

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

OR

TRANSITION REPORT UNDER SECTION 13 OF 15(d) OF THE EXCHANGE ACT OF 1934

From the transition period from _____ to _____

Commission File Number 001-37853

AZURRX BIOPHARMA, INC.

(Exact name of small business issuer as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

46-4993860

(IRS Employer Identification No.)

760 Parkside Avenue
Downstate Biotechnology Incubator, Suite 304
Brooklyn, New York 11226
(Address of principal executive offices)

(646) 699-7855

(Issuer's telephone number)

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 (Sec.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

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	AZRX	Nasdaq Capital Market

As of May 15, 2019, there were 21,060,055 shares of the registrant's common stock, \$0.0001 par value, issued and outstanding.

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PART I

FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS

In our opinion, the accompanying unaudited consolidated financial statements contain all adjustments (consisting only of normal recurring adjustments) necessary to present fairly our financial position, results of operations, and cash flows for the interim periods presented. We have condensed such financial statements in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”). Therefore, such financial statements do not include all disclosures required by accounting principles generally accepted in the United States of America. In preparing these consolidated financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through the date the consolidated financial statements were issued by filing with the SEC.

These financial statements should be read in conjunction with our audited financial statements for the year ended December 31, 2018 included in our Annual Report filed on Form 10-K, filed with the SEC on April 1, 2019.

The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the fiscal year ended December 31, 2019.

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AZURRX BIOPHARMA, INC.
Consolidated Balance Sheets (unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash	\$ 413,858	\$ 1,114,343
Other receivables	2,051,028	3,172,676
Prepaid expenses	338,656	512,982
Total Current Assets	<u>2,803,542</u>	<u>4,800,001</u>
Property, equipment, and leasehold improvements, net	<u>125,135</u>	<u>128,854</u>
Other Assets:		
In process research and development, net	-	258,929
License agreements, net	-	311,548
Patents	3,802,745	-
Goodwill	1,887,358	1,924,830
Operating lease right-of-use assets	288,653	-
Deposits	49,077	45,233
Total Other Assets	<u>6,027,833</u>	<u>2,540,540</u>
Total Assets	<u>\$ 8,956,510</u>	<u>\$ 7,469,395</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 2,580,709	\$ 2,070,396
Accounts payable and accrued expenses - related party	643,428	670,095
Note payable	160,584	255,032
Convertible debt	1,728,442	-
Other current liabilities	643,530	-
Total Current Liabilities	<u>5,756,693</u>	<u>2,995,523</u>
Other liabilities	486,492	-
Total Liabilities	<u>6,243,185</u>	<u>2,995,523</u>
Stockholders' Equity:		
Convertible preferred stock - Par value \$0.0001 per share; 10,000,000 shares authorized and 0 shares issued and outstanding at March 31, 2019 and December 31, 2018; liquidation preference approximates par value	-	-
Common stock - Par value \$0.0001 per share; 100,000,000 shares authorized; 18,537,958 and 17,704,925 shares issued and outstanding, respectively, at March 31, 2019 and December 31, 2018	1,853	1,771
Additional paid-in capital	56,134,666	53,139,259
Accumulated deficit	(52,177,801)	(47,517,046)
Accumulated other comprehensive loss	(1,245,393)	(1,150,112)
Total Stockholders' Equity	<u>2,713,325</u>	<u>4,473,872</u>
Total Liabilities and Stockholders' Equity	<u>\$ 8,956,510</u>	<u>\$ 7,469,395</u>

See accompanying notes to consolidated financial statements

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AZURRX BIOPHARMA, INC.
Consolidated Statements of Operations and Comprehensive Loss (unaudited)

	Three Months Ended 03/31/19	Three Months Ended 03/31/18
Research and development expenses	\$ 2,118,533	\$ 1,678,029
General and administrative expenses	2,485,111	1,916,333
Fair value adjustment, contingent consideration	-	(10,000)
Loss from operations	<u>(4,603,644)</u>	<u>(3,584,362)</u>
Other:		
Interest expense	(57,111)	(48,635)
Total other	<u>(57,111)</u>	<u>(48,635)</u>
Loss before income taxes	(4,660,755)	(3,632,997)
Income taxes	-	-
Net loss	(4,660,755)	(3,632,997)
Other comprehensive loss:		
Foreign currency translation adjustment	(95,281)	106,020
Total comprehensive loss	<u>\$ (4,756,036)</u>	<u>\$ (3,526,977)</u>
Basic and diluted weighted average shares outstanding	<u>17,719,902</u>	<u>12,447,438</u>
Loss per share - basic and diluted	<u>\$ (0.26)</u>	<u>\$ (0.29)</u>

See accompanying notes to consolidated financial statements

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**AZURRX
BIOPHARMA, INC.**
**Consolidated Statements of Changes in
Stockholders' Equity (unaudited)**

	Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Subscriptions Receivable	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares	Amount	Shares	Amount					
Balance, January 1, 2018	-	\$ -	12,042,574	\$ 1,205	\$7,669,601	\$(1,071,070)	\$33,983,429	\$ (955,715)	\$1,660,592
Common stock issued to consultants			751	-	-				-
Common stock issued for warrant exercises			503,070	49	1,253,623	1,071,070			2,324,742
Stock-based compensation					29,018				29,018
Restricted stock granted to employees/directors			30,000	3	113,697				113,700
Convertible debt converted into common stock			26,000	3	68,670				68,673
Warrant modification					428,748				428,748
Foreign currency translation adjustment								106,020	106,020
Net loss							(3,632,997)		(3,632,997)
Balance, March 31, 2018	<u>-</u>	<u>\$ -</u>	<u>12,602,395</u>	<u>\$ 1,260</u>	<u>\$9,563,357</u>	<u>\$ -</u>	<u>\$37,616,426</u>	<u>\$ (849,695)</u>	<u>\$1,098,496</u>
Balance, January 1, 2019	-	\$ -	17,704,925	\$ 1,771	\$3,139,259	\$ -	\$47,517,046	\$(1,150,112)	\$4,473,872
Common stock issued to consultants			27,102	2	59,998				60,000
Common stock issued to Mayoly for patents			775,931	77	1,740,882				1,740,959
Stock-based compensation					511,335				511,335
Restricted stock granted to employees/directors			30,000	3	296,282				296,285
Warrant modification					325,320				325,320
Received from stockholder in relation to warrant modification					61,590				61,590
Foreign currency translation adjustment								(95,281)	(95,281)
Net loss							(4,660,755)		(4,660,755)
Balance, March 31, 2019	<u>-</u>	<u>\$ -</u>	<u>18,537,958</u>	<u>\$ 1,853</u>	<u>\$6,134,666</u>	<u>\$ -</u>	<u>\$52,177,801</u>	<u>\$(1,245,393)</u>	<u>\$2,713,325</u>

See accompanying notes to consolidated financial statements

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AZURRX BIOPHARMA, INC.
Consolidated Statements of Cash Flows (unaudited)

