right-of-use assets, net	478	247
Intangible assets, net	8,036	8,211
Investments	7,300	6,536
Other assets	3,713	5,876
<b>Total assets</b>	<u>\$ 86,455</u>	<u>\$ 51,694</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Notes payable	\$ 1,782	\$ 539
Operating lease obligations	74	247
Accounts payable	1,443	1,116
Accrued expenses	3,440	4,830
Accrued severance	223	339
Deferred income	—	272
<b>Total current liabilities</b>	<u>6,962</u>	<u>7,343</u>
<b>Long-term liabilities:</b>		
Operating lease obligations	407	—
Severance obligations	72	241
<b>Total liabilities</b>	<u>7,441</u>	<u>7,584</u>
<b>Commitments and contingencies (Note 11)</b>		
<b>Shareholders' equity</b>		
10,000,000 preferred shares, \$.00001 par value		
300,000,000 common shares, \$.00001 par value		
Capital stock issued and outstanding:		
162,735,483 common shares (139,061,690 at December 31, 2020)		
Common stock value	2	1
Capital in excess of par value	243,087	189,439
Accumulated other comprehensive (loss) income	(27)	74
Accumulated deficit	(164,048)	(145,404)
<b>Total shareholders' equity</b>	<u>79,014</u>	<u>44,110</u>
<b>Total liabilities and shareholders' equity</b>	<u>\$ 86,455</u>	<u>\$ 51,694</u>

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
**(Unaudited)**  
**(\$ in thousands, except per-share data)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Revenue:</b>				
Sale of products, net	\$ 7,811	\$ 7,310	\$ 22,988	\$ 20,803
<b>Cost of goods sold (exclusive of depreciation shown separately below):</b>				
Products	7,362	6,948	21,306	19,953
Gross profit (loss)	449	362	1,682	850
<b>Operating expenses:</b>				
Research and development	854	906	2,287	2,676
Research and development - MRTPT	2	4	16	158
Sales, general and administrative	6,821	3,169	17,827	9,809
Impairment of intangible assets	—	—	—	146
Depreciation	173	160	461	473
Amortization	168	163	471	524
Total operating expenses	8,018	4,402	21,062	13,786
Operating loss	(7,569)	(4,040)	(19,380)	(12,936)
<b>Other income (expense):</b>				
Unrealized gain (loss) on investments	(1,900)	(429)	(2,040)	(562)
Impairment of Panacea investment	—	—	—	(1,062)
Gain on Panacea investment conversion	—	—	2,548	—
Gain on the sale of property, plant and equipment	—	1	—	1
Interest income, net	52	270	272	1,344
Interest expense	(23)	(23)	(44)	(54)
Total other income (expense)	(1,871)	(181)	736	(333)
Loss before income taxes	(9,440)	(4,221)	(18,644)	(13,269)
Income taxes	—	—	—	38
Net loss	\$ (9,440)	\$ (4,221)	\$ (18,644)	\$ (13,307)
<b>Other comprehensive income (loss):</b>				
Unrealized gain (loss) on short-term investment securities	(28)	87	(101)	132
Other comprehensive income (loss)	(28)	87	(101)	132
<b>Comprehensive loss</b>	<b>\$ (9,468)</b>	<b>\$ (4,134)</b>	<b>\$ (18,745)</b>	<b>\$ (13,175)</b>
<b>Net loss per common share - basic and diluted</b>	<b>\$ (0.06)</b>	<b>\$ (0.03)</b>	<b>\$ (0.12)</b>	<b>\$ (0.10)</b>
<b>Weighted average common shares outstanding - basic and diluted (in thousands)</b>	<b>162,721</b>	<b>138,857</b>	<b>153,998</b>	<b>138,774</b>

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC.**  
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**  
**(Unaudited)**  
**(\$ in thousands)**

	Three and Nine Months Ended September 30, 2021					
	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
<b>Balance at December 31, 2020</b>	<b>139,061,690</b>	<b>\$ 1</b>	<b>\$ 189,439</b>	<b>\$ 74</b>	<b>\$ (145,404)</b>	<b>\$ 44,110</b>
Stock issued in connection with RSU vesting	1,196,258	—	—	—	—	—
Stock issued in connection with option exercises	846,342	—	1,153	—	—	1,153
Stock issued in connection with warrant exercises	11,293,211	1	11,781	—	—	11,782
Equity-based compensation	—	—	507	—	—	507
Unrealized gain (loss) on short-term investment securities	—	—	—	(32)	—	(32)
Net loss	—	—	—	—	(5,030)	(5,030)
<b>Balance at March 31, 2021</b>	<b>152,397,501</b>	<b>\$ 2</b>	<b>\$ 202,880</b>	<b>\$ 42</b>	<b>\$ (150,434)</b>	<b>\$ 52,490</b>
Stock issued in connection with RSU vesting, net of shares withheld for taxes	200,103	—	(469)	—	—	(469)
Stock issued in connection with option exercises	87,879	—	106	—	—	106
Stock issued in connection with capital raise	10,000,000	—	38,206	—	—	38,206
Equity-based compensation	—	—	1,245	—	—	1,245
Unrealized gain (loss) on short-term investment securities	—	—	—	(41)	—	(41)
Net loss	—	—	—	—	(4,174)	(4,174)
<b>Balance at June 30, 2021</b>	<b>162,685,483</b>	<b>\$ 2</b>	<b>\$ 241,968</b>	<b>\$ 1</b>	<b>\$ (154,608)</b>	<b>\$ 87,363</b>
Stock issued in connection with RSU vesting	50,000	—	—	—	—	—
Equity-based compensation	—	—	1,119	—	—	1,119
Unrealized gain (loss) on short-term investment securities	—	—	—	(28)	—	(28)
Net loss	—	—	—	—	(9,440)	(9,440)
<b>Balance at September 30, 2021</b>	<b>162,735,483</b>	<b>\$ 2</b>	<b>\$ 243,087</b>	<b>\$ (27)</b>	<b>\$ (164,048)</b>	<b>\$ 79,014</b>

	Three and Nine Months Ended September 30, 2020					
	Common Shares Outstanding	Par Value of Common Shares	Capital in Excess of Par Value	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Shareholders' Equity
<b>Balance at December 31, 2019</b>	<b>138,362,809</b>	<b>\$ 1</b>	<b>\$ 187,735</b>	<b>\$ 7</b>	<b>\$ (125,693)</b>	<b>\$ 62,050</b>
Stock issued in connection with RSU vesting	491,384	—	—	—	—	—
Equity-based compensation	—	—	480	—	—	480
Unrealized gain (loss) on short-term investment securities	—	—	—	(196)	—	(196)
Reclassification of losses (gains) to net loss	—	—	—	3	—	3
Net loss	—	—	—	—	(4,029)	(4,029)
<b>Balance at March 31, 2020</b>	<b>138,854,193</b>	<b>\$ 1</b>	<b>\$ 188,215</b>	<b>\$ (186)</b>	<b>\$ (129,722)</b>	<b>\$ 58,308</b>
Equity-based compensation	—	—	376	—	—	376
Unrealized gain (loss) on short-term investment securities	—	—	—	241	—	241
Reclassification of losses (gains) to net loss	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(5,057)	(5,057)
<b>Balance at June 30, 2020</b>	<b>138,854,193</b>	<b>\$ 1</b>	<b>\$ 188,591</b>	<b>\$ 52</b>	<b>\$ (134,779)</b>	<b>\$ 53,865</b>
Stock issued in connection with RSU vesting	5,000	—	—	—	—	—
Equity-based compensation	—	—	306	—	—	306
Unrealized gain (loss) on short-term investment securities	—	—	—	87	—	87
Net loss	—	—	—	—	(4,221)	(4,221)
<b>Balance at September 30, 2020</b>	<b>138,859,193</b>	<b>\$ 1</b>	<b>\$ 188,897</b>	<b>\$ 139</b>	<b>\$ (139,000)</b>	<b>\$ 50,037</b>

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(Unaudited)**  
**(\$ in thousands)**

	Nine Months Ended September 30,	
	2021	2020
<b>Cash flows from operating activities:</b>		
Net loss	\$ (18,644)	\$ (13,307)
Adjustments to reconcile net loss to cash used in operating activities:		
Impairment of intangible assets	—	146
Impairment of Panacea investment	—	1,062
Amortization and depreciation	745	810
Amortization of license fees	187	187
Amortization of ROU Asset	214	232
Unrealized (gain) loss on investment	2,040	562
Gain on the sale of machinery and equipment	—	(1)
Gain on Panacea investment conversion	(2,548)	—
Accretion of non-cash interest expense (income)	13	(222)
Equity-based employee compensation expense	2,871	1,162
Inventory write-off	—	219
(Increase) decrease in assets:		
Accounts receivable	980	(692)
Inventory	(669)	(264)
Prepaid expenses and other assets	(1,494)	(1,754)
Increase (decrease) in liabilities:		
Operating lease obligations	(212)	(228)
Accounts payable	289	(924)
Accrued expenses	(1,422)	481
Accrued severance	(285)	(88)
Deferred income	(272)	(5)
<b>Net cash provided by (used in) operating activities</b>	<b>(18,207)</b>	<b>(12,624)</b>
<b>Cash flows from investing activities:</b>		
Acquisition of patents, trademarks, and licenses	(239)	(342)
Acquisition of property, plant and equipment	(470)	(33)
Sales and maturities of short-term investment securities	52,203	28,960
Purchase of short-term investment securities	(84,701)	(15,830)
<b>Net cash provided by (used in) investing activities</b>	<b>(33,207)</b>	<b>12,755</b>
<b>Cash flows from financing activities:</b>		
Payment on note payable	(1,417)	(1,269)
Proceeds from note payable issuance	2,653	2,195
Net proceeds from option exercise	1,259	—
Net proceeds from warrant exercise	11,782	—
Net proceeds from issuance of common stock	38,206	—
Taxes paid related to net share settlement of RSUs	(469)	—
Proceeds from SBA loan	—	1,183
Repayment of SBA loan	—	(1,183)
<b>Net cash provided by (used in) financing activities</b>	<b>52,014</b>	<b>926</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>600</b>	<b>1,057</b>
<b>Cash and cash equivalents - beginning of period</b>	<b>1,029</b>	<b>485</b>
<b>Cash and cash equivalents - end of period</b>	<b>\$ 1,629</b>	<b>\$ 1,542</b>
<b>Supplemental disclosures of cash flow information:</b>		
Net cash paid for:		
Cash paid during the period for interest	\$ 26	\$ 19
Non-cash transactions:		
Patent and trademark additions included in accounts payable	\$ 35	\$ 19
Property, plant and equipment additions included in accounts payable	\$ 4	\$ 9
Property, plant and equipment additions included in accrued expenses	\$ 10	\$ —
Right-of-use assets and corresponding operating lease obligations	\$ 497	\$ 198
Patent and trademark additions included in accrued expenses	\$ 22	\$ 46
Panacea investment conversion	\$ 12,485	\$ —

See accompanying notes to consolidated financial statements.

**22nd CENTURY GROUP, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2021**  
**(Unaudited)**  
**Amounts in thousands, except for share and per-share data**

**NOTE 1. - NATURE OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation** - The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments consisting of normal recurring accruals considered necessary for a fair and non-misleading presentation of the financial statements have been included.

Operating results for the nine months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021. The balance sheet as of December 31, 2020 has been derived from the audited consolidated financial statements at that date but does not include all the information and footnotes required by GAAP for complete financial statements.

These interim consolidated financial statements should be read in conjunction with the December 31, 2020 audited consolidated financial statements and the notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on March 11, 2021.

**Principles of Consolidation** - The accompanying consolidated financial statements include the accounts of (i) 22nd Century Group, Inc. (“22nd Century Group”); (ii) its four wholly-owned subsidiaries, 22nd Century Limited, LLC (“22nd Century Ltd”), NASCO Products, LLC (“NASCO”), Botanical Genetics, LLC (“Botanical Genetics”), and 22nd Century Group Canada, Inc. (“22nd Century Group Canada”); (iii) two wholly-owned subsidiaries of 22nd Century Ltd, Goodrich Tobacco Company, LLC (“Goodrich Tobacco”) and Heracles Pharmaceuticals, LLC (“Heracles Pharma”); and (iv) one wholly-owned subsidiary of Botanical Genetics, 22nd Century Holdings, LLC (“22nd Century Holdings”). This group of subsidiaries is referred to as collectively with 22nd Century Group as the “Company”. All intercompany accounts and transactions have been eliminated.

**Nature of Business** – 22nd Century Group is a leading agricultural biotechnology and intellectual property company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. 22nd Century Ltd performs research and development related to the level of nicotine and other nicotinic alkaloids in tobacco plants and Botanical Genetics performs research and development related to hemp/cannabis plants. Goodrich Tobacco and Heracles Pharma are business units for the Company’s potential modified risk tobacco products. NASCO is a federally licensed tobacco products manufacturer, a subsequent participating member under the tobacco Master Settlement Agreement (“MSA”) between the tobacco industry and the settling states under the MSA and operates the Company’s tobacco products manufacturing business in North Carolina. 22nd Century Holdings and 22nd Century Group Canada are two newly formed subsidiaries where 22nd Century Holdings will own and operate the newly acquired Needle Rock Farm assets and 22nd Century Group Canada will allow for future international business opportunities in Canada.

**Reclassifications** – Certain prior period amounts have been reclassified to conform to the current period’s classification. None of these reclassifications had a material impact on our consolidated financial statements.

**COVID-19 Pandemic** – The COVID-19 pandemic has adversely impacted the U.S. economy and supply chains and created volatility in U.S. financial markets. The COVID-19 pandemic has had a minimal impact on the Company’s operations in 2020 and thus far in 2021, but there is a risk that state and federal authorities’ responses to the COVID-19 pandemic or another pandemic may disrupt our business in the future.

During April 2021, the Company relocated its corporate headquarters into downtown Buffalo, NY. The new office, as well as all of our facilities, continue to operate in compliance with New York and North Carolina guidance (as applicable) related to the prevention of COVID-19 transmission and employee safety. We also continue to allow remote work arrangements by our employees where job duties permit.

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Our executive leadership team and staff are monitoring this evolving situation and its impacts on our business. We will continue to monitor the local, state, and federal guidance regarding our business practices.

**Use of Estimates** - The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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 financial statements and the reported amounts of income and expenses during the reporting period. Actual results could differ from those estimates.

**Intangible Assets** – Intangible assets are recorded at cost and consist primarily of (1) expenditures incurred with third-parties related to the processing of patent claims and trademarks with government authorities, as well as costs to acquire patent rights from third-parties, (2) license fees paid for third-party intellectual property, (3) costs to become a signatory under the tobacco MSA, and (4) license fees paid to acquire a predicate cigarette brand. The amounts capitalized relate to intellectual property that the Company owns or to which it has rights to use.

The Company's capitalized intellectual property costs are amortized using the straight-line method over the remaining statutory life of the patent assets in each of the Company's patent families, which have estimated expiration dates ranging from 2026 to 2041. Periodic maintenance or renewal fees are expensed as incurred. Annual minimum license fees are charged to expense. License fees paid for third-party intellectual property are amortized on a straight-line basis over the last to expire patents, which have expected expiration dates ranging from 2028 through 2036. The Company believes that costs associated with becoming a signatory to the MSA and costs related to the acquisition of a predicate cigarette brand have an indefinite life. As such, no amortization is taken. At each reporting period, the Company evaluates whether events and circumstances continue to support the indefinite-lived classification.

**Impairment of Long-Lived Assets** – The Company reviews the carrying value of its amortizing long-lived assets whenever events or changes in circumstances indicate that the historical cost-carrying value of an asset may no longer be recoverable. On at least an annual basis, the Company assesses whether events or changes in circumstances indicate that the carrying amount may not be recoverable. If any such indicators are present, the Company will test for recoverability in accordance with ASC 360-Property, plant, and equipment or ASC 350- Intangibles, Goodwill, and Other.

Intangible assets subject to amortization are reviewed for strategic importance and commercialization opportunity prior to expiration. If it is determined that the asset no longer supports the Company's strategic objectives and/or will not be commercially viable prior to expiration, the asset is impaired. In addition, the Company will assess the expected future undiscounted cash flows for its intellectual property based on consideration of future market and economic conditions, competition, federal and state regulations, and licensing opportunities. If the carrying value of such assets are not recoverable, the carrying value will be reduced to fair value.

Indefinite-lived intangible asset carrying values are reviewed at least annually or more frequently if events or changes in circumstances indicate that it is more likely than not that an impairment exists. The Company first performs a qualitative assessment and considers its current strategic objectives, future market and economic conditions, competition, and federal and state regulations to determine if an impairment is more likely than not. If it is determined that an impairment is more likely than not, a quantitative assessment is performed to compare the asset carrying value to fair value.

**Fair Value of Financial Instruments** - The Company's financial instruments include cash and cash equivalents, short-term investment securities, accounts receivable, investments, a convertible note receivable, a promissory note receivable, accounts payable, accrued expenses, and notes payable. The carrying values of these financial instruments approximate fair value. The Company carries cash equivalents, short-term investment securities, certain investments, and certain other assets at fair value which is described further in Note 6.

**Investments** – The Company's equity securities are recorded at fair value with changes in fair value included within the statement of operations. Equity securities without a readily determinable market value are carried at cost less impairment, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer. The Company considers certain debt instruments as available-for-sale securities, and accordingly, all unrealized gains and losses incurred on the short-term investment securities (the adjustment to fair value) are recorded in other comprehensive income or loss on the Company's Consolidated Statements of Operations and Comprehensive Loss.



**Right-of-use assets (“ROU”) and Lease Obligations** – The Company reviews any lease arrangements in accordance with ASU 2016-02, Subtopic ASC 842, Leases. Any lease having a lease term greater than twelve months will be recognized on the Consolidated Balance Sheets as a ROU asset with an associated lease obligation—all other leases are considered short-term in nature and will be expensed as payments are made over the lease term. The ROU assets and lease obligations are recognized as of the commencement date at the net present value of the fixed minimum lease payments for the lease term. The lease term is determined based on the contractual conditions, including whether renewal options are reasonably certain to be exercised. The discount rate used is the interest rate implicit in the lease, if available, or the Company’s incremental borrowing rate which is determined using a base line rate plus an applicable spread.

**Stock Based Compensation** – The Company’s Omnibus Incentive Plan allows for various types of equity-based incentive awards. Stock based compensation expense is based on awards that are expected to vest over the requisite service periods and are based on the fair value of the award measured on the grant date. Vesting requirements vary for directors, officers, and employees. In general, time-based awards fully vest after one year for directors and vest in equal annual installments over a three-year period for officers and employees. Performance-based awards vest upon achievement of certain milestones. Forfeitures are accounted for when they occur.

**Income Taxes** - For interim income tax reporting, due to a full valuation allowance on net deferred tax assets, no income tax expense or benefit is recorded unless it is an unusual or infrequently occurring item. The tax effects of unusual or infrequently occurring items, including changes in judgment about valuation allowances and effects of changes in tax laws or rates, are reported in the interim period in which they occur.

**Recent Accounting Pronouncement(s)** – In June 2016, the FASB issued ASU 2016-13, “Measurement of Credit Losses on Financial Instruments.” The standard replaces the incurred loss model with the current expected credit loss (CECL) model to estimate credit losses for financial assets measured at amortized cost and certain off-balance sheet credit exposures. The CECL model requires companies to estimate credit losses expected over the life of the financial assets based on historical experience, current conditions and reasonable and supportable forecasts. The provisions of the ASU are effective for fiscal years beginning after December 15, 2019 and interim periods within those fiscal years—excluding small reporting companies (SRCs), based on a determination date as of November 15, 2019, which have an effective date beginning after December 15, 2022 and interim periods within those fiscal years. The Company is evaluating the expected impacts of the ASU.

We consider the applicability and impact of all ASUs. If the ASU is not listed above, it was determined that the ASU was either not applicable or would have an immaterial impact on our financial statements and related disclosures.

## **NOTE 2. - INVENTORY**

Inventories are valued at the lower of historical cost or net realizable value. Cost is determined using an average cost method for tobacco leaf inventory, hemp/cannabis inventory, and raw materials inventory. Standard cost is primarily used for finished goods inventory. Inventories are evaluated to determine whether any amounts are not recoverable based on slow moving or obsolete condition and are written off or reserved as appropriate. During the nine months ended September 30, 2020, the Company wrote off inventory totaling \$219 on the Company’s Consolidated Statement of Operations and Comprehensive Loss (\$58 included within research and development expenses and \$161 included within cost of goods sold).

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Inventories at September 30, 2021 and December 31, 2020 consisted of the following:

	September 30, 2021	December 31, 2020
Inventory - tobacco leaf	\$ 876	\$ 821
Inventory - hemp/cannabis	132	—
Inventory - finished goods		
Cigarettes and filtered cigars	331	171
Inventory - raw materials		
Cigarette and filtered cigar components	1,464	1,142
Less: inventory reserve	(100)	(100)
	<u>\$ 2,703</u>	<u>\$ 2,034</u>

**NOTE 3. – PROPERTY, PLANT, AND EQUIPMENT, NET**

Property, plant, and equipment, net at September 30, 2021 and December 31, 2020 consisted of the following:

	Useful Life	September 30, 2021	December 31, 2020
Land		\$ 1,665	\$ —
Building and leasehold improvements	7 to 40 years	309	123
Manufacturing equipment	3 to 10 years	5,539	4,893
Office furniture, fixtures and equipment	5 years	129	20
Laboratory equipment	5 years	198	117
Construction in progress		42	—
Less: accumulated depreciation		(3,128)	(2,670)
Property, plant and equipment, net		<u>\$ 4,754</u>	<u>\$ 2,483</u>

Depreciation expense was \$173 and \$461 for the three and nine months ended September 30, 2021 (\$160 and \$473 for the three and nine months ended September 30, 2020).

**NOTE 4. - RIGHT-OF-USE ASSETS, LEASE OBLIGATIONS, AND OTHER LEASES**

The Company leases a manufacturing facility and warehouse in North Carolina, and a corporate headquarters in Buffalo, New York.

The following table summarizes the Company's discount rate and remaining lease terms:

Weighted average remaining lease term in years	6.3
Weighted average discount rate	3.7 %

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Future minimum lease payments as of September 30, 2021 are as follows:

2021	\$	33
2022		76
2023		78
2024		80
2025		82
Thereafter		192
Total lease payments		<u>541</u>
Less: imputed interest		(60)
Total	\$	<u><u>481</u></u>

On July 28, 2021, the Company signed a lease agreement for a new research and development (“R&D”) laboratory in Rockville, MD. The new laboratory space has over four thousand square feet and will support the Company’s continued growth and R&D partnerships. The lease has an initial monthly base rent of \$12 (escalating 2.5% annually after the first year), a term of 51 months, and an expected commencement date of early fourth quarter of this year. The lease also calls for abatement of 100% of the base rent for the first five months following the lease commencement date. The Company will recognize the respective right-of-use asset and lease liability for the lease upon lease commencement, which is anticipated during the fourth quarter of 2021.

On October 18, 2021, the Company signed a lease extension for its manufacturing facility and warehouse in North Carolina. The lease has a commencement date upon expiration of the current lease term, which is November 1, 2021. The lease has a monthly base rent of \$17 and an initial term of twenty-four months—with one twenty-four month renewal option at the Company’s discretion. The Company will recognize the respective right-of-use asset and lease liability during the fourth quarter of 2021.

#### NOTE 5. – INVESTMENTS & OTHER ASSETS

The total carrying value of the Company’s investments and other assets at September 30, 2021 and December 31, 2020 consisted of the following:

	September 30, 2021	December 31, 2020
Aurora stock warrants	\$ 18	\$ 239
Panacea preferred stock	—	5,173
Panacea stock warrant	—	1,124
Exactus common stock	7,282	—
Total Investments	<u>\$ 7,300</u>	<u>\$ 6,536</u>
Convertible note receivable	\$ —	\$ 5,876
Promissory note receivable	<u>\$ 3,713</u>	<u>\$ —</u>

#### *Investment in Panacea Life Sciences, Inc.*

##### *Initial Investment:*

On December 3, 2019, the Company entered into a securities purchase agreement with Panacea Life Sciences, Inc. (“Panacea”) for consideration valued at \$13,297 (\$12,000 cash and \$1,297 of the Company’s shares of common stock valued at \$1 per share) in exchange for a 15.8% ownership interest. The Company’s investment consisted of three instruments: shares of Series B preferred stock (“preferred stock”); a convertible note receivable with a \$7,000 face value; and a warrant (“stock warrant”) to purchase additional shares of Series B preferred stock, to obtain 51% ownership of Panacea, at an exercise price of \$2.344 per share. The convertible note receivable had a term of five years, interest of 10% per annum, and could be converted to shares of Series B preferred stock at the Company’s discretion. The embedded conversion option was not considered a derivative instrument for accounting purposes. The preferred stock carried an annual 10% cumulative dividend, compounded annually, and had an implicit put option after

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the fifth anniversary date so long that the stock warrants had not been exercised. The put option was not considered a derivative instrument for accounting purposes. The stock warrant was exercisable at any time after the fifth anniversary date and would be accelerated if Panacea achieved certain sales targets for two consecutive years. The Series B preferred stock also included first priority equity preferences in the event of a liquidation, sale, or transfer of Panacea assets. These rights entitled the Company to the original Series B issuance price of \$7,000 plus any unpaid accrued dividends.