	Three Months Ended 03/31/19	Three Months Ended 03/31/18
Cash flows from operating activities:		
Net loss	\$ (4,660,755)	\$ (3,632,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	17,114	14,763
Amortization	561,289	191,681
Fair value adjustment, contingent consideration	-	(10,000)
Stock-based compensation	511,335	29,018
Restricted stock granted to employees/directors	296,285	113,700
Restricted stock granted to consultants	60,000	-
Accreted interest on convertible debt	24,658	-
Accreted interest on debt discount - warrants	29,104	46,795
Warrant modification	-	428,748
Changes in assets and liabilities:		
Other receivables	(149,508)	120,877
Prepaid expenses	172,886	59,625
Right of use assets	(289,830)	-
Deposits	(4,125)	-
Accounts payable and accrued expenses	514,950	423,523
Other liabilities	288,800	-
Net cash used in operating activities	<u>(2,627,797)</u>	<u>(2,214,267)</u>
Cash flows from investing activities:		
Purchase of property and equipment	(13,352)	(29,521)
Net cash used in investing activities	<u>(13,352)</u>	<u>(29,521)</u>
Cash flows from financing activities:		
Issuances of common stock	-	2,324,742
Issuances of convertible debt	2,000,000	-
Received from stockholder in relation to warrant modification	61,590	-
Repayments of note payable	(94,448)	(79,041)
Net cash provided by financing activities	<u>1,967,142</u>	<u>2,245,701</u>
(Decrease) increase in cash	(674,007)	1,913
Effect of exchange rate changes on cash	(26,478)	(910)
Cash, beginning balance	<u>1,114,343</u>	<u>573,471</u>
Cash, ending balance	<u>\$ 413,858</u>	<u>\$ 574,474</u>
Supplemental disclosures of cash flow information:		
Cash paid for interest	<u>\$ 3,933</u>	<u>\$ 1,840</u>
Cash paid for income taxes	<u>\$ -</u>	<u>\$ -</u>
Non-cash investing and financing activities:		
Conversion of convertible debt into common stock	<u>\$ -</u>	<u>\$ 68,673</u>

Common stock issued for patents purchased from Mayoly	<u>\$ 1,740,959</u>	<u>\$ -</u>
Warrant modification related to convertible debt issuance	<u>\$ 325,320</u>	<u>\$ -</u>

See accompanying notes to consolidated financial statements

Note 1 - The Company and Basis of Presentation

The Company

AzurRx BioPharma, Inc. (“AzurRx” or “Parent”) was incorporated on January 30, 2014 in the State of Delaware. In June 2014, the Company acquired 100% of the issued and outstanding capital stock of AzurRx SAS (formerly “ProteaBio Europe SAS”), a company incorporated in October 2008 under the laws of France. AzurRx and its wholly-owned subsidiary, AzurRx SAS (“ABS”), are collectively referred to as the “Company.”

The Company is engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders. Non-systemic biologics are non-absorbable drugs that act locally, i.e. the intestinal lumen, skin or mucosa, without reaching an individual’s systemic circulation. The Company’s current product pipeline consists of two therapeutic proteins under development:

MS1819-SD

MS1819-SD is a yeast derived recombinant lipase for exocrine pancreatic insufficiency (“EPI”) associated with chronic pancreatitis (“CP”) and cystic fibrosis (“CF”). A lipase is an enzyme that breaks up fat molecules. MS1819-SD is considered recombinant because it was created from new combinations of genetic material in yeast called *Yarrowia lipolytica*. In June 2018, the Company completed an open-label, dose escalation Phase IIa trial of MS1819-SD in France, Australia, and New Zealand to investigate both the safety of escalating doses of MS1819-SD, and the efficacy of MS1819-SD through the analysis of each patient’s coefficient of fat absorption (“CFA”) and its change from baseline. A total of 11 CP patients with EPI were enrolled in the study and final data showed a strong safety and efficacy profile. Although the study was not powered for efficacy, in a pre-planned analysis, the highest dose cohort of MS1819-SD showed statistically significant and clinically meaningful increases in CFA compared to baseline with a mean increase of 21.8% and a p value of $p=0.002$ on a per protocol basis. Additionally, maximal absolute CFA response to treatment was up to 57%, with an inverse relationship to baseline CFA. In October 2018, the U.S. Food and Drug Administration (“FDA”) cleared the Company’s Investigational New Drug (“IND”) application for MS1819-SD in patients with EPI due to CF. In connection with the FDA’s clearance of the IND, in the fourth quarter of 2018 the Company initiated the multi-center Phase II OPTION study in the United States and Europe (the “OPTION Study”), which the Company expects will include approximately 30 patients. The Company dosed the first patients in the OPTION Study in February 2019 and reached 50% of its enrollment target for the OPTION Study in April 2019. The Company expects to conclude and announce topline results from the OPTION Study in the summer of 2019.

b-Lactamase Program

The Company’s b-lactamase program focuses on products with an enzymatic combination of bacterial origin for the prevention of hospital-acquired infections and antibiotic-associated diarrhea (“AAD”) by resistant bacterial strains induced by parenteral administration of several antibiotic classes. Currently, the Company has two compounds in pre-clinical development in this program, AZX1101 and AZX1103. Both AZX1101 and AZX1103 are composed of several distinct enzymes that break up individual classes of antibiotic molecules. AZX1103 is a b-lactamase enzyme combination that has shown positive pre-clinical activity, with degradation of amoxicillin in the presence of clavulanic acid in the upper gastrointestinal tract in the Gottingen minipig model. Currently, the Company is focused on advancing pre-clinical development of AZX1103. The Company is also currently assessing its plans for the continuation of the development of AZX1101.

Recent Developments

Asset Purchase Agreement with Mayoly

On March 27, 2019, the Company entered into an Asset Purchase Agreement with Mayoly (the “Mayoly APA”), pursuant to which the Company purchased all rights, title and interest in and to MS1819-SD. Upon execution of the Mayoly APA, the Joint Development and License Agreement (the “JDLA”) previously executed by AzurRx SAS and Mayoly was terminated. In addition, the Company granted to Mayoly an exclusive, royalty-bearing right to revenue received from commercialization of MS1819-SD within certain territories.

In accordance with the Mayoly APA, the Company provided to Mayoly the following consideration for the purchase of MS1819-SD:

- (i) the Company assumed certain of Mayoly's liabilities with respect to MS1819-SD;
- (ii) the Company forgave all amounts currently owed to AzurRx SAS by Mayoly under the JDLA;
- (iii) the Company agreed to pay, within 30 days after the execution of the Mayoly APA, all amounts incurred by Mayoly for the maintenance of patents related to MS1819-SD from January 1, 2019 through the date of the Mayoly APA;
- (iv) the Company made an initial payment to Mayoly of €800,000, which amount was paid by the issuance of 400,481 shares of the Company's common stock at a price of \$2.29 per share (the "Closing Payment Shares") and the Company recognized \$917,101 as part of stockholders' equity; and
- (v) the Company agreed to pay to Mayoly an additional €1,500,000, payable in a mix of cash and shares of the Company's common stock as follows (the "Milestone Payments"): (y) on December 31, 2019, a cash payment of €400,000 and 200,240 shares of common stock (the "2019 Escrow Shares") and (z) on December 31, 2020, a cash payment of €350,000 and 175,210 shares of common stock (the "2020 Escrow Shares" and, together with the 2019 Escrow Shares, the "Escrow Shares") and the Company recognized \$823,858 as part of stockholders' equity.

The Closing Payment Shares and the Escrow Shares were all issued upon execution of the Mayoly APA; *provided, however*, per the terms of the Mayoly APA, the Escrow Shares will be held in escrow until the applicable Milestone Payment date, at which time the respective Escrow Shares will be released to Mayoly. See Note 6.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying unaudited interim consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, and cash flows. The consolidated balance sheet at December 31, 2018, has been derived from audited financial statements of that date. The unaudited interim consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the Securities and Exchange Commission ("SEC"). The Company believes that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report Form 10-K for the year ended December 31, 2018, filed with the SEC on April 1, 2019.

The unaudited interim consolidated financial statements include the accounts of AzurRx and its wholly-owned subsidiary, AzurRx SAS. Intercompany transactions and balances have been eliminated upon consolidation.

Going Concern Uncertainty

The accompanying unaudited interim consolidated financial statements have been prepared as if the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operations since inception, had negative working capital at March 31, 2019 of approximately \$2,953,000, and had an accumulated deficit of approximately \$52,178,000 at March 31, 2019. The Company is dependent on obtaining, and continues to pursue, additional working capital funding from the sale of securities and debt in order to continue to execute its development plan and continue operations. Without adequate working capital, the Company may not be able to meet its obligations and continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Note 2 - Significant Accounting Policies and Recent Accounting Pronouncements

Use of Estimates

The accompanying consolidated financial statements are prepared in conformity with U.S. GAAP and include certain estimates and assumptions which affect the reported amounts of assets and liabilities at the date of the financial statements (including goodwill, intangible assets and contingent consideration), and the reported amounts of revenues and expenses during the reporting period, including contingencies. Accordingly, actual results may differ from those estimates.