To allocate the cost of the stock warrant, the Company calculated a fair value based on the following assumptions: volatility of 70%, discount of 25% for lack of marketability, and a risk-free rate of 2%. The value of the stock warrant was allocated to the preferred stock and the convertible note receivable, equally, at a discount to the acquisition price. The discount on the preferred stock was determined to be for lack of control and the discount on the convertible note receivable was determined to be for issuing the note at a below market interest rate for similar instruments.

The convertible note receivable and the preferred stock investment were considered available for sale debt securities with a private company that was not traded in active markets. Since observable price quotations were not available at acquisition, fair value was estimated based on cost less an appropriate discount upon acquisition. The discount of each instrument is accreted into interest income over the respective term as shown within the Company's Consolidated Statements of Operations and Comprehensive Loss. See Note 6 for additional information on these fair value measurements. The stock warrant was recorded at its cost basis in accordance with the practicability exception under ASU 2016-01.

### *Impairment of Panacea Investment:*

As a result of increased competition and other macroeconomic factors, the Company recognized an impairment of \$1,062 on the Panacea stock warrant during the second quarter of 2020. The impairment is recorded within the Consolidated Statements of Operations and Comprehensive Loss as "Impairment of Panacea Investment." During the fourth quarter of 2020, the Company entered into a non-binding agreement with Panacea to potentially restructure the investment and business relationship—including the transfer of an agricultural facility and other assets. As of December 31, 2020, the Company adjusted certain assets to represent the fair value outlined in the non-binding agreement.

### *Conversion of Panacea Investment:*

On June 30, 2021, the Company entered into a Promissory Note Exchange Agreement with Panacea and a Securities Exchange Agreement with Panacea, Exactus, Inc. ("Exactus") (OTCQB:EXDI) and certain other Panacea shareholders. Pursuant to the Securities Exchange Agreement, Exactus fully acquired Panacea. These transactions effected the (i) conversion of all of the Company's Series B Preferred Stock in Panacea into 91,016,026 shares of common stock in Exactus valued at \$9,102 as of June 30, 2021 and (ii) the conversion of the Company's existing debt in Panacea by converting the outstanding \$7,000 principal balance convertible note receivable and all accrued but unpaid interest thereon for fee simple ownership of Needle Rock Farms (224 acres in Delta County, Colorado) and equipment valued at \$2,248, \$500 in Panacea's Series B Preferred Stock (which was subsequently converted to Exactus common stock under the Securities Exchange Agreement), and a new \$4,300 promissory note (the "Promissory note receivable") with a maturity date of June 30, 2026 and a 0% interest rate. The Promissory note receivable is with a related party of Panacea and is fully secured by a first priority lien on Panacea's headquarters located in Golden, Colorado. All other rights and obligations of the Company in Panacea and Panacea's affiliate, Quintel-MC Incorporated, were terminated by this transaction—including all warrant rights and obligations for future investment. The conversion was recorded as a non-monetary transaction, based on the fair value of the assets received, and resulted in a gain of \$2,548 which is included within the Consolidated Statements of Operations and Comprehensive Loss as "Gain on Panacea investment conversion."

The Promissory note receivable was valued at \$3,684 (\$4,300 face value less \$616 discount) and is included within the Consolidated Balance Sheets as "Other Assets." The Company intends to hold the Promissory note receivable to maturity and the associated discount will be amortized into interest income over the term of the note. The ownership of Needle Rock Farms and related equipment is included within "Property, plant, and equipment, net" on the Consolidated Balance Sheets. The common shares of Exactus, Inc. are considered equity securities in accordance with ASC 321 and are recorded at fair value—changes in fair value will be included within the statement of operations. See Note 6 for additional information on the fair value measurements.

On October 28, 2021, Exactus announced the completion of a 1 for 28 reverse stock split as well as an entity name change to Panacea Life Sciences Holdings, Inc (OTCQB: PLSH). Panacea Life Sciences Holdings, Inc. has been assigned a temporary stock

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symbol of “EXDID” which will formally change to “PLSH” after twenty business days. As a result of the reverse stock split, our 91,016,026 shares were adjusted to 3,250,573 shares.

**Investment in Aurora Cannabis, Inc.**

The Company has an investment in Aurora Cannabis Inc. (“Aurora”) stock warrants that are considered equity securities under ASC 321 – Investments – Equity Securities and a derivative instrument under ASC 815 – Derivatives and Hedging. The stock warrants are not designated as a hedging instrument, and in accordance with ASC 815, the Company’s investment in stock warrants are recorded at fair value with changes in fair value recorded to unrealized gain/loss as shown within the Company’s Consolidated Statements of Operations and Comprehensive Loss. See Note 6 for additional information on the fair value measurements.

**NOTE 6. – FAIR VALUE MEASUREMENTS AND SHORT-TERM INVESTMENTS**

FASB ASC 820 - “Fair Value Measurements and Disclosures” establishes a valuation hierarchy for disclosure of the inputs to valuation used to measure fair value. This hierarchy prioritizes the inputs into three broad levels as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument; and
- Level 3 inputs are unobservable inputs based on the Company’s own assumptions used to measure assets and liabilities at fair value.

A financial asset’s or a financial liability’s classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

The following table presents information about our assets and liabilities measured at fair value as of September 30, 2021 and December 31, 2020, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	Fair Value September 30, 2021			Total
	Level 1	Level 2	Level 3	
<b>Assets</b>				
Short-term investment securities:				
Money market funds	\$ 18,481	\$ —	\$ —	\$ 18,481
Corporate bonds	—	35,051	—	35,051
Total short-term investment securities	\$ 18,481	\$ 35,051	\$ —	\$ 53,532
Investment - Aurora stock warrants	\$ —	\$ —	\$ 18	\$ 18
Investment - Exactus common shares	\$ 7,282	\$ —	\$ —	\$ 7,282

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	Fair Value December 31, 2020			
	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Short-term investment securities:				
Money market funds	\$ 8,636	\$ —	\$ —	\$ 8,636
Corporate bonds	—	12,677	—	12,677
Total short-term investment securities	\$ 8,636	\$ 12,677	\$ —	\$ 21,313
Investment - Aurora stock warrants	\$ —	\$ —	\$ 239	\$ 239
Investment - Panacea preferred stock	\$ —	\$ —	\$ 5,173	\$ 5,173
Convertible note receivable	\$ —	\$ —	\$ 5,876	\$ 5,876

Money market mutual funds are valued at their daily closing price as reported by the fund. Money market mutual funds held by the Company are open-end mutual funds that are registered with the SEC that generally transact at a stable \$1.00 Net Asset Value (“NAV”) representing its estimated fair value. On a daily basis the fund’s NAV is determined by the fund based on the amortized cost of the funds underlying investments.

Corporate bonds are valued using pricing models maximizing the use of observable inputs for similar securities.

The investment in the Aurora (“ACB”) stock warrants is measured at fair value using the Black-Scholes pricing model and is classified within Level 3 of the valuation hierarchy. The unobservable input is an estimated volatility factor of 94% and 137% as of September 30, 2021 and December 31, 2020, respectively. Therefore, changes in market volatility will impact the fair value measurement of our ACB investment.

A 20% increase or decrease in the volatility factor used as of September 30, 2021 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by approximately \$22. A 20% increase or decrease in the volatility factor used at December 31, 2020 would have the impact of increasing or decreasing the fair value measurement of the stock warrants by approximately \$115.

The investment in Exactus common shares is considered an equity security with a readily determinable fair value. The fair value is determined using the quotable market price as of the last trading day of the fiscal quarter.

The Panacea convertible note receivable and the preferred stock investment were considered available-for-sale debt securities with a private company not traded in active markets. Since observable price quotations were not available, fair value was estimated based on cost less an appropriate discount upon acquisition.

The following table sets forth a summary of the changes in fair value of the Company’s Level 3 investments for the nine months ended September 30, 2021:

Fair Value at December 31, 2020	\$ 11,288
Unrealized gain (loss) on ACB stock warrants	(220)
Accretion of interest on Panacea preferred stock	142
Panacea investment conversion	(11,192)
Fair Value at September 30, 2021	\$ 18

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The following tables set forth a summary of the Company's available-for-sale debt securities from amortized cost basis to fair value as of September 30, 2021 and December 31, 2020:

	Available for Sale Debt Securities			
	September 30, 2021			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 35,078	\$ 7	\$ (34)	\$ 35,051

  

	Available for Sale Debt Securities			
	December 31, 2020			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate bonds	\$ 12,603	\$ 74	\$ —	\$ 12,677
Convertible note receivable	5,876	—	—	5,876
Investment - Panacea preferred stock	5,173	—	—	5,173
	\$ 23,652	\$ 74	\$ —	\$ 23,726

The following table sets forth a summary of the Company's available-for-sale securities at amortized cost basis and fair value by contractual maturity as of September 30, 2021 and December 31, 2020:

	Available for Sale Debt Securities			
	September 30, 2021		December 31, 2020	
	Amortized Cost Basis	Fair Value	Amortized Cost Basis	Fair Value
Due in one year or less	\$ 3,581	\$ 3,585	\$ 11,692	\$ 11,753
Due after one year through five years	31,497	31,466	11,960	11,973
	\$ 35,078	\$ 35,051	\$ 23,652	\$ 23,726

**NOTE 7. - INTANGIBLE ASSETS**

Total intangible assets at September 30, 2021 and December 31, 2020 consisted of the following:

	September 30, 2021	December 31, 2020
Intangible assets, net		
Patent and trademark costs	\$ 5,951	\$ 5,667
Less: accumulated amortization	(3,207)	(2,936)
Patent and trademark costs, net	2,744	2,731
License fees	3,876	3,876
Less: accumulated amortization	(1,136)	(948)
License fees, net	2,740	2,928
MSA signatory costs	2,202	2,202
License fee for predicate cigarette brand	350	350
	\$ 8,036	\$ 8,211

Amortization expense relating to the above intangible assets for the three and nine months ended September 30, 2021 amounted to \$168 and \$471 (\$163 and \$524 for the three and nine months ended September 30, 2020). Impairment expense for the three and nine months ended September 30, 2020 amounted to \$0 and \$146 (cost of approximately \$448 less accumulated amortization of approximately \$302), respectively, and related to patent intellectual property that would be expired prior to expected commercialization.

**NOTE 8. – NOTES PAYABLE***License Fees*

On June 22, 2018, the Company entered into the Second Amendment to the License Agreement (the “Second Amendment”) with North Carolina State University (“NCSU”) that amended an original License Agreement between the Company and NCSU, dated December 8, 2015, and the First Amendment, dated February 14, 2018, to the original License Agreement. Under the terms of the Second Amendment, the Company was obligated to pay NCSU milestone payments totaling \$1,200, which originally amounted to a present value of \$1,175. As of June 30, 2020, the Company paid the final milestone payment of \$300. The cost of the of acquired license amounted to \$1,175 and is included in Intangible assets, net on the Company’s Consolidated Balance Sheets, and is amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2036.

On October 22, 2018, the Company entered into a License Agreement with the University of Kentucky. Under the terms of the License Agreement, the Company is obligated to pay the University of Kentucky milestone payments totaling \$1,200, of which \$300 was payable upon execution, and \$300 will be payable annually over three years on the anniversary of the execution of the License Agreement. The Company has recorded the present value of the obligations under the License Agreement as a note payable that originally amounted to \$1,151. The cost of the of acquired licenses amounted to \$1,151 and is included in Intangible assets, net on the Company’s Consolidated Balance Sheets and will be amortized on a straight-line basis over the last-to-expire patent, which is expected to be in 2033.