Concentrations

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash. The Company primarily maintains its cash balances with financial institutions in federally-insured accounts in the U.S. The Company may from time to time have cash in banks in excess of FDIC insurance limits. At March 31, 2019 and December 31, 2018, the Company had approximately \$133,984 and \$754,261, respectively, in one account in the U.S. in excess of these limits. The Company has not experienced any losses to date resulting from this practice.

The Company also has exposure to foreign currency risk as its subsidiary in France has a functional currency in Euros.

Leases

Effective January 1, 2019, the Company adopted Accounting Standards Update (“ASU”) No. 2016-02, "Leases." This ASU requires substantially all leases be recorded on the balance sheet as right of use assets and lease obligations. The Company adopted the ASU using a modified retrospective adoption method at January 1, 2019, as outlined in ASU No. 2018-11, "Leases - Targeted Improvements." Under this method of adoption, there is no impact to the comparative condensed consolidated statement of operations and condensed consolidated balance sheet. The Company determined that there was no cumulative-effect adjustment to beginning retained earnings on the consolidated balance sheet. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed carryforward of historical lease classifications. Adoption of this standard did not materially impact the Company’s results of operations and had no impact on the consolidated statement of cash flows.

Equity-Based Payments to Non-Employees

Equity-based payments to non-employees are measured at fair value on the grant date per ASU No. 2018-07, Improvements to Nonemployee Share-Based Payment Accounting.

Research and Development

Research and development costs are charged to operations when incurred and are included in operating expenses. Research and development costs consist principally of compensation of employees and consultants that perform the Company’s research activities, the fees paid to maintain the Company’s licenses, and the payments to third parties for clinical trial and additional product development and testing.

Foreign Currency Translation

For foreign subsidiaries with operations denominated in a foreign currency, assets and liabilities are translated to U.S. dollars, which is the functional currency, at period end exchange rates. Income and expense items are translated at average rates of exchange prevailing during the periods presented. Gains and losses from translation adjustments are accumulated in a separate component of shareholders’ equity.

Recent Accounting Pronouncements

In January 2017, the FASB issued guidance to simplify the subsequent measurement of goodwill impairment. The new guidance eliminates the two-step process that required identification of potential impairment and a separate measure of the actual impairment. Goodwill impairment charges, if any, would be determined by reducing the goodwill balance by the difference between the carrying value and the reporting unit’s fair value (impairment loss is limited to the carrying value). This standard is effective for annual or any interim goodwill impairment tests beginning after December 15, 2019. The Company believes that the adoption of this pronouncement will not have an impact on the Company’s measurement of goodwill impairment.

Note 3 - Fair Value Disclosures

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework that prioritizes and ranks the level of observability of inputs used in measuring fair value.

The fair value of the Company's financial instruments are as follows:

	Carrying Amount	Fair Value Measured at Reporting Date Using			Fair Value
		Level 1	Level 2	Level 3	
At March 31, 2019:					
Cash	\$ 413,858	\$ -	\$ 413,858	\$ -	\$ 413,858
Other receivables	\$2,051,028	\$ -	\$ -	\$2,051,028	\$2,051,028
Note payable	\$ 160,584	\$ -	\$ -	\$ 160,584	\$ 160,584
Convertible debt	\$1,728,442	\$ -	\$ -	\$1,728,442	\$1,728,442
At December 31, 2018:					
Cash	\$1,114,343	\$ -	\$1,114,343	\$ -	\$1,114,343
Other receivables	\$3,172,676	\$ -	\$ -	\$3,172,676	\$3,172,676
Note payable	\$ 255,032	\$ -	\$ -	\$ 255,032	\$ 255,032

The fair value of other receivables approximates carrying value as these consist primarily of French R&D tax credits that are normally received the following year and amounts due from our collaboration partner Mayoly, see Note 14.

The fair value of note payable approximates carrying value due to the terms of such instruments and applicable interest rates.

The fair value of convertible debt is based on the par value plus accrued interest through the date of reporting due to the terms of such instruments and interest rates, or the current interest rates of similar instruments.

Note 4 - Other Receivables

Other receivables consisted of the following:

	March 31, 2019	December 31, 2018
R&D tax credits	\$ 2,038,311	\$ 2,162,373
Other	12,717	1,010,303
Total other receivables	\$ 2,051,028	\$ 3,172,676

The research and development ("R & D") tax credits are the 2017 and 2018 refundable tax credits for research conducted in France. The tax credits for the years 2016 through 2018 are currently being examined by the French tax authorities which is in the normal course of business. At December 31, 2018, Other consists primarily of amounts due from collaboration partner Mayoly.

Note 5 - Property, Equipment and Leasehold Improvements

Property, equipment and leasehold improvements consisted of the following:

	March 31, 2019	December 31, 2018
Laboratory equipment	\$ 193,661	\$ 190,406

Computer equipment	78,986	75,417
Office equipment	37,264	37,262
Leasehold improvements	35,711	29,163
Total property, plant and equipment	<u>345,622</u>	<u>332,248</u>
Less accumulated depreciation	(220,487)	(203,394)
Property, plant and equipment, net	<u>\$ 125,135</u>	<u>\$ 128,854</u>

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Depreciation expense for the three months ended March 31, 2019 and December 31, 2018 was \$17,114 and \$14,763, respectively. Depreciation expense is included in general and administrative (“G&A”) expenses.

Note 6 - Intangible Assets and Goodwill

Patents

Pursuant to the Mayoly APA entered into on March 27, 2019, in which the Company purchased all rights, title and interest in and to MS1819-SD (see Note 14), the Company recorded Patents in the amount of \$3,802,745 as follows:

Common stock issued at signing to Mayoly	\$ 1,740,959
Due to Mayoly at 12/31/19 - €400,000	449,280
Due to Mayoly at 12/31/20 - €350,000	393,120
Assumed Mayoly liabilities and forgiveness of Mayoly debt	1,219,386
	<u>\$ 3,802,745</u>

Intangible assets are as follows:

	March 31, 2019	December 31, 2018
In process research and development	\$ -	\$ 416,600
Less accumulated amortization	-	(157,671)
In process research and development, net	<u>\$ -</u>	<u>\$ 258,929</u>
License agreements	\$ -	\$ 3,398,702
Less accumulated amortization	-	(3,087,154)
License agreements, net	<u>\$ -</u>	<u>\$ 311,548</u>
Patents	\$ 3,802,745	\$ -
Less accumulated amortization	-	-
Patents, net	<u>\$ 3,802,745</u>	<u>\$ -</u>

Amortization expense for the three months ended March 31, 2019 and 2018 was \$561,289 and \$191,681, respectively. Amortization expense for the three months ended March 31, 2019 included \$384,234 from In process research and development and License agreements written off as a result of the Mayoly APA.

As of March 31, 2019, amortization expense is expected to be as follows for the next five years:

2019	\$ 395,661
2020	527,548
2021	527,548
2022	527,548
2023	527,548

Goodwill is as follows:

	Goodwill
Balance at January 1, 2018	\$ 2,016,240
Foreign currency translation	(91,410)
Balance at December 31, 2018	1,924,830
Foreign currency translation	(37,472)
Balance at March 31, 2019	<u>\$ 1,887,358</u>

Note 7 - Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	March 31, 2019	December 31, 2018
Trade payables	\$ 2,243,574	\$ 1,532,110
Accrued expenses	69,930	285,061
Accrued payroll	267,205	253,225
Total accounts payable and accrued expenses	<u>\$ 2,580,709</u>	<u>\$ 2,070,396</u>

Note 8 - Note Payable

On December 14, 2018, the Company entered into a 9-month financing agreement for its directors and officer's liability insurance in the amount of \$286,203 that bears interest at an annual rate of 5.99%. Monthly payments, including principal and interest, are \$32,599 per month. The balance due under this financing agreement at March 31, 2019 was \$160,584.

Note 9 – Convertible Notes and Original Issue Discounted Convertible Notes with Warrants

ADEC Notes

On February 14, 2019, the Company entered into a Note Purchase Agreement (the "NPA") with ADEC Private Equity Investments, LLC ("ADEC"), pursuant to which the Company issued to ADEC two Senior Convertible Notes ("Note A" and "Note B," respectively, each a "Note," and together, the "Notes"), in the principal amount of \$1,000,000 per Note, resulting in gross proceeds to the Company of \$2,000,000. ADEC is controlled by Burke Ross, a significant stockholder of the Company.

The Notes accrue interest at a rate of 10% per annum (the "Interest Rate"); provided, however, that in the event the Company elects to repay the full balance due under the terms of both Notes prior to December 31, 2019, then the interest rate will be reduced to 6% per annum. Interest is payable at the time all outstanding Principal Amounts owed under each Note is repaid. The Notes will mature on the earlier to occur of (i) the tenth business day following the receipt by ABS of certain tax credits that the Company expects to receive prior to July 2019 in the case of Note A (the "2019 Tax Credit") and July 2020 in the case of Note B (the "2020 Tax Credit"), respectively, or (ii) December 31, 2019 in the case of Note A and December 31, 2020 in the Case of Note B (the "Maturity Dates"). As a condition to entering into the NPA, ABS and ADEC also entered into a Pledge Agreement, pursuant to which ABS agreed to pledge an interest in the 2019 and 2020 Tax Credits to ADEC in order to guarantee payment of all amounts due under the terms of the Notes.

Prior to their respective Maturity Dates, each of the Notes is convertible, at ADEC's option, into shares of the Company's common stock, at a conversion price equal to the principal and accrued interest due under the terms of the Notes divided by \$2.50 ("Conversion Shares"); provided, however, that pursuant to the term of the Notes, ADEC may not convert all or a portion of the Notes if such conversion would result in Mr. Ross and/or entities affiliated with him beneficially owning in excess of 19.99% of the Company's shares of common stock issued and outstanding immediately after giving effect to the issuance of the Conversion Shares.

As additional consideration for entering into the NPA, pursuant to a Warrant Amendment Agreement, the Company agreed to reduce the exercise price of 1,009,565 outstanding warrants previously issued by the Company to ADEC and its affiliates (the "Warrants") to \$1.50 per share. The Warrant Amendment does not alter any other terms of the Warrants. This resulted in a debt discount of \$325,320 that will be accreted to additional interest expense over the lives of the Notes.

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In connection with the above transaction, the Company also entered into a registration rights agreement with ADEC, pursuant to which the Company agreed to file a registration statement with the Securities and Exchange Commission no later than 45 days after the closing date of February 14, 2019 in order to register, on behalf of ADEC, the Conversion Shares. ADEC subsequently agreed to extend the date to file a registration statement to April 30, 2019. The registration statement was filed on April 25, 2019.

During the three months ended March 31, 2019, the Company accrued \$24,658 of interest expense in connection with these convertible notes. During the three months ended March 31, 2019, the Company recorded \$29,104 of interest expense in the form of amortization of debt discount related to the repriced warrants.

LPC OID Debenture

On April 11, 2017, the Company entered into a Note Purchase Agreement with Lincoln Park Capital Fund, LLC (“LPC”), pursuant to which the Company issued a 12% Senior Secured Original Issue Discount Convertible Debenture (the “Debenture”) to LPC.

On July 11, 2018, the Company paid off the remaining amount due under the terms of this Debenture in the amount of \$286,529.

For the three months ended March 31, 2018, the Company recorded \$46,795 of interest expense related to the amortization of the debt discount related to the warrant features of the Debenture.

Convertible Debt consisted of:

	March 31, 2019	December 31, 2018
Convertible debt	\$ 2,000,000	\$ -
Unamortized debt discount - revalued warrants	(296,216)	-
Total convertible debt	<u>\$ 1,703,784</u>	<u>\$ -</u>

Note 10 – Other Liabilities

Other liabilities consisted of the following:

	March 31, 2019	December 31, 2018
Current		
Due to Mayoly	\$ 449,280	\$ -
Lease liabilities	194,250	-
	<u>\$ 643,530</u>	<u>\$ -</u>

	March 31, 2019	December 31, 2018
Long-term		
Due to Mayoly	\$ 393,120	\$ -
Lease liabilities	93,372	-
	<u>\$ 486,492</u>	<u>\$ -</u>

Note 11 - Equity

On July 13, 2016, the Company amended its Certificate of Incorporation to increase the authorized shares of its common stock, \$0.0001 par value, to 100,000,000 shares from 9,000,000 shares and increase the authorized shares of its preferred stock, \$0.0001 par value, to 10,000,000 shares from 1,000,000 shares.

Common Stock

At March 31, 2019 and December 31, 2018, the Company had 18,537,958 and 17,704,925, respectively, of shares of its common stock issued and outstanding.

Voting

Each holder of common stock has one vote for each share held.

Stock Option Plan

The Company's board of directors and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan (the "2014 Plan"), which took effect on May 12, 2014. During the three months ended March 31, 2019 and 2018, the Company did not grant any stock options under the 2014 Plan.

Series A Convertible Preferred Stock

At March 31, 2019 and December 31, 2018, there were no Series A Convertible Preferred Stock ("Series A Preferred") outstanding. However, all terms of the Series A Preferred are still in effect.

Restricted Stock

During the three months ended March 31, 2019, 102,583 restricted shares of common stock vested with a fair value of \$296,285. 58,833 of these 102,583 shares having a fair value of \$178,852 vested during the three months ended March 31, 2019 due to the Company dosing the first patients in the Company's Phase II study to investigate MS1819-SD in CF patients. 30,000 of these 102,583 shares having a fair value of \$72,600 vested during the three months ended March 31, 2019 and have been issued to our directors as a part of Board compensation. 13,750 of these 102,583 shares having a fair value of \$44,833 vested during the three months ended March 31, 2019 due to the terms of such grants.

During the three months ended March 31, 2019, the Company issued 27,102 shares of its common stock to a consultant as payment of \$60,000 of accounts payable.

As of March 31, 2019, the Company had unrecognized restricted common stock expense of \$438,528. \$337,193 of this unrecognized expense will be recognized over the average remaining vesting term of the restricted common stock of 2.04 years. \$101,335 of this unrecognized expense vests upon the enrollment of the first 30 patients in a CF trial. This milestone was not considered probable at March 31, 2019.

During the three months ended March 31, 2018, 61,500 shares of restricted common stock were granted or accrued to employees and consultants with a total value of \$202,810. During the three months ended March 31, 2018, 66,917 restricted shares of common stock vested with a value of \$222,310 of which an aggregate of 30,000 shares with a value of \$94,200 have been issued to our directors as a part of Board compensation.

Note 12 - Warrants

In February 2019, as additional consideration for issuing convertible notes with ADEC and pursuant to a Warrant Amendment Agreement, the Company agreed to reduce the exercise price of certain outstanding warrants previously issued by the Company to ADEC and its affiliates, see Note 9.