*D&O Insurance*

During the second quarter of 2021, the Company renewed its Director and Officer (“D&O”) insurance for a one-year policy premium totaling \$3,315. The Company paid \$662 as a premium down payment and financed the remaining \$2,653 of policy premiums over nine months at a 3.49% annual percentage rate.

During the second quarter of 2020, the Company renewed its D&O insurance for a one-year policy premium totaling \$2,744. The Company paid \$549 as a premium down payment and financed the remaining \$2,195 of policy premiums over nine months at a 3.19% annual percentage rate.

*CARES Act Paycheck Protection Program Loan*

On May 1, 2020, the Company received an U.S. Small Business Administration Loan (“SBA Loan”) from Bank of America, N.A. related to the COVID-19 pandemic in the amount of \$1.2 million. On May 12, 2020, the Company repaid the SBA loan in full.

The table below outlines our notes payable balances as of September 30, 2021 and December 31, 2020:

	September 30, 2021	December 31, 2020
License Fees	\$ 299	\$ 293
D&O Insurance	1,483	246
Total current notes payable	<u>\$ 1,782</u>	<u>\$ 539</u>

Accretion of non-cash interest expense amounted to \$2 and \$6 for the three and nine months ended September 30, 2021 and \$4 and \$17 for the three and nine months ended September 30, 2020.

**NOTE 9. – SEVERANCE LIABILITY**

During the second quarter of 2020, the Company recorded severance benefits related to a resignation of \$306. The benefits were provided over a twelve-month period.

During 2019, the Company recorded severance benefits of \$881. Consistent with certain contractual obligations, \$771 of the related benefit will be provided over a period of forty-two months.



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The current and long-term accrued severance balance remaining as of September 30, 2021 was \$223 and \$72, respectively. The current and long-term accrued severance balance remaining as of December 31, 2020 was \$339 and \$241, respectively.

**NOTE 10. – CAPITAL RAISE AND WARRANT EXERCISE**

On June 7, 2021, the Company entered into a placement agent agreement (the “Placement Agent Agreement”) with Cowen and Company, LLC (the “Placement Agent”) relating to the Company’s registered direct offering (the “Offering”) to a select investor (the “Investor”). In addition, on June 7, 2021, the Company and the Investor entered into a securities purchase agreement relating to the issuance and sale of shares of common stock pursuant to which the Investor purchased 10,000,000 shares of common stock at \$4.00 per share. The net proceeds to the Company from the Offering, after deducting Placement Agent fees and offering expenses, was \$38,206.

During the first quarter of 2021, the Company’s warrant holders exercised all 11,293,211 outstanding warrants for cash in exchange for common stock. In connection with these exercises, the Company received net proceeds of \$11,782. No warrants remain outstanding as of September 30, 2021. The following table summarizes the Company’s outstanding warrant activity since December 31, 2020:

	Number of Warrants
Warrants outstanding at December 31, 2020	11,293,211
Warrants exercised in Q1 2021	(11,293,211)
Warrants outstanding at September 30, 2021	—

**NOTE 11. - COMMITMENTS AND CONTINGENCIES**

**License agreements and sponsored research** – The Company has entered into various license, sponsored research, collaboration, and other agreements (the “Agreements”) with various counter parties in connection with the Company’s plant biotechnology business relating to tobacco and hemp/cannabis. The schedule below summarizes the Company’s commitments, both financial and other, associated with each Agreement. Costs incurred under the Agreements are generally recorded as research and development expenses on the Company’s Consolidated Statements of Operations and Comprehensive Loss.

Commitment	Counter Party	Product Relationship	Commitment Type	Future Commitments					Total
				2021	2022	2023	2024	2025 & After	
Research Agreement	KeyGene	Hemp / Cannabis	Contract fee	\$ 115	\$ 1,150	\$ 1,200	\$ 1,227	\$ 2,893	\$ 6,585 (1)
License Agreement	NCSU	Tobacco	Annual royalty fee	68	225	—	—	—	293 (2), (3)
License Agreement	NCSU	Tobacco	Minimum annual royalty	7	50	50	50	600	757 (3)
License Agreement	NCSU	Tobacco	Minimum annual royalty	14	50	50	50	500	664 (3)
Sublicense Agreement	Anandia Laboratories, Inc.	Hemp / Cannabis	Annual license fee	10	10	10	10	110	150 (4)
Research Agreement	Cannametrix	Hemp / Cannabis	Contract fee	51	50	—	—	—	101 (5)
Growing Agreement	Various	Various	Contract fee	127	38	—	—	—	165 (6)
Consulting Agreement	Various	Various	Contract fee	119	286	—	—	—	405 (7)
				\$ 511	\$ 1,859	\$ 1,310	\$ 1,337	\$ 4,103	\$ 9,120

- (1) Exclusive agreement with the Company with respect to the *Cannabis Sativa L.* plant (the "Field"). The initial term of the agreement was five years with an option for an additional two years. On April 30, 2021, the Company and KeyGene entered into a First Amended and Restated Framework Collaborative Research Agreement which extended the agreement term, from first-quarter 2024 to first-quarter 2027, and preserves the Company’s option for an additional 2-year extension, now through first quarter of 2029.

The Company will exclusively own all results and all intellectual property relating to the results of the collaboration with KeyGene (the "Results"). The Company will pay royalties in varying amounts to KeyGene relating to the Company's commercialization in the Field of certain Results. The Company has also granted KeyGene a license to commercialize the Results outside of the Field and KeyGene will pay royalties in varying amounts to the Company relating to KeyGene's commercialization of the Results outside of the Field.

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- (2) The license agreement also requires a milestone payment of \$150 upon FDA approval or clearance of a product that uses the NCSU licensed technology. The annual royalty fee is credited against running royalties on sales of licensed products.
- (3) The Company is also responsible for reimbursing NSCU for actual third-party patent costs incurred, including capitalized patent costs and patent maintenance costs. These costs vary from year to year and the Company has certain rights to direct the activities that result in these costs.
- (4) The Company is also responsible for the payment of certain costs, including, capitalized patent costs and patent maintenance costs, a running royalty on future net sales of products made from the sublicensed intellectual property, and a sharing of future sublicensing consideration received from sublicensing to third parties in all countries except for Canada. Anandia retains all patent rights, and is responsible for all patent maintenance, in Canada.
- (5) On March 1, 2021, the Company entered into a 14-month research agreement with Cannametrix for hemp/cannabis product development, formulation, and validation.
- (6) Various R&D growing and consulting agreements for hemp / cannabis and tobacco.
- (7) General corporate consulting agreements.

**Modified Risk Tobacco Product Application (“MRTP Application”)** – In connection with the Company’s MRTP Application for its Very Low Nicotine Content (“VLNC”) cigarettes with the FDA, the Company has entered in various contracts with third-party service providers to fulfill various requirements of the MRTP Application. Such contracts include services for clinical trials, perception studies, legal guidance, product testing, and consulting expertise. During the three and nine months ended September 30, 2021, the Company incurred expenses relating to these contracts in the approximate amount of \$2 and \$16, respectively, and \$4 and \$158 for the three and nine months ended September 30, 2020, respectively. The Company will continue to incur consulting and legal expenses as the MRTP Application continues through the FDA review process. The Company cannot currently quantify the additional expenses that the Company will incur in the FDA review process because it will involve various factors that are within the discretion and control of the FDA.

**Litigation** - In accordance with applicable accounting guidance, the Company establishes an accrued liability for litigation and regulatory matters when those matters present loss contingencies that are both probable and estimable. In such cases, there may be an exposure to loss in excess of any amounts accrued. When a loss contingency is not both probable and estimable, the Company does not establish an accrued liability. As a litigation or regulatory matter develops, the Company, in conjunction with any outside counsel handling the matter, evaluates on an ongoing basis whether such matter presents a loss contingency that is probable and estimable. If, at the time of evaluation, the loss contingency related to a litigation or regulatory matter is not both probable and estimable, the matter will continue to be monitored for further developments that would make such loss contingency both probable and estimable. When a loss contingency related to a litigation or regulatory matter is deemed to be both probable and estimable, the Company will establish an accrued liability with respect to such loss contingency and record a corresponding amount of related expenses. The Company will then continue to monitor the matter for further developments that could affect the amount of any such accrued liability.

### *Class Action*

On January 21, 2019, Matthew Jackson Bull, a resident of Denver, Colorado, filed a Complaint against the Company, the Company’s then Chief Executive Officer, Henry Sicignano III, and the Company’s then Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Matthew Bull, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 1:19 cv 00409.

On January 29, 2019, Ian M. Fitch, a resident of Essex County Massachusetts, filed a Complaint against the Company, the Company’s then Chief Executive Officer, Henry Sicignano III, and the Company’s then Chief Financial Officer, John T. Brodfuehrer, in the United States District Court for the Eastern District of New York entitled: Ian Fitch, Individually and on behalf of all others similarly situated, v. 22nd Century Group, Inc., Henry Sicignano III, and John T. Brodfuehrer, Case No. 2:19 cv 00553.

On May 28, 2019, the plaintiff in the Fitch case voluntarily dismissed that action. On August 1, 2019, the Court in the Bull case issued an order designating Joseph Noto, Garden State Tire Corp, and Stephens Johnson as lead plaintiffs.

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On September 16, 2019, pursuant to a joint motion by the parties, the Court in the Bull case transferred the class action to federal district court in the Western District of New York, where it remains pending as Case No. 1:19-cv-01285.

Plaintiffs in the Bull case filed an Amended Complaint on November 19, 2019 that alleges three counts: Count I sues the Company and Messrs. Sicignano and Brodfuehrer and alleges that the Company's quarterly and annual reports, SEC filings, press releases and other public statements and documents contained false statements in violation of Section 10(b) of the Securities Exchange Act and Rule 10b-5; Count II sues Messrs. Sicignano and Brodfuehrer pursuant to Section 10(b) of the Securities Exchange Act and Rule 10b5(a) and (c); and Count III sues Messrs. Sicignano and Brodfuehrer for the allegedly false statements pursuant to Section 20(a) of the Securities Exchange Act. The Amended Complaint seeks to certify a class, and unspecified compensatory and punitive damages, and attorney's fees and costs.

On January 29, 2020, the Company and Messrs. Sicignano and Brodfuehrer filed a Motion to Dismiss the Amended Complaint. On July 31, 2020, the Court heard oral arguments on the motion to dismiss. On January 14, 2021, the Court granted motion, dismissing all claims with prejudice. The Plaintiffs filed a notice of appeal on February 12, 2021 to the Second Circuit Court of Appeals. The Second Circuit has granted an expedited briefing schedule and Plaintiff's/Appellant's was filed on April 12, 2021 and the Company's was filed on May 17, 2021. The Second Circuit heard oral arguments on September 2, 2021 and the matter remains pending with the Second Circuit.

We believe that the claims are frivolous, meritless and that the Company and Messrs. Sicignano and Brodfuehrer have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and Messrs. Sicignano and Brodfuehrer against such claims.

### *Shareholder Derivative Cases*

On February 6, 2019, Melvyn Klein, a resident of Nassau County New York, filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the United States District Court for the Eastern District of New York entitled: Melvyn Klein, derivatively on behalf of 22nd Century Group v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer and 22nd Century Group, Inc., Case No. 1:19 cv 00748. Mr. Klein brings this action derivatively alleging that (i) the director defendants supposedly breached their fiduciary duties for allegedly allowing the Company to make false statements; (ii) the director defendants supposedly wasted corporate assets to defend this lawsuit and the other related lawsuits; (iii) the defendants allegedly violated Section 10(b) of the Securities Exchange Act and Rule 10b 5 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made; and (iv) the director defendants allegedly violated Section 14(a) of the Securities Exchange Act and Rule 14a 9 promulgated thereunder for allegedly approving or allowing false statements regarding the Company to be made in the Company's proxy statement.