Stock warrant transactions for the periods January 1 through March 31, 2019 and 2018 are as follows:

	<u>Warrants</u>	<u>Exercise Price Per Share</u>	<u>Weighted Average Exercise Price</u>
Warrants outstanding and exercisable at January 1, 2018	3,371,385	\$3.17 - \$7.37	\$ 5.28
Granted during the period	-	-	-
Expired during the period	-	-	-
Exercised during the period	(503,070)	\$ 2.50	\$ 2.50
Warrants outstanding and exercisable at March 31, 2018	<u>2,868,315</u>	<u>\$3.17 - \$7.37</u>	<u>\$ 5.28</u>
Warrants outstanding and exercisable at January 1, 2019	3,112,715	\$2.55 - \$7.37	\$ 4.83
Granted during the period	-	-	-
Expired during the period	-	-	-
Exercised during the period	-	-	-
Warrants outstanding and exercisable at March 31, 2019	<u>3,112,715</u>	<u>\$1.50 - \$7.37</u>	<u>\$ 3.53</u>

<u>Exercise Price</u>	<u>Number of Shares Under Warrants</u>	<u>Weighted Average Remaining Contract Life in Years</u>	<u>Weighted Average Exercise Price</u>
\$ 1.50 - \$2.99	1,253,965	2.88	
\$ 3.00 - \$3.99	636,972	3.06	
\$ 4.00 - \$4.99	196,632	2.76	
\$ 5.00 - \$5.99	805,476	2.88	
\$ 6.00 - \$6.99	187,750	2.51	
\$ 7.00 - \$7.37	31,920	1.71	
Total	<u>3,112,715</u>	<u>2.88</u>	\$3.53

In January 2018, the Company offered certain warrant holders the opportunity to exercise their warrants at a reduced strike price of \$2.50, and if so elected, would also have the opportunity to reprice other warrants that they continued to hold unexercised to \$3.25. The offer, which was effective January 12, 2018, was for the repricing only and did not modify the life of the warrants. Warrant holders of approximately 503,000 shares exercised their warrants and had other warrants modified on approximately 197,000 shares, which resulted in a charge of approximately \$429,000 in January 2018.

During the three months ended March 31, 2019 and 2018, no warrants were issued to non-employees.

Note 13 - Stock-Based Compensation Plan

Under the 2014 Plan, the fair value of options granted is estimated on the grant date using the Black-Scholes option valuation model. This valuation model for stock-based compensation expense requires the Company to make assumptions and judgments about the variables used in the calculation, including the expected term (weighted-average period of time that the options granted are expected to be outstanding), the volatility of the common stock price and the assumed risk-free interest rate. The Company recognizes stock-based compensation expense for only those shares expected to vest over the requisite service period of the award. No compensation cost is recorded for options that do not vest and the compensation cost from vested options, whether forfeited or not, is not reversed.

During the three months ended March 31, 2019 and 2018, no stock options were granted. During the three months ended March 31, 2019, 244,500 options vested having a fair value of \$511,335 and an intrinsic value of \$0. 242,000 of these options valued at \$501,666 vested due to the Company having its first CF patient dosed with MS1819-SD anywhere in the world, which was achieved by the dosing of the first patient in the OPTION Study. During the three months ended March 31, 2018, 7,500 options vested having a fair value of \$29,018 and an intrinsic value of \$0.

The expected term of the options is based on expected future employee exercise behavior. Volatility is based on the historical volatility of several public entities that are similar to the Company. The Company bases volatility this way because it does not have sufficient historical transactions in its own shares on which to solely base expected volatility. The risk-free interest rate is based on the U.S. Treasury rates at the date of grant with maturity dates approximately equal to the expected term at the grant date. The Company has not historically declared any dividends and does not expect to in the future.

The Company realized no income tax benefit from stock option exercises in each of the periods presented due to recurring losses and valuation allowances.

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Stock option activity under the 2014 Plan is as follows:

	<u>Number of Shares</u>	<u>Average Exercise Price</u>	<u>Remaining Contract Life in Years</u>	<u>Intrinsic Value</u>
Stock options outstanding at January 1, 2018	545,000	\$ 4.05	7.13	\$ -
Granted during the period	-	-		
Expired during the period	-	-		
Exercised during the period	-	-		
Stock options outstanding at March 31, 2018	<u>545,000</u>	<u>\$ 4.05</u>	<u>6.89</u>	<u>\$ -</u>
Exercisable at March 31, 2018	<u>165,000</u>	<u>\$ 4.48</u>	<u>8.85</u>	<u>\$ -</u>
Non-vested stock options outstanding at January 1, 2018	387,500	\$ 3.89	6.39	\$ -
Granted during the period	-	-		
Vested during the period	7,500	\$ 4.48	6.39	\$ -
Expired during the period	-	-		
Exercised during the period	-	-		
Non-vested stock options outstanding at March 31, 2018	<u>380,000</u>	<u>\$ 3.87</u>	<u>6.03</u>	<u>\$ -</u>
Stock options outstanding at January 1, 2019	994,000	\$ 3.58	5.42	\$ -
Granted during the period	-	-		
Expired during the period	-	-		
Canceled during the period	-	-		
Exercised during the period	-	-		
Stock options outstanding at March 31, 2019	<u>994,000</u>	<u>\$ 3.58</u>	<u>5.17</u>	<u>\$ -</u>
Exercisable at March 31, 2019	<u>994,000</u>	<u>\$ 3.58</u>	<u>5.17</u>	<u>\$ -</u>
Non-vested stock options outstanding at January 1, 2019	244,500	\$ 3.05	4.53	\$ -
Granted during the period	-	-		
Vested during the period	(244,500)	\$ 3.05	4.53	
Expired during the period	-	-		
Canceled during the period	-	-		
Exercised during the period	-	-		
Non-vested stock options outstanding at March 31, 2019	<u>-</u>	<u>\$ -</u>	<u>-</u>	<u>\$ -</u>

635,067 shares of common stock were available for future issuance under the 2014 Plan as of March 31, 2019.

As of March 31, 2019, the Company did not have any unrecognized stock-based compensation expense.

Note 14 - Agreements

Mayoly Agreement

During the three months ended March 31, 2019 and 2018, the Company charged \$403,020 and \$125,986, respectively, to Mayoly under the JDLA that was in effect during both periods.

On March 27, 2019, the Company entered into the Mayoly APA pursuant to which the Company purchased substantially all rights, title and interest in and to MS1819-SD, see Recent Developments above.

INRA Agreement

In February 2006, Mayoly and INRA TRANSFERT, on behalf of INRA and CNRS, entered into a Usage and Cross-Licensing Agreement granting Mayoly exclusive worldwide rights to exploit *Yarrowia lipolytica* and other lipase proteins based on their patents for use in humans. The INRA Agreement provides for the payment by Mayoly of royalties on net sales, subject to Mayoly's right to terminate such obligation upon the payment of a lump sum specified in the agreement. Upon execution of the Mayoly APA, all rights, obligations and interests under the INRA Agreement were transferred to the Company.

TransChem Sublicense

On August 7, 2017, the Company entered into a Sublicense Agreement with TransChem, Inc. ("*TransChem*"), pursuant to which TransChem granted the Company an exclusive license to patents and patent applications relating to *Helicobacter pylori* 5'-methylthioadenosine nucleosidase inhibitors (the "*Licensed Patents*") currently held by TransChem (the "*Sublicense Agreement*"). The Company may terminate the Sublicense Agreement and the licenses granted therein for any reason and without further liability on 60 days' notice. Unless terminated earlier, the Sublicense Agreement will expire upon the expiration of the last Licensed Patents. Upon execution, the Company paid an upfront fee to TransChem and agreed to reimburse TransChem for certain expenses previously incurred in connection with the preparation, filing, and maintenance of the Licensed Patents. The Company also agreed to pay TransChem certain future periodic sublicense maintenance fees, which fees may be credited against future royalties. The Company may also be required to pay TransChem additional payments and royalties in the event certain performance-based milestones and commercial sales involving the Licensed Patents are achieved. The Licensed Patents will allow the Company to develop compounds for treating gastrointestinal and other infections which are specific to individual bacterial species. *H.pylori* bacterial infections are a major cause of chronic gastritis, peptic ulcer disease, gastric cancer and other diseases. No payments were made under this agreement in the three months ended March 31, 2019 and 2018.

Employment Agreements

Johan (Thijs) Spoor

On January 3, 2016, the Company entered into an employment agreement with its President and Chief Executive Officer, Johan Spoor. The employment agreement provides for a term expiring January 2, 2019. Either party may terminate Mr. Spoor's employment at any time and for any reason, or for no reason. During the term and for a period of twelve (12) months thereafter, Mr. Spoor shall not engage in competition with the Company either directly or indirectly, in any manner or capacity.

The Company will pay Mr. Spoor a base salary of \$350,000 per year, which automatically increased to \$425,000 per year upon the consummation of the IPO which occurred on October 11, 2016. At the sole discretion of the board of directors or the compensation committee of the board, following each calendar year of employment, Mr. Spoor shall be eligible to receive an additional cash bonus based on his attainment of certain financial, clinical development, and/or business milestones to be established annually by the board of directors or the compensation committee.

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Mr. Spoor was originally entitled to 380,000 10-year stock options pursuant to the 2014 Plan. In the first quarter of 2017, 100,000 options having a value of \$386,900 were granted and expensed. On September 29, 2017, Mr. Spoor was granted 100,000 shares of restricted common stock subject to vesting conditions as follows: (i) 75% upon FDA acceptance of a U.S. IND application for MS1819-SD, and (ii) 25% upon the Company completing a Phase IIa clinical trial for MS1819-SD, in satisfaction of the Company's obligation to issue the additional 280,000 options to Mr. Spoor described above, with an estimated fair value at the grant date of \$425,000 to be expensed when the probability of these milestones can be determined. All of these shares vested and the \$425,000 was expensed in the second and fourth quarters in 2018 due to the Company completing both milestones.

On June 28, 2018, Mr. Spoor was granted 200,000 shares of restricted common stock subject to vesting conditions as follows: (i) 50% shall vest in three equal installments beginning one year from the date of issuance, and (ii) the remaining 50% shall vest as follows: one-third shall vest upon U.S. acceptance of IND for MS1819-SD, one-third upon the first dosing of a CF patient with MS1819-SD anywhere in the world, and the remaining one-third upon enrollment of the first 30 patients in a CF trial. These restricted shares had an estimated fair value at the grant date of \$608,000 to be expensed when the above milestones are probable. 8,333 shares with a fair value of \$25,332 vested and was expensed in the three months ended March 31, 2019 due to being earned over that time. 33,333 shares with a fair value of \$101,332 vested and was expensed in the three months ended March 31, 2019 due to the first dosing of CF patients with MS1819-SD anywhere in the world.

On June 28, 2018, the Board approved a 2017 annual incentive bonus pursuant to his employment agreement in the amount of \$212,500.

Maged Shenouda

On September 26, 2017, the Company entered into an employment agreement with Maged Shenouda, a member of the Company's Board of Directors, pursuant to which Mr. Shenouda serves as the Company's Chief Financial Officer. Mr. Shenouda's employment agreement provides for the issuance of stock options to purchase 100,000 shares of the Company's common stock, issuable pursuant to the 2014 Plan. These options will vest as follows so long as Mr. Shenouda is serving as either Executive Vice-President of Corporate Development or as Chief Financial Officer (i) 75% upon FDA acceptance of a U.S. IND application for MS1819-SD, and (ii) 25% upon the Company completing a Phase IIa clinical trial for MS1819-SD. The option is exercisable for \$4.39 per share and will expire on September 25, 2027. All of these shares vested and the \$336,500 was expensed in 2018 due to the Company completing both milestones listed above in 2018.

On June 28, 2018, Mr. Shenouda was granted stock options to purchase 100,000 shares of the Company's common stock, issuable pursuant to the 2014 Plan, subject to vesting conditions as follows: (i) 50% upon U.S. acceptance of an IND for MS1819-SD, and (ii) 50% upon the first CF patient doses with MS1819-SD anywhere in the world. These options had an estimated fair value at the grant date of \$207,300 to be expensed when the above milestones are probable. 50,000 of these options having a fair value of \$103,650 vested and was expensed in 2018 due to the FDA acceptance of the Company's IND application for MS1819-SD. The remaining 50,000 options having a fair value of \$103,650 vested and was expensed in the three months ended March 31, 2019 due to the first dosing of CF patients with MS1819-SD anywhere in the world.

On June 28, 2018, the Board approved a 2017 annual incentive bonus pursuant to his employment agreement in the amount of \$82,500.

Dr. James E. Pennington

On May 28, 2018, the Company entered into an employment agreement with Dr. Pennington to serve as the Company's Chief Medical Officer. The employment agreement with Dr. Pennington provides for a base annual salary of \$250,000. In addition to his salary, Dr. Pennington is eligible to receive an annual milestone bonus, awarded at the sole discretion of the Board based on his attainment of certain financial, clinical development, and/or business milestones established annually by the Board or Compensation Committee. The employment agreement is terminable by either party at any time. In the event of termination by the Company other than for cause, Dr. Pennington is entitled to three months' severance payable over such period. In the event of termination by the Company other than for cause in connection with a Change of Control, Dr. Pennington will receive six months' severance payable over such period.

On June 28, 2018, Mr. Pennington was granted stock options to purchase 75,000 shares of the Company's common stock, issuable pursuant to the 2014 Plan, subject to vesting conditions as follows: (i) 50% upon U.S. acceptance of an IND for MS1819-SD, and (ii) 50% upon the first CF patient doses with MS1819-SD anywhere in the world. These options had an estimated fair value at the grant date of \$155,475 to be expensed when the above milestones are probable. 37,500 of these options vested and \$77,738 was expensed in 2018 due to the FDA acceptance of the Company's IND application for MS1819-SD in 2018. 37,500 of these options having a fair value of \$77,738 vested and was expensed in the three months ended March 31, 2019 due to the first dosing of CF patients with MS1819-SD anywhere in the world.

Note 15 - Leases

The Company adopted ASU 2016-02, Leases, as of January 1, 2019, using the modified retrospective approach. Prior year financial statements were not recast under the new standard.

The Company leases its office and research facilities under operating leases which are subject to various rent provisions and escalation clauses expiring at various dates through 2020. The escalation clauses are indeterminable and considered not material and have been excluded from minimum future annual rental payments.

Lease expense amounted to \$50,655 and \$31,227, respectively, in the three months ended March 31, 2019 and 2018.

The weighted-average remaining lease term and weighted-average discount rate under operating leases at March 31, 2019 are:

	March 31, 2019
Lease term and discount rate	
Weighted-average remaining lease term	1.5 years
Weighted-average discount rate	6.0%

Maturities of operating lease liabilities at March 31, 2019 are as follows:

2019	\$ 152,100
2020	154,448
Total lease payments	<u>306,548</u>
Less imputed interest	(18,926)
Present value of lease liabilities	<u>\$ 287,622</u>

Note 16 - Income Taxes

The Company is subject to taxation at the federal level in both the United States and France and at the state level in the United States. At March 31, 2019 and December 31, 2018, the Company had no tax provision for either jurisdiction.

At March 31, 2019 and December 31, 2018, the Company had gross deferred tax assets of approximately \$13,650,000 and \$12,490,000, respectively. As the Company cannot determine that it is more likely than not that the Company will realize the benefit of the deferred tax asset, a valuation allowance of approximately \$13,650,000 and \$12,490,000, respectively, has been established at March 31, 2019 and December 31, 2018. The change in the valuation allowance in the three months ended March 31, 2019 and 2018 was \$1,160,000 and \$925,000, respectively.