On February 11, 2019, Stephen Mathew filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: Stephen Mathew, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, John T. Brodfuehrer, Richard M. Sanders, Joseph Alexander Dunn, James W. Cornell, Nora B. Sullivan and 22nd Century Group, Inc., Index No. 801786/2019. Mr. Mathew brings this action derivatively generally alleging the same allegations as in the Klein case. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and attorney's fees and costs. On August 15, 2019, the Court consolidated the Mathew and Klein actions pursuant to a stipulation by the parties (Western District of New York, Case No. 1-19-cv-0513). We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

On June 10, 2019, Judy Rowley filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and each member of the Company's Board of Directors in the Supreme Court of the State of New York, County of Erie, entitled: Judy Rowley, derivatively on behalf of 22nd Century Group, Inc. v. Henry Sicignano, III, Richard M. Sanders, Joseph Alexander Dunn, Nora B. Sullivan, James W. Cornell, John T. Brodfuehrer, and 22nd Century Group, Inc., Index No. 807214/2019. Ms. Rowley brings this action derivatively alleging that the director defendants supposedly breached their fiduciary duties by allegedly allowing the Company to make false statements. The Complaint seeks declaratory relief, unspecified monetary damages, corrective corporate governance actions, and

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attorney's fees and costs. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims. On September 13, 2019, the Court ordered the litigation stayed pursuant to a joint stipulation by the parties.

On January 15, 2020, Kevin Broccuto filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and certain members of the Company's prior Board of Directors in the District Court of the State of Nevada, County of Clark, entitled: Kevin Broccuto, derivatively on behalf of 22nd Century Group, Inc. v. James W. Cornell, Richard M. Sanders, Nora B. Sullivan, Henry Sicignano, III, and John T. Brodfuehrer, Case No. A-20-808599. Mr. Broccuto brings this action derivatively alleging three counts: Count I alleges that the defendants breached their fiduciary duties; Count II alleges they committed corporate waste; and Count III that they were unjustly enriched, by allegedly allowing the Company to make false statements.

On February 11, 2020, Jerry Wayne filed a shareholder derivative claim against the Company, the Company's then Chief Executive Officer, Henry Sicignano III, the Company's Chief Financial Officer, John T. Brodfuehrer, and certain members of the Company's prior Board of Directors in the District Court of the State of Nevada, County of Clark, entitled: Jerry Wayne, derivatively on behalf of 22nd Century Group, Inc. v. James W. Cornell, Richard M. Sanders, Nora B. Sullivan, Henry Sicignano, III, and John T. Brodfuehrer, Case No. A-20-808599. Mr. Wayne brings this action derivatively alleging generally the same allegations as the Broccuto case. The Complaint seeks unspecified monetary damages, corrective corporate governance actions, disgorgement of alleged profits and imposition of constructive trusts, and attorney's fees and costs. The Complaint also seeks to declare as unenforceable the Company's Bylaw requiring derivative lawsuits to be filed in Erie County, New York, where the Company is headquartered.

On March 25, 2020, the Court ordered the Broccuto and Wayne cases consolidated and stayed pursuant to a joint stipulation from the parties. We believe that the claims are frivolous, meritless and that the Company and the individual defendants have substantial legal and factual defenses to the claims. We intend to vigorously defend the Company and the individual defendants against such claims.

**NOTE 12 – EQUITY- BASED COMPENSATION**

On May 20, 2021, the stockholders of 22nd Century Group, Inc. (the “Company”) approved the 22nd Century Group, Inc. 2021 Omnibus Incentive Plan (the “Plan”). The Plan allows for the granting of equity awards to eligible individuals over the life of the Plan, including the issuance of up to 5,000,000 shares of the Company's common stock and any remaining shares under the Company's 2014 Omnibus Incentive Plan pursuant to awards under the Plan. The Plan has a term of ten years and is administered by the Compensation Committee of the Company's Board of Directors to determine the various types of incentive awards that may be granted to recipients under the Plan and the number of shares of common stock to underlie each such award under the Plan. As of September 30, 2021, the Company had available 7,449,946 shares remaining for future awards under the Plan.

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*Restricted Stock Units (“RSUs”).* We typically grant RSUs to employees and non-employee directors. The following table summarizes the changes in unvested RSUs from December 31, 2020 through September 30, 2021.

	Unvested RSUs	
	Number of Shares in thousands	Weighted Average Grant-date Fair Value \$ per share
Unvested at December 31, 2020	2,938	\$ 0.85
Granted	1,995	\$ 3.20
Vested	(1,234)	\$ 0.85
Forfeited	(216)	\$ 0.67
Unvested at March 31, 2021	3,483	\$ 2.21
Granted	15	\$ 4.60
Vested	(288)	\$ 0.86
Forfeited	(25)	\$ 1.04
Unvested at June 30, 2021	3,185	\$ 2.35
Granted	190	\$ 3.71
Vested	(50)	\$ 0.80
Forfeited	(10)	\$ 1.90
Unvested at September 30, 2021	3,315	\$ 2.45

The fair value of RSUs that vested during the nine months ended September 30, 2021 was approximately \$5,057 based on the stock price at the time of vesting.

*Stock Options.* Our outstanding stock options were valued using the Black-Scholes option-pricing model on the date of the award. A summary of all stock option activity since December 31, 2020 is as follows:

	Number of Options in thousands	Weighted Average Exercise Price \$ per share	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2020	6,581	\$ 1.50		
Granted	235	\$ 3.10		
Exercised	(846)	\$ 1.36		
Expired	(6)	\$ 2.76		
Outstanding at March 31, 2021	5,964	\$ 1.59	4.3 years	\$ 7,480
Exercised	(88)	\$ 1.21		
Forfeited	(100)	\$ 0.80		
Outstanding at June 30, 2021	5,776	\$ 1.60	4.1 years	\$ 13,265
Expired	(40)	\$ 2.58		
Forfeited	(500)	\$ 1.04		
Outstanding at September 30, 2021	5,236	\$ 1.65	3.8 years	\$ 6,885
Exercisable at September 30, 2021	4,900	\$ 1.56	3.7 years	\$ 6,848

The intrinsic value of a stock option is the amount by which the current market value or the market value upon exercise of the underlying stock exceeds the exercise price of the option.

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The weighted average of fair value assumptions used in the Black-Scholes option-pricing model for such grants were as follows:

	2021
Risk-free interest rate (1)	0.54 %
Expected dividend yield (2)	— %
Expected volatility (3)	87.92 %
Expected term of stock options (4)	4.09 years

- (1) The risk-free interest rate is based on the period matching the expected term of the stock options based on the U.S. Treasury yield curve in effect on the grant date.
- (2) The expected dividend yield is assumed as zero. The Company has never paid cash dividends nor does it anticipate paying dividends in the foreseeable future.
- (3) The expected volatility is based on historical volatility of the Company's stock.
- (4) The expected term represents the period of time that options granted are expected to be outstanding based on vesting date and contractual term.

*Compensation Expense.* The Company recognized the following compensation costs, net of actual forfeitures, related to RSUs and stock options:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Sales, general, and administrative	\$ 1,073	\$ 278	\$ 2,750	\$ 1,051
Research and Development	46	28	121	111
<b>Total RSUs and stock option compensation</b>	<b>\$ 1,119</b>	<b>\$ 306</b>	<b>\$ 2,871</b>	<b>\$ 1,162</b>

As of September 30, 2021, unrecognized compensation expense amounted to \$5,931 which is expected to be recognized over a weighted average period of approximately 1.1 years. In addition, there is approximately \$517 of unrecognized compensation expense that requires the achievement of certain milestones which are not yet probable.

#### NOTE 13. – REVENUE RECOGNITION

The Company recognizes revenue when it satisfies a performance obligation by transferring control of the product to a customer. The Company's customer contracts consist of obligations to manufacture the customer's branded filtered cigars and cigarettes. For certain contracts, the performance obligation is satisfied over time as the Company determines, due to contract restrictions, it does not have an alternative use of the product and it has an enforceable right to payment as the product is manufactured. The Company recognizes revenue under those contracts at the unit price stated in the contract based on the units manufactured. Revenue from the sale of the Company's products is recognized net of cash discounts, sales returns and allowances. There was no allowance for discounts or returns and allowances at September 30, 2021 and December 31, 2020.

#### *Contract Assets and Liabilities*

Unbilled receivables (contract assets) represent revenues recognized for performance obligations that have been satisfied but have not been billed. These receivables are included as Accounts receivable, net on the Consolidated Balance Sheets. Customer payment terms vary depending on the terms of each customer contract, but payment is generally due prior to product shipment or within extended credit terms up to twenty-one (21) days after shipment. Deferred Revenue (contract liabilities) relate to down payments received from customers in advance of satisfying a performance obligation. This deferred revenue is included as Deferred income on the Consolidated Balance Sheets.

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Total contract assets and contract liabilities are as follows:

	September 30, 2021	December 31, 2020
Unbilled receivables	\$ 494	\$ 349
Deferred Revenue	—	(272)
Net contract assets	<u>\$ 494</u>	<u>\$ 77</u>

*Disaggregation of Revenue*

The Company's net sales revenue is derived from customers located primarily in the United States of America and is disaggregated by the timing of revenue recognition—net sales transferred over time and net sales transferred at a point in time. All revenue is related to contract manufacturing.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net sales-over time	\$ 5,344	\$ 4,339	\$ 16,461	\$ 12,769
Net sales-point in time	2,467	2,971	6,527	8,034
Total Revenue	<u>\$ 7,811</u>	<u>\$ 7,310</u>	<u>\$ 22,988</u>	<u>\$ 20,803</u>

**NOTE 14. – EARNINGS PER SHARE**

The following table sets forth the computation of basic and diluted earnings (loss) per common share for the three and nine months ended September 30, 2021 and 2020, respectively. Outstanding warrants, options, and RSUs were excluded from the calculation of diluted EPS as the effect was antidilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (9,440)	\$ (4,221)	\$ (18,644)	\$ (13,307)
Weighted average common shares outstanding - basic and diluted	162,721	138,857	153,998	138,774
Net loss per common share - basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.03)</u>	<u>\$ (0.12)</u>	<u>\$ (0.10)</u>

Anti-dilutive shares are as follows:

Warrants	—	11,293	—	11,293
Options	5,236	7,259	5,236	7,259
Restricted stock units	3,315	2,878	3,315	2,878
	<u>8,551</u>	<u>21,430</u>	<u>8,551</u>	<u>21,430</u>

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

*The following Management’s Discussion and Analysis of Financial Condition and Results of Operations (“MD&A”) should be read in conjunction with, our audited consolidated financial statements, the accompanying notes and the MD&A included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as well as our consolidated financial statements and the accompanying notes included in Item 1 of this Form 10-Q. Note references are to the notes to consolidated financial statements included in Item 1 of this Form 10-Q.*

*For purposes of this MD&A, references to the “Company,” “we,” “us” or “our” refer to the operations of 22nd Century Group, Inc. and its direct and indirect subsidiaries for the periods described herein.*

### **Forward Looking Statements**

*Except for historical information, all of the statements, expectations, and assumptions contained in this section are forward-looking statements. Forward-looking statements typically contain terms such as “anticipate,” “believe,” “consider,” “continue,” “could,” “estimate,” “expect,” “explore,” “foresee,” “goal,” “guidance,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “preliminary,” “probable,” “project,” “promising,” “seek,” “should,” “will,” “would,” and similar expressions. Actual results might differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in “Risk Factors” in our Annual Report on Form 10-K filed on March 11, 2021. We undertake no obligation to publicly update or revise any forward-looking statement as a result of new information, future events, or otherwise, except as otherwise required by law. All information provided in this quarterly report is as of the date hereof, and we assume no obligation to and do not intend to update these forward-looking statements, except as required by law.*

### **Corporate Business Overview**

22nd Century Group, Inc. (Nasdaq: XXII) is a leading agricultural biotechnology and intellectual property company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. We utilize modern plant breeding technologies, gene-editing, and molecular breeding to create new, proprietary tobacco, hemp/cannabis and hop plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits. With dozens of patents allowing us to control nicotine biosynthesis in the tobacco plant, we have developed our proprietary reduced nicotine content (RNC) tobacco plants and cigarettes which have become the cornerstone of the FDA’s Comprehensive Plan to address the widespread death and disease caused by smoking. We have also begun to leverage its plant science expertise and existing partnerships to create and commercialize new, proprietary hemp/cannabis and hop plants to optimize genetics and create valuable new intellectual property.



## **Tobacco Franchise Overview**

In tobacco, we have developed unique and proprietary bright and burley Very Low Nicotine Content (“VLNC”) tobaccos that grow with at least 95% less nicotine than tobacco used in conventional cigarettes. In the year 2011, we developed our SPECTRUM<sup>®</sup> variable nicotine research cigarettes in collaboration with independent researchers, officials from the FDA, the National Institute on Drug Abuse (“NIDA”), which is part of the National Institutes of Health (“NIH”), the National Cancer Institute (“NCI”), and the Centers for Disease Control and Prevention (“CDC”). Since 2011, we have provided more than 31.6 million variable nicotine research cigarettes for use in numerous independent clinical studies funded in large part by agencies of the United States federal government. These independent clinical studies are estimated to have been performed at a cost of more than \$125 million. The results of these independent clinical studies have been published in peer-reviewed publications (including the New England Journal of Medicine, the Journal of the American Medical Association, and many others). The results of these studies indicate that our VLNC tobaccos have been associated with reductions in smoking, nicotine exposure and nicotine dependence with little to no evidence of compensatory smoking and without serious adverse events. Lists of published and on-going clinical studies using our variable nicotine research cigarettes shown on our website at <https://www.xxiiicentury.com/vln-clinical-studies/published-clinical-studies-on-very-low-nicotine-content-vlnc-cigarettes> and <https://www.xxiiicentury.com/vln-clinical-studies/on-going-clinical-studies-on-very-low-nicotine-content-vlnc-cigarettes>. We do not incorporate third party studies or the information on our website into this Quarterly Report on Form 10-Q.

We believe that our proprietary reduced nicotine content cigarettes, VLN<sup>®</sup>, have a large global market opportunity. According to a 2018 report by the Foundation for a Smoke Free World, the global tobacco market was worth \$817 billion and of that, \$714 billion, or approximately 90% of the global tobacco market is comprised of combustible cigarettes. According to the CDC, there are more than 1 billion global and 34 million U.S. adult smokers. CDC statistics go on to state that more than two-thirds of adult smokers want to quit, yet less than ten percent of them are able to quit successfully. We believe that smokers are actively seeking alternatives to addictive combustible cigarettes. Based on our consumer perception studies, 60% of adult smokers indicate a likelihood to use VLN<sup>®</sup>.

Our VLN<sup>®</sup> cigarettes contain 95% less nicotine than conventional cigarettes and are a familiar combustible product format that replicates the conventional cigarette experience, including the sensory and experiential elements of taste, scent, smell, and “hand-to-mouth” behavior. VLN<sup>®</sup> contains 0.5 milligrams of nicotine per gram of tobacco, an amount cited by the FDA, based on clinical studies, to be “minimally or non-addictive”. Smoking VLN<sup>®</sup> cigarettes creates a dissociation between the act of smoking and the impact of nicotine which helps adult smokers reduce the harm caused by smoking.

Since 2011, our reduced nicotine content cigarettes have been used in more than 50 independent scientific clinical studies by universities and institutions. The studies, using our reduced nicotine content tobacco cigarettes, show that smokers who use our products: (i) reduce their nicotine exposure and dependence, (ii) smoke fewer cigarettes per day, (iii) increase their number of smoke-free days, and (iv) double their quit attempts – all with minimal or no evidence of nicotine withdrawal or compensatory smoking.

In December 2019, the FDA granted a Premarket Tobacco Application (“PMTA”) authorization for our reduced nicotine content cigarettes, giving us the ability to sell the product. In order to market our reduced nicotine content cigarettes under the brand name VLN<sup>®</sup>, with pack and advertising claims stating that the product contains 95% less nicotine than conventional tobacco cigarettes, as well as related claims regarding nicotine exposure, we are pursuing a Modified Risk Tobacco Product (“MRTP”) authorization from the FDA.

As a part of the MRTP application process, on February 14, 2020, we presented our application for our reduced nicotine content cigarettes, VLN<sup>®</sup> to the FDA’s Tobacco Products Scientific Advisory Committee (“TPSAC”). The FDA’s deadline for the submission of public comments on our MRTP application has now passed. The public comment period is now closed, and we believe that we are in the final stages of the review and decision-making process.

Our research cigarettes, SPECTRUM<sup>®</sup>, continue to fuel numerous independent, scientific studies to validate the enormous public health benefit identified by the FDA and others of implementing a national standard requiring all cigarettes to contain “minimally or non-addictive” levels of nicotine. In December 2020, the FDA in coordination with the National Institute on Drug Abuse (NIDA) and others, submitted an order to us for 3.6 million variable nicotine research cigarettes. On April 26, 2021, we announced the fulfillment of the order bringing the total number of research cigarettes provided for public health research to more than 31.6 million cigarettes.

M RTP is only the beginning of our global journey for the tobacco franchise. We believe it will serve as a catalyst for U.S. and international sales of the VLN<sup>®</sup> brand, including non-genetically modified (“non-GMO”) versions of VLN<sup>®</sup> 2.0 currently in development. We believe that our next generation non-GMO plant research is the key to commercializing our reduced nicotine content tobacco and technology in international markets. Non-GMO products are critical for success in international markets where non-GMO products are preferred, or genetically modified (“GMO”) products are banned. We continue to make progress in our non-GMO tobacco research. In partnership with North Carolina State University, we have completed successful research field trials that have validated new non-GMO methodologies for reducing nicotine in tobacco plants and have consistently achieved reductions in nicotine levels by as much as 99%. During the fourth quarter of 2020, we announced that we were granted a new U.S. patent, No. 10,669,552, entitled “Up-regulation of auxin response factor NbTF7”, related to the reduction of nicotine in the tobacco plant. The new technology provides us with a rapid pathway to introduce very low nicotine traits into virtually any variety of tobacco, including bright, burley, and oriental tobacco varieties. We have successfully applied our non-GMO technology to bright and burley varieties of tobacco and have developed a VLN<sup>®</sup> 2.0 prototype cigarette. We are also using our non-GMO technology to introduce reduced nicotine traits into oriental varieties of tobacco.

### **Hemp/Cannabis Franchise Overview**

In hemp/cannabis, we are developing proprietary hemp/cannabis varieties with increased levels of certain cannabinoids and other desirable agronomic traits with the goal of generating new and valuable intellectual property and plant lines. Our activities in the United States involve only work with legal hemp in full compliance with U.S. federal and state laws. The hemp and the marijuana plants are both part of the same cannabis genus, except that hemp does not have more than 0.3% dry weight content of delta-9-tetrahydrocannabinol (“THC”). While the 2018 Farm Bill legalized hemp and cannabinoids extracted from hemp in the U.S., such extracts remain subject to state laws and regulation by other U.S. federal agencies such as the FDA, U.S. Drug Enforcement Administration (“DEA”), and the U.S. Department of Agriculture (“USDA”). The same plant, with a higher THC content is marijuana, which is legal under certain state laws but not yet legal under U.S. federal law. The similarities between these plants can cause confusion. To reflect this difference in law, sometimes we refer to legal hemp and the legal hemp industry as hemp/cannabis to distinguish this as being separate and apart from marijuana/cannabis which is not legal under U.S. federal law. Our activities with legal hemp have sometimes been incorrectly perceived as us being involved in federally illegal marijuana/cannabis. This is not the case. In the United States, we work only with legal hemp in full compliance with federal and state laws, and outside the U.S., we operate in full compliance with the laws of each country in which we operate.

Our goal is to provide leading companies in the life science, consumer product, and pharmaceutical end-use markets with new, disruptive, and highly differentiated plant lines or ingredients (flower, extracts, distillates, isolates, etc.) derived from hemp/cannabis plants. Most existing hemp/cannabis plant lines do not exhibit the stable genetics, predictable yield, and specific composition of cannabinoids required to fully unlock the value of the hemp/cannabis industry. Our plant genetics and innovative upstream cannabinoid value chain provide for rapid development and optimization of plant products and scale-up as the industry evolves toward mass production.

### **Hops Franchise Overview**

We are leveraging our experience with tobacco and hemp/cannabis to accelerate the development of proprietary specialty hop varieties with valuable competitive advantages to increase yields and distinctive aroma, flavor, nutraceuticals, medicinal properties, and disease/pest resistance.

We believe that our innovative upstream alkaloid plant value chain is critical to unlocking new disruptive hop plant varieties and IP at large-scale. We are leveraging research findings from the closely related hemp/cannabis plant and our strategic partnerships to support the development of our new technologies based on molecular breeding, flowering time, and double haploid breeding to accelerate the stabilization or creation of hop varieties. Industry reliance on high-risk traditional breeding techniques makes hops ripe for disruption with our new accelerated molecular breeding technologies and gene-editing tools.

Hops is a large global addressable market with well-established hops providers and consumer brands. We are actively engaged in discussions with multiple hops grower and consumer product partners to develop specific desired traits in leading hop strains that are already well-accepted by the brewing industry. We believe hops presents a faster route to commercialization than tobacco and hemp/cannabis due to lower regulatory barriers.

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Additional information about our business and operations is contained in our Annual Report on Form 10-K for the year ended December 31, 2020.

### **Notable Accomplishments and Recent Announcements**

#### Tobacco Franchise:

- Securing MRTP designation for VLN<sup>®</sup> remains our number one priority. On October 14, 2021, we attended a meeting with senior FDA staff regarding our MRTP application. Our U.S. pilot program and manufacturing capabilities are in place to launch VLN<sup>®</sup> in the U.S. within 90 days of receiving MRTP designation.
- We continued our international launch process for VLN<sup>®</sup>. We are focusing on several of the leading markets in Asia and a test market in Europe. We believe these markets have a strong affinity for new, modified risk tobacco products and will likely require minimal interaction with regulators to launch VLN<sup>®</sup>. Sales to local partners in one or more markets are expected to begin in the first quarter of 2022. We also plan to establish an overseas branch in New Zealand.
- Our growth in tobacco contract manufacturing volumes and disciplined operations continued in the third quarter and confirms readiness of our operations ahead of VLN<sup>®</sup> launching:
  - In July 2021, we secured a new agreement with a tobacco industry partner that specializes in exporting cigarettes to countries outside the United States.
  - In October 2021, we secured an additional new contract manufacturing customer.
  - We completed the expansion of our in-house nicotine content testing capabilities, which allows for rapid, in-house analysis of our tobacco. This initiative improves the production cost per VLN<sup>®</sup> sample, while significantly reducing the lead time to uncover key data. Internal testing of our current crop of VLN<sup>®</sup> leaf commenced in August, using the newly installed testing equipment.
- Our 2021 VLN<sup>®</sup> tobacco growing program in the U.S. is driven by our latest sales projections. The new crop and our existing inventory of VLN<sup>®</sup> tobacco are earmarked for the launch and sales of VLN<sup>®</sup> cigarettes.
- We signed a partnership agreement to grow and harvest VLN<sup>®</sup> in the southern hemisphere providing us with year-round growing capabilities.
- We continue to leverage our non-GMO technology to rapidly introduce reduced nicotine traits into virtually any variety of tobacco expands business prospects.
- In April 2021, we submitted our formal response to the New Zealand Ministry of Health's Smokefree Aotearoa 2025 Action Plan. This follows the release of a new proposal by the New Zealand Ministry of Health Manatū Hauora that calls for reducing the amount of nicotine allowed in smoked tobacco products to "minimal levels".

#### Hemp/Cannabis Franchise:

- The Company and KeyGene reached a collaborative agreement with the National Institute of Science and Technology (NIST) to establish the first-ever quality and measurement standards for cannabinoids, terpenes, and other compounds across the hemp/cannabis industry. Through the Company's collaboration with KeyGene, the two partners will provide diverse lines of cannabis plants containing varying levels of cannabinoid profiles and compounds. Utilizing these samples, NIST will look to establish quality standards for the entire hemp/cannabis industry, distinguishing higher quality products from the saturated marketplace.

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- We added strategic partnerships with additional alkaloid plant producer-breeders, including Extractas Bioscience, Sawatch Agriculture, and Folium Botanical for next-generation commercial hemp/cannabis plant breeding and commercial scale-up. The partnerships facilitate year-round growing capabilities at locations in both the southern and northern hemispheres.
- We are in the process of applying for a USDA Organic Certification for our hemp farm, Needle Rock Farms.

### Hops Franchise:

- We announced entry into the global specialty hops market, our third and newest plant franchise, on August 30, 2021.
- We are actively engaged in discussions with multiple hops growers and consumer product partners to develop specific desired traits in leading hops strains.
- We are securing hop plant germplasm for use in breeding, and it is advancing valuable IP on those plants.
- We are advancing our hop genome sequencing efforts through our partnership with KeyGene, which has been accelerated by our knowledge of genome sequencing in hemp/cannabis, which is closely related to the hop plant.
- We are in the process of establishing a new subsidiary in the Netherlands, 22nd Century Group Europe B.V.