At March 31, 2019, the Company has gross net operating loss (“NOL”) carry-forwards for U.S. federal and state income tax purposes of approximately \$23,983,000 and \$24,058,000, respectively. The NOL’s expire between the years 2034 and 2039. The Company’s ability to use its NOL carryforwards may be limited if it experiences an “ownership change” as defined in Section 382 (“Section 382”) of the Internal Revenue Code of 1986, as amended. An ownership change generally occurs if certain stockholders increase their aggregate percentage ownership of a corporation’s stock by more than 50 percentage points over their lowest percentage ownership at any time during the testing period, which is generally the three-year period preceding any potential ownership change.

At March 31, 2019 and December 31, 2018, the Company had approximately \$16,113,000 and \$15,406,000, respectively, in net operating losses which it can carryforward indefinitely to offset against future French income.

At March 31, 2019 and December 31, 2018, the Company had taken no uncertain tax positions that would require disclosure under ASC 740, Accounting for Income Taxes.

Note 17 - Net Loss per Common Share

Basic net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflect, in periods in which they have a dilutive effect, the impact of common shares issuable upon exercise of stock options and warrants and conversion of convertible debt that are not deemed to be anti-dilutive. The dilutive effect of the outstanding stock options and warrants is computed using the treasury stock method.

At March 31, 2019, diluted net loss per share did not include the effect of 3,112,715 shares of common stock issuable upon the exercise of outstanding warrants, 416,000 shares of restricted stock not yet issued, and 994,000 shares of common stock issuable upon the exercise of outstanding options as their effect would be antidilutive during the periods prior to conversion.

At March 31, 2018, diluted net loss per share did not include the effect of 2,868,315 shares of common stock issuable upon the exercise of outstanding warrants, 545,000 shares of common stock issuable upon the exercise of outstanding options, and 74,000 shares of common stock issuable upon the conversion of convertible debt as their effect would be antidilutive during the periods prior to conversion.

Note 18 - Related Party Transactions

During the year ended December 31, 2015, the Company employed the services of JIST Consulting (“JIST”), a company controlled by Johan (Thijs) Spoor, the Company’s current Chief Executive Officer and president, as a consultant for business strategy, financial modeling, and fundraising. Included in accounts payable at both March 31, 2019 and December 31, 2018 is \$478,400 for JIST relating to Mr. Spoor’s services. Mr. Spoor received no other compensation from the Company other than as specified in his employment agreement.

During the year ended December 31, 2015, the Company’s President, Christine Rigby-Hutton, was employed through Rigby-Hutton Management Services (“RHMS”). Ms. Rigby-Hutton resigned from the Company effective April 20, 2015. Included in accounts payable at both March 31, 2019 and December 31, 2018 is \$38,453 for RHMS for Ms. Rigby-Hutton’s services.

Starting on October 1, 2016 until his appointment as the Company’s Chief Financial Officer on September 25, 2017, the Company used the services of Maged Shenouda as a financial consultant. Included in accounts payable at March 31, 2019 and December 31, 2018 is \$10,000 and \$50,000, respectively, for Mr. Shenouda’s services.

Note 19 – Subsequent Events

April 2019 Public Offering of Common Stock

On April 2, 2019, the Company completed a public offering of 1,294,930 shares of its common stock at a public offering price of \$2.13 per share, resulting net proceeds of approximately \$2,500,000, after deducting the selling agent fee payable to Alexander Capital, L.P. (“*Alexander Capital*”) and other offering expenses payable by the Company (the “*April 2019 Public Offering*”). The April 2019 Public Offering was completed pursuant to the terms of a Selling Agent Agreement executed by the Company and Alexander Capital on April 1, 2019. The April 2019 Public Offering was completed pursuant to the Company’s effective shelf registration statement on Form S-3 (File No. 333-225935) and the prospectus supplement was filed on May 1, 2019.

In connection with the April 2019 Public Offering, the Company entered into a Selling Agent Agreement with Alexander Capital, pursuant to which the Company paid Alexander Capital (i) a cash fee equal to 7% of the aggregate gross proceeds of the April 2019 Public Offering, and (ii) to issue Alexander Capital warrants to purchase 38,848 shares of the Company’s common stock (the “*Selling Agent Warrants*”), an amount equal to 3% of the aggregate number of shares of the Company’s common stock sold in the April 2019 Public Offering. The Company also agreed to reimburse Alexander Capital for its expenses in connection with the April 2019 Public Offering on a non-accountable basis in an amount equal to 1% of the gross proceeds of the Offering and up to \$50,000 for other accountable expenses. The Selling Agent Warrants will become exercisable one year from the date of issuance, expire on April 2, 2024 and have an exercise price of \$2.55 per share.

May 2019 Public Offering of Common Stock

In May 2019, the Company completed a public offering of 1,227,167 shares of its common stock at a public offering price of \$2.35 per share, resulting in net proceeds of approximately \$2.55 million, after deducting the selling agent fee payable to Alexander Capital and other offering expenses payable by the Company (the “*May 2019 Public Offering*”). The May 2019 Public Offering was completed pursuant to the Company’s effective shelf registration statement on Form S-3 (File No. 333-225935) and the prospectus supplement was filed on May 9, 2019.

In connection with the May 2019 Public Offering, the Company entered into a Selling Agent Agreement with Alexander Capital, pursuant to which the Company paid to Alexander Capital (i) a cash fee equal to 7.0% of the aggregate gross proceeds of the May 2019 Public Offering, and (ii) issued to Alexander Capital 36,815 Selling Agent Warrants, an amount equal to 3.0% of the aggregate number of shares of common stock sold in the May 2019 Public Offering. The Company also reimbursed Alexander Capital for its expenses on a non-accountable basis in an amount equal to 1.0% of the gross proceeds of the May 2019 Offering and up to \$50,000 for other accountable expenses. The Selling Agent Warrants will become exercisable one year from the date of issuance, expire on May 9, 2024, and have an exercise price of \$2.82 per share.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

References in this report to "AzurRx," "Company," "we," "us," "our," or similar references mean AzurRx BioPharma, Inc. and its subsidiaries on a consolidated basis. References to "AzurRx BioPharma" refer to AzurRx BioPharma, Inc. on an unconsolidated basis. References to "AzurRx SAS" refer to AzurRx BioPharma's wholly owned subsidiary through which we conduct our European operations. References to the "SEC" refer to the U.S. Securities and Exchange Commission.

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this interim report. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words "expect," "anticipate," "intend," "believe," or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" included in our Annual Report filed on Form 10-K for the year ended December 31, 2018, filed with the SEC on April 1, 2019. Readers are cautioned not to place undue reliance on these forward-looking statements.

Overview

AzurRx BioPharma, Inc. was incorporated on January 30, 2014 in the State of Delaware. In June 2014, the Company acquired 100% of the issued and outstanding capital stock of AzurRx SAS (formerly "ProteaBio Europe SAS"), a company incorporated in October 2008 under the laws of France. AzurRx and its wholly-owned subsidiary, AzurRx SAS ("ABS"), are collectively referred to as the "Company."

We are engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders. Non-systemic biologics are non-absorbable drugs that act locally, i.e. the intestinal lumen, skin or mucosa, without reaching an individual's systemic circulation.