### Corporate Business:

- The Company began trading on Nasdaq Capital Markets on August 16, 2021. Uplisting to the Nasdaq aligns the Company with other high-achieving, innovative, and growth-oriented global science and technology companies.
- The Company appointed accomplished life sciences and biotechnology executive Anthony Johnson to its Board of Directors.

### **Third Quarter 2021 Financial Highlights:**

- Net sales for the third quarter of 2021 were \$7.8 million, an increase of 6.9% from \$7.3 million in the prior year period. Net sales for the nine months ended September 30, 2021 were a record \$23.0 million, an increase of 10.5% from \$20.8 million in the prior year period.
- Gross profit for the third quarter of 2021 improved by \$87 thousand, or 24% to \$449 thousand compared to the prior year period – a seventh consecutive quarter of year-over-year improvement in gross profit.
- Net loss in the third quarter of 2021 was \$(9.4) million, an increase of \$5.1 million compared to the prior year period primarily due to an increase in non-cash charges off-set by benefits to other income and expenses, representing a net loss per share of \$(0.06). This compares to the third quarter of 2020 net loss of \$(4.2) million, or \$(0.03) per share.
- We ended the quarter with a cash position of \$55.2 million as of September 30, 2021, which we believe provides sufficient runway to execute on our strategic objectives for the foreseeable future.

**Results of Operations**

***Quarter and Year-to-Date September 30, 2021 compared to Quarter and Year-to-Date September 30, 2020.***

*All amounts in thousands, except for share and per share data.*

***Revenue - Sale of products, net***

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Sale of products, net	\$ 7,811	\$ 7,310	\$ 22,988	\$ 20,803
Dollar Change from Prior Year	\$ 501		\$ 2,185	

The increase in sales revenue for the three months ended September 30, 2021, compared to the three months ended September 30, 2020, was due to an increase in sales of contract manufactured filtered cigars offset by a decrease in sales of cigarettes. Filtered cigar sales increased by approximately \$1,126 and cigarette sales decreased by \$625.

The increase in sales revenue for the nine months ended September 30, 2021, was the result of increased sales of contract manufactured filtered cigars of \$3,008, primarily driven by increased volume, and fulfillment of our SPECTRUM® cigarette order of \$680 which did not occur in the prior period. This was partially offset by decreased sales of contract manufactured cigarettes of \$1,503 which was primarily due to lower volume of orders received.

***Cost of goods sold - Products / Gross profit (loss)***

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Cost of goods sold	\$ 7,362	\$ 6,948	\$ 21,306	\$ 19,953
Percent of Product Sales	94.3 %	95.0 %	92.7 %	95.9 %
Dollar Change from Prior Year	\$ 414		\$ 1,353	

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Gross profit	\$ 449	\$ 362	\$ 1,682	\$ 850
Percent of Product Sales	5.7 %	5.0 %	7.3 %	4.1 %
Dollar Change from Prior Year	\$ 87		\$ 832	

The increase in gross profit for the three months ended September 30, 2021, compared to the three months ended September 30, 2020, was driven by improved contract manufactured filtered cigar sales mix due to new customer contracts and price increases taken on contract manufactured cigarettes.

The increase in gross profit for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020, was primarily driven by improved contract manufactured filtered cigar sales mix due to new customer contracts, cigarette price increases during the second quarter of 2021, and fulfillment of our SPECTRUM® cigarette order.

**Research and development (“R&D”) expense**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Research and Development	\$ 854	\$ 906	\$ 2,287	\$ 2,676
Percent of Product Sales	10.9 %	12.4 %	9.9 %	12.9 %
Dollar Change from Prior Year	\$ (52)		\$ (389)	

The decrease in R&D expense for the three months ended September 30, 2021, compared to the three months ended September 30, 2020, was primarily due to tobacco leaf inventory impairment in the prior year period of \$58, which did not reoccur in the current year period, and lower personnel expense of \$38. This was partially offset by higher license and contract costs of \$48.

Lower R&D expense for the nine months ended September 30, 2021, compared to the nine months ended September 30, 2020, was driven by a decrease in R&D personnel expense of \$210, lower facilities expense of \$102, a decrease in R&D contract costs of \$51, a decrease in consulting and professional services of \$50, and a 2020 tobacco leaf inventory impairment of \$58, which did not reoccur in the current year period. This decrease was partially offset by increased patent expenses of \$139 for the nine months ended September 30, 2021, compared to the prior year period. We continue to prioritize our R&D activities to achieve our strategic and investment priorities.

**Research and development expense - MRTP**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Research and Development - MRTP	\$ 2	\$ 4	\$ 16	\$ 158
Percent of Product Sales	0.0 %	0.0 %	0.1 %	0.8 %
Dollar Change from Prior Year	\$ (2)		\$ (142)	

MRTP expenses for three and nine months ended September 30, 2021 declined as we submitted our MRTP application to the FDA during 2019. MRTP-related expenses for 2021 are primarily related to continued consulting services related to our application while 2020 expenses are primarily related to our February 14, 2020 Tobacco Products Scientific Advisory Committee (TPSAC) hearing.

**Sales, general and administrative expense**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Sales, general and administrative	\$ 6,821	\$ 3,169	\$ 17,827	\$ 9,809
Percent of Product Sales	87.3 %	43.4 %	77.6 %	47.2 %
Dollar Change from Prior Year	\$ 3,652		\$ 8,018	

The increase in SG&A expense during the three months ended September 30, 2021, as compared to the respective prior year period, was driven by increased investor relations and consulting expenses of \$2,399, increased equity compensation expense of \$795, increased personnel expenses of \$244, increased legal fees of \$187, and increased insurance expenses of \$155. This was partially offset by lower sales and marketing expenses of \$129 compared to the respective prior year period.

The increase in SG&A expense during the nine months ended September 30, 2021, as compared to the respective prior year period, was driven by increased investor relations and consulting expenses of \$4,131, increased equity compensation expense of \$1,700, increased insurance expenses of \$1,034, increased personnel expenses of \$941 due to the hiring of the new management team including the Chief Executive Officer and Chief Financial Officer in the second quarter of 2020, and increased board of director fees of \$249. These increases in SG&A expense were partially offset by lower legal fees of \$54 compared to the respective prior year period.

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We have deployed this incremental SG&A spending to continue our corporate investment as we move quickly to market readiness in both tobacco and hemp/cannabis. We will continue to incur incremental SG&A spending as growth and investment opportunities present themselves.

**Impairment expense**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Impairment of intangible assets	\$ —	\$ —	\$ —	\$ 146
Percent of Product Sales	— %	— %	— %	0.7 %
Dollar Change from Prior Year	\$ —		\$ (146)	

The decrease in impairment expense for the nine months ended September 30, 2021, was due to a one-time impairment charge of \$146, in the prior year period, which was required for certain patent and trademark costs.

**Depreciation expense**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Depreciation	\$ 173	\$ 160	\$ 461	\$ 473
Percent of Product Sales	2.2 %	2.2 %	2.0 %	2.3 %
Dollar Change from Prior Year	\$ 13		\$ (12)	

The increase in depreciation expense for the three months ended September 30, 2021, as compared to the prior year period, was primarily due to new assets acquired from the conversion of our Panacea investment, as described within Note 5 to our financial statements included herein.

The decrease in depreciation expense for the nine months ended September 30, 2021, as compared to the respective prior year period, was due to a lower property, plant, and equipment depreciable base primarily due to impairments taken for the former Williamsville corporate office during the fourth quarter of 2020.

**Amortization expense**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Amortization	\$ 168	\$ 163	\$ 471	\$ 524
Percent of Product Sales	2.2 %	2.2 %	2.1 %	2.5 %
Dollar Change from Prior Year	\$ 5		\$ (53)	

Amortization expense was consistent with prior year for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020. The decrease in amortization expense during the nine months ended September 30, 2021, as compared to the respective prior year period, was due to a lower intangible asset depreciable base primarily due to impairments taken during 2020.

**Impairment of Panacea investment**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Impairment of Panacea Investment	\$ —	\$ —	\$ —	\$ (1,062)
Percent of Product Sales	— %	— %	— %	(5.1)%
Dollar Change from Prior Year	\$ —		\$ 1,062	

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For the nine months ended September 30, 2020, we incurred impairment charges on our investment in Panacea. Refer to Note 5 to our consolidated financial statements for additional information regarding our investment in Panacea.

***Gain on Panacea investment conversion***

On June 30, 2021, the Company entered into a Promissory Note Exchange Agreement with Panacea and a Securities Exchange Agreement with Panacea, Exactus, Inc. (“Exactus”) (OTCQB:EXDI) and certain other Panacea shareholders. Pursuant to the Securities Exchange Agreement, Exactus fully acquired Panacea. These transactions effect the (i) conversion of all of the Company’s existing Series B Preferred Stock in Panacea into 91,016,026 shares of common stock in Exactus valued at \$9,102 as of June 30, 2021 and (ii) the conversion of the Company’s existing debt in Panacea by converting the outstanding \$7,000 principal balance convertible note receivable and all accrued but unpaid interest thereon for fee simple ownership of Needle Rock Farms (224 acres in Delta County, Colorado) and equipment valued at \$2,248, \$500 in Panacea’s Series B Preferred Stock (which was subsequently converted to Exactus common stock under the Securities Exchange Agreement), and a new \$4,300 promissory note (the “Promissory note receivable”) with a maturity date of June 30, 2026 and a 0% interest rate. The Promissory note receivable is with a related party of Panacea and is fully secured by a first priority lien on Panacea’s headquarters located in Golden, Colorado.

The conversion was recorded as a non-monetary transaction, based on the fair value of the assets received, and resulted in a gain of \$2,548 which is included within the Consolidated Statements of Operations. Our shares of Exactus common stock were valued based on a closing share price of \$.10 per share as published on June 30, 2021. Our investment is described further within Note 5 to our financial statements included herein.

***Unrealized gain (loss) on investment***

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Unrealized gain (loss) on investments	\$ (1,900)	\$ (429)	\$ (2,040)	\$ (562)
Percent of Product Sales	(24.3)%	(5.9)%	(8.9)%	(2.7)%
Dollar Change from Prior Year	\$ (1,471)		\$ (1,478)	

Unrealized gain (loss) on investment includes fair value adjustments for our investment in Aurora Cannabis, Inc (“Aurora”) stock warrants and our investment in Exactus common stock. Both investments are considered equity securities and are adjusted to fair value at each reporting period as discussed within Note 6 to our consolidated financial statements included herein.

The warrants to purchase 81,164 shares of Aurora common stock were valued at \$18 as of September 30, 2021, using the Black-Scholes pricing model, which amounted to an unrealized loss of \$80 for the three months ended September 30, 2021 and an unrealized loss of \$220 for the nine months ended September 30, 2021.

Our shares of Exactus common stock were valued based on the closing share price as of September 30, 2021. As of September 30, 2021, the shares were valued at \$7,281 which amounted to an unrealized loss of \$1,820. Our investment in Exactus is considered an investment in a small microcap stock which can be subject to large market volatility resulting in fluctuations to our net loss and loss per share—due to unrealized gains or losses that will be recognized within the Consolidated Statements of Operations. Our investment is described further within Note 5 to our financial statements included herein.



***Gain on the sale of property, plant and equipment***

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Gain on the sale of property, plant and equipment	\$ —	\$ 1	\$ —	\$ 1
Percent of Product Sales	— %	— %	— %	— %
Dollar Change from Prior Year	\$ (1)		\$ (1)	

We recognized a small gain on equipment sold during the three and nine months ended September 30, 2020. No similar sales occurred in 2021.

***Interest income, net***

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Interest Income, net	\$ 52	\$ 270	\$ 272	\$ 1,344
Percent of Product Sales	0.7 %	3.7 %	1.2 %	6.5 %
Dollar Change from Prior Year	\$ (218)		\$ (1,072)	

Interest income, net (interest income less investment fees) is comprised of cash interest income and non-cash interest accretion. Cash interest income is primarily derived from interest earned on our short-term investment securities and non-cash interest income is primarily related to accretion of short-term investment securities purchased at a discount or premium and accretion of certain other assets recorded at a discount.

Cash interest income for the three months ended September 30, 2021 increased \$1, as compared to the respective prior year period, and non-cash interest accretion decreased \$219 primarily due to our Panacea investment conversion further described within Note 5 to our financial statements included herein.

Cash interest income for the nine months ended September 30, 2021 decreased \$285, as compared to the respective prior year period, primarily due to lower bond interest yields on our short-term investment securities. Non-cash interest accretion for the nine months ended September 30, 2021 decreased \$787, as compared to the respective prior year period, primarily due to our Panacea investment conversion which is further described within Note 5 to our financial statements included herein.

***Interest expense***

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Interest Expense	\$ (23)	\$ (23)	\$ (44)	\$ (54)
Percent of Product Sales	(0.3)%	(0.3)%	(0.2)%	(0.3)%
Dollar Change from Prior Year	\$ —		\$ 10	

Interest expense decreased for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, primarily due to the interest accretion on a note payable to NCSU which was fully paid off during the second quarter of 2020.

**Net loss**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Net Loss	\$ (9,440)	\$ (4,221)	\$ (18,644)	\$ (13,307)
Percent of Product Sales	(120.9)%	(57.7)%	(81.1)%	(64.0)%
Dollar Change from Prior Year	\$ (5,219)		\$ (5,337)	

The increase in net loss for the three months ended September 30, 2021, as compared to the same prior year period, was primarily the result of increased operating expenses of \$3,529, an increase in unrealized loss on investments of \$1,471, primarily relating to our Aurora stock warrants and Exactus common stock investments, and lower interest income of \$218.

The increase in net loss for the nine months ended September 30, 2021, as compared to the same period during the prior year, was primarily the result of increased operating expenses of \$7,276, an increase in unrealized loss on investments of \$1,478, primarily relating to our Aurora stock warrants and Exactus common stock investments, and lower interest income in the amount of \$1,072. This was partially offset by an increase in gross profit of \$832, a gain on our Panacea investment conversion of \$2,548, and a 2020 impairment of \$1,062 which did not repeat in 2021.

**Other Comprehensive Income (Loss)**

	Quarter-to-Date		Year-to-Date	
	September 30 2021	September 30 2020	September 30 2021	September 30 2020
Other Comprehensive Income (Loss)	\$ (28)	\$ 87	\$ (101)	\$ 132
Percent of Product Sales	(0.4)%	1.2 %	(0.4)%	0.6 %
Dollar Change from Prior Year	\$ (115)		\$ (233)	

We maintain an account for short-term investment securities that are classified as available-for-sale securities and consist of money market funds and corporate bonds with maturities greater than three months at the time of acquisition. Unrealized gains and losses on short-term investment securities (the adjustment to fair value) are recorded as other comprehensive income or loss.

We recorded an unrealized loss on short-term investment securities in the amount of \$28 resulting in other comprehensive loss of \$28 for the three months ended September 30, 2021, as compared to an unrealized gain of \$87 for the prior year respective period. For the nine months ended September 30, 2021, we recorded an unrealized loss on short-term investment securities in the amount of \$101 resulting in other comprehensive loss of \$101, as compared to an unrealized gain of \$132 for the prior year respective period.

**Liquidity and Capital Resources**

	Year-to-Date	
	September 30 2021	September 30 2020
Net cash provided by (used in) operating activities	\$ (18,207)	\$ (12,624)
Net cash provided by (used in) investing activities	(33,207)	12,755
Net cash provided by (used in) financing activities	52,014	926
Net increase (decrease) in cash and cash equivalents	600	1,057
Cash and cash equivalents - beginning of period	1,029	485
Cash and cash equivalents - end of period	\$ 1,629	\$ 1,542
Short-term investment securities	\$ 53,532	\$ 25,276

**Working Capital**

As of September 30, 2021, we had working capital of approximately \$55,212 compared to working capital of approximately \$20,998 at December 31, 2020 an increase of \$34,214. This increase in working capital was primarily due to a \$32,819 increase in

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cash, cash equivalents and short-term investment securities resulting from (i) net proceeds of \$11,782 from the cash exercises of all outstanding warrants during the first quarter of 2021; and (ii) net proceeds of \$38,206 from a capital raise in June 2021 described below, offset primarily by cash and cash equivalents consumed in the operating activities of the Company.

On June 7, 2021, we entered into a placement agent agreement (the “Placement Agent Agreement”) with Cowen and Company, LLC (the “Placement Agent”) relating to a registered direct offering (the “Offering”) to a select investor (the “Investor”). Pursuant to the Placement Agent Agreement, we agreed to pay the Placement Agent a cash fee of 3.0% of the gross proceeds from the Offering. The Placement Agent Agreement requires us to indemnify the Placement Agent and certain of its affiliates against certain customary liabilities. In addition, on June 7, 2021, we and the Investor entered into a securities purchase agreement (the “Securities Purchase Agreement”) relating to the issuance and sale of shares of common stock. The Investor purchased \$40,000 of shares, consisting of an aggregate of 10,000,000 shares of common stock at \$4.00 per share, resulting in net proceeds of \$38,206. The common stock was offered and sold pursuant to our Form S-3 shelf registration statement.

### ***Net cash used in operating activities***

The increase of cash used in operations in the amount of \$5,583 was due to an increase in the cash portion of the net loss in the amount of \$5,972 and a decrease in cash used for working capital components related to operations in the amount of \$389 for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020.

### ***Net cash provided by investing activities***

The increase in cash used in investing activities of \$45,962 was primarily the result of a net increase in the net cash used for our short-term investments in the amount of \$45,628 and an increase in the cash used for acquisition of property, plant and equipment and the acquisition of patents, trademarks and licenses in the amount of \$334 for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020. The increase in cash used in our short-term investments was primarily due to increased funds for investment, from the warrant exercises and capital raise described above, while the increased cash used for acquisition of machinery and equipment and the acquisition of patents, trademarks and licenses was primarily due to new office furnishings and additional intellectual property costs.

### ***Net cash provided by financing activities***

During the nine months ended September 30, 2021, cash provided by financing activities increased by \$51,088 resulting from (i) the net proceeds of \$11,782 resulting from the cash exercises of all outstanding warrants during the first quarter of 2021; (ii) net proceeds of \$38,206 resulting from a capital raise in June 2021; (iii) increased net proceeds from note payable issuances and payments of \$310; and (iv) net proceeds from stock option exercises of \$1,259. This increase was partially offset by cash paid for taxes related to settlement of restricted stock units of \$469.

### ***Cash demands on operations***

Our principal sources of liquidity are our cash and cash equivalents, short-term investment securities, and cash generated from our contract manufacturing business. As of September 30, 2021, we had approximately \$55,161 of cash and cash equivalents and short-term investments which is an increase of \$32,819 from December 31, 2020. This increase was primarily due to the cash exercise of our outstanding warrants in the first quarter of 2021 and a capital raise in the second quarter of 2021. Our short-term investment securities, along with sustained contract manufacturing sales, provide sufficient resources for estimated contractual commitments, described further in Note 11 to our consolidated financial statements included herein, and normal cash requirements for operations well beyond the next twelve months. In addition to the commitments described in Note 11 to our consolidated financial statements included herein, we have secured contracts with select tobacco farmers to assist with the 2021 growing of our VLNC tobacco. These contracts will increase the quantity of our current leaf inventory which will help support expected demand of VLN<sup>®</sup>, if MTRP authorization is granted by the FDA. The cost of such growing efforts is dependent on the final agricultural yields and leaf quality, but we expect the cost to range between \$1.5 million and \$1.9 million. We also believe that we have appropriate liquidity to successfully manufacture and distribute our VLN<sup>®</sup> cigarette within 90 days of MRTP authorization by the FDA, if granted in 2021, and appropriate liquidity for continued R&D investment in all of our plant franchises.

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We also have an effective S-3 shelf registration statement on file with the U.S. Securities and Exchange Commission (SEC), which provides us flexibility and optionality to raise additional capital as needed. However, there can be no assurance that capital will be available to us on acceptable terms or at all.

**Critical Accounting Policies and Estimates**

There have been no material changes to the information set forth in our Annual Report on Form 10-K for the year ended December 31, 2020.

**Inflation**

Inflation did not have a material effect on our operating results for the nine months ended September 30, 2021 and 2020, respectively.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined by Item 303(a)(4) of Regulation S-K.

**Item 4. Controls and Procedures**

**(a) Evaluation of Disclosure Controls and Procedures:**

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in its Securities Exchange Act of 1934 (“Exchange Act”) reports are 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 the Company’s management, including the Company’s chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our chief executive officer and chief financial officer, after evaluating the effectiveness of the Company’s “disclosure controls and procedures” (as defined in the Exchange Act Rules 13a-15(e) or 15d-15(e)) as of the end of the period covered by this quarterly report, have concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Form 10-Q to ensure information required to be disclosed is recorded, processed, summarized and reported within the time period specified by SEC rules, based on their evaluation of these controls and procedures as required by paragraph (b) of Exchange Act Rules 13a-15 or 15d-15.

**(b) Changes in Internal Control over Financial Reporting:**

There were no changes in the Company’s internal controls over financial reporting during the third quarter of 2021 that have materially affected, or are reasonably likely to materially affect, the Company’s internal controls over financial reporting.

## **Part II. OTHER INFORMATION**

### **Item 1. Legal Proceedings**

See Note 11 - Commitments and Contingencies – Litigation - to our consolidated financial statements included in this Quarterly Report for information concerning our on-going litigation. In addition to the lawsuits described in Note 11, from time to time we may be involved in claims arising in the ordinary course of business. To our knowledge other than the cases described in Note 11 to our consolidated financial statements, no material legal proceedings, governmental actions, investigations or claims are currently pending against us or involve us that, in the opinion of our management, could reasonably be expected to have a material adverse effect on our business and financial condition.

### **Item 1A. Risk Factors**

There have been no material changes from the risk factors disclosed in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the SEC on March 11, 2021.

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

None

### **Item 3. Default Upon Senior Securities.**

None

### **Item 4. Mine Safety Disclosures**

None

### **Item 5. Other Information**

None

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**Item 6. Exhibits**

- Exhibit 31.1 [Section 302 Certification - Chief Executive Officer](#)
- Exhibit 31.2 [Section 302 Certification - Chief Financial Officer](#)
- Exhibit 32.1 [Certification of Principal Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 101.INS XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
- 101.SCH XBRL Taxonomy Extension Schema Document
- 101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF XBRL Taxonomy Extension Definition Linkbase Document
- 101.LAB XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE XBRL Taxonomy Extension Presentation Linkbase Document
- Exhibit 104 Cover Page Interactive Data File - The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

**SIGNATURES**

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

22nd CENTURY GROUP, INC.

Date: November 4, 2021

/s/ James A. Mish  
\_\_\_\_\_  
James A. Mish  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 4, 2021

/s/ John Franzino  
\_\_\_\_\_  
John Franzino  
Chief Financial Officer  
(Principal Accounting and Financial Officer)

## CERTIFICATIONS

I, James A. Mish, Chief Executive Officer of 22nd CENTURY GROUP, INC., certify that:

1. I have reviewed this quarterly report on Form 10-Q of 22nd CENTURY GROUP, INC.;
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 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.
5. The registrant's other certifying officer 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 registrant's board of directors (or persons performing 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.

Date: November 4, 2021

/s/ James A. Mish  
James A. Mish  
Chief Executive Officer  
(Principal Executive Officer)

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## CERTIFICATIONS

I, **John Franzino, Chief Financial Officer of 22nd CENTURY GROUP, INC.**, certify that:

1. I have reviewed this quarterly report on Form 10-Q of 22nd CENTURY GROUP, INC.;
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 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.
5. The registrant's other certifying officer 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 registrant's board of directors (or persons performing 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.

Date: November 4, 2021

/s/ John Franzino  
John Franzino  
Chief Financial Officer  
(Principal Accounting and Financial Officer)

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**Written Statement of the Principal Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. §1350**

Solely for the purposes of complying with 18 U.S.C. §1350, I, the undersigned Chief Executive Officer of 22nd CENTURY GROUP, INC. (the “Company”), and I, the undersigned Chief Financial Officer of the Company, hereby certify, to the best of my knowledge, that the quarterly report on Form 10-Q of the Company for the quarter ended September 30, 2021 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is being furnished solely to accompany this Report pursuant to 18 U.S.C. 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and is not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Date: November 4, 2021

/s/ James A. Mish  
James A. Mish  
Chief Executive Officer

Date: November 4, 2021

/s/ John Franzino  
John Franzino  
Chief Financial Officer

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