Our current product pipeline consists of two therapeutic programs under development, each of which are described below:

MS1819-SD

MS1819-SD is a yeast derived recombinant lipase for exocrine pancreatic insufficiency ("EPI") associated with chronic pancreatitis ("CP") and cystic fibrosis ("CF"). A lipase is an enzyme that breaks up fat molecules. MS1819-SD is considered recombinant because it was created from new combinations of genetic material in yeast called *Yarrowia lipolytica*. In June 2018, we completed an open-label, dose escalation Phase IIa trial of MS1819-SD in France, Australia, and New Zealand to investigate both the safety of escalating doses of MS1819-SD, and the efficacy of MS1819-SD through the analysis of each patient's coefficient of fat absorption ("CFA") and its change from baseline. A total of 11 CP patients with EPI were enrolled in the study and final data showed a strong safety and efficacy profile. Although the study was not powered for efficacy, in a pre-planned analysis, the highest dose cohort of MS1819-SD showed statistically significant and clinically meaningful increases in CFA compared to baseline with a mean increase of 21.8% and a p value of p=0.002 on a per protocol basis. Additionally, maximal absolute CFA response to treatment was up to 57%, with an inverse relationship to baseline CFA. In October 2018, the U.S. Food and Drug Administration ("FDA") cleared our Investigational New Drug ("IND") application for MS1819-SD in patients with EPI due to CF. In connection with the FDA's clearance of the IND, in the fourth quarter of 2018 we initiated the multi-center Phase II OPTION study in the United States and Europe (the "OPTION Study"), which we expect will include approximately 30 patients. We dosed the first patients in the OPTION Study in February 2019 and reached 50% of our enrollment target for the OPTION Study in April 2019. We expect to conclude and announce topline results from the OPTION Study in the summer of 2019.

b-Lactamase Program

Our b-lactamase program focuses on products with an enzymatic combination of bacterial origin for the prevention of hospital-acquired infections and antibiotic-associated diarrhea (“AAD”) by resistant bacterial strains induced by parenteral administration of several antibiotic classes. Currently, we have two compounds in pre-clinical development in this program, AZX1101 and AZX1103. Both AZX1101 and AZX1103 are composed of several distinct enzymes that break up individual classes of antibiotic molecules. AZX1103 is a b-lactamase enzyme combination that has shown positive pre-clinical activity, with degradation of amoxicillin in the presence of clavulanic acid in the upper gastrointestinal tract in the Gottingen minipig model. Currently, we are focused on advancing pre-clinical development of AZX1103. We are also currently assessing our plans for the continuation of the development of AZX1101.

We do not expect to generate revenue from drug candidates that we develop until we obtain approval for one or more of such drug candidates and commercialize our product or enter into a collaborative agreement with a third party. We do not have any products approved for sale at the present and have never generated revenue from product sale.

Recent Developments

Private Note Offering

On February 14, 2019, we entered into a Note Purchase Agreement (the “NPA”) with ADEC Private Equity Investments, LLC (“ADEC”), pursuant to which we issued to ADEC two Senior Convertible Notes (“Note A” and “Note B,” respectively, each a “Note,” and together, the “Notes”), in the principal amount of \$1,000,000 per Note, resulting in gross proceeds to us of \$2,000,000. ADEC is controlled by Burke Ross, one of our significant stockholders.

The Notes accrue interest at a rate of 10% per annum; *provided, however*, that in the event we elect to repay the full balance of both Notes prior to December 31, 2019, then the interest rate will be reduced to 6% per annum. The Notes will mature on the earlier to occur of (i) the tenth business day following our receipt of certain tax credits from the French government, which we expect to receive prior to July 2019 in the case of Note A (the “2019 Tax Credit”) and July 2020 in the case of Note B (the “2020 Tax Credit”), respectively, or (ii) December 31, 2019 in the case of Note A and December 31, 2020 in the Case of Note B (the “Maturity Dates”). As a condition to entering into the NPA, ABS and ADEC also entered into a Pledge Agreement, pursuant to which ABS agreed to pledge an interest in the 2019 Tax Credit and 2020 Tax Credit to ADEC in order to guarantee payment of all amounts due under the terms of the Notes.

Prior to their respective Maturity Dates, each of the Notes is convertible, at ADEC’s option, into shares of our common stock, at a conversion price equal to the principal and accrued interest due under the terms of the Notes divided by \$2.50 (“Conversion Shares”); *provided, however*, that pursuant to the term of the Notes, ADEC may not convert all or a portion of the Notes if such conversion would result in Mr. Ross and/or entities affiliated with him beneficially owning in excess of 19.99% of our shares of common stock issued and outstanding immediately after giving effect to the issuance of the Conversion Shares.

As additional consideration for entering into the NPA, we reduced the exercise price of all outstanding warrants previously issued by us to ADEC and its affiliates (the “ADEC Warrants”) to \$1.50 per share. None of the other terms of the ADEC Warrants were modified in connection with the NPA and the issuance of the Notes.

In connection with the above transaction, we also entered into a registration rights agreement with ADEC, pursuant to which we agreed to file a registration statement with the Securities and Exchange Commission no later than 45 days after the closing date of February 14, 2019 in order to register, on behalf of ADEC, the Conversion Shares. ADEC subsequently agreed to extend the date to file a registration statement to April 30, 2019 and we filed this registration statement on April 26, 2019.

Asset Purchase Agreement with Mayoly

On March 27, 2019, we entered into an Asset Purchase Agreement with Laboratoires Mayoly Spindler SAS (“Mayoly”), a European pharmaceutical company and our former development partner for MS1819-D, pursuant to which we purchased all rights, title and interest in and to MS1819-SD (the “Mayoly APA”). Upon execution of the Mayoly APA, the Joint Development and License Agreement (the “JDLA”) previously executed by AzurRx SAS and Mayoly was terminated. In addition, we granted to Mayoly an exclusive, royalty-bearing right to revenue received from commercialization of MS1819-SD within certain territories.

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In accordance with the Mayoly APA, we provided to Mayoly the following consideration for the purchase of MS1819-SD:

- (i) we assumed certain of Mayoly's liabilities with respect to MS1819-SD;
- (ii) we forgave all amounts previously owed to AzurRx SAS by Mayoly under the JDLA;
- (iii) we paid all amounts incurred by Mayoly for the maintenance of patents related to MS1819-SD from January 1, 2019 through the date of the Mayoly APA;
- (iv) we made an initial payment to Mayoly of € 800,000, which amount was paid by the issuance of 400,481 shares of our common stock at a price of \$2.29 per share (the "*Closing Payment Shares*") and the Company recognized \$898,560 as part of stockholders' equity; and
- (v) we agreed to pay to Mayoly an additional € 1,500,000, payable in a mix of cash and shares of our common stock as follows (the "*Milestone Payments*"): (y) on December 31, 2019, a cash payment of € 400,000 and 200,240 shares of common stock (the "*2019 Escrow Shares*") and (z) on December 31, 2020, a cash payment of € 350,000 and 175,210 shares of common stock (the "*2020 Escrow Shares*" and, together with the 2019 Escrow Shares, the "*Escrow Shares*") and the Company recognized \$842,399 as part of stockholders' equity.

The Closing Payment Shares and the Escrow Shares were all issued upon execution of the Mayoly APA; *provided, however*, per the terms of the Mayoly APA, the Escrow Shares will be held in escrow until the applicable Milestone Payment date, at which time the respective Escrow Shares will be released to Mayoly.

April 2019 Public Offering of Common Stock

In April 2019, we completed a public offering of 1,294,930 shares of its common stock at a public offering price of \$2.13 per share, resulting net proceeds of approximately \$2.5 million, after deducting the selling agent fee payable to Alexander Capita, L.P. ("*Alexander Capital*") and other offering expenses payable by the Company (the "*April 2019 Public Offering*"). The April 2019 Public Offering was completed pursuant to our effective shelf registration statement on Form S-3 (File No. 333-225935) and the prospectus supplement was filed on May 1, 2019.

In connection with the April 2019 Public Offering, we entered into a Selling Agent Agreement with Alexander Capital, pursuant to which we paid to Alexander Capital (i) a cash fee equal to 7.0% of the aggregate gross proceeds of the April 2019 Public Offering, and (ii) issue to Alexander Capital warrants to purchase 38,848 shares of our common stock (the "*Selling Agent Warrants*"), an amount equal to 3.0% of the aggregate number of shares of common stock sold in the April 2019 Public Offering. We also reimbursed Alexander Capital for its expenses on a non-accountable basis in an amount equal to 1.0% of the gross proceeds of the April 2019 Offering and \$50,000 for other accountable expenses. The Selling Agent Warrants will become exercisable one year from the date of issuance, expire on April 2, 2024 and have an exercise price of \$2.55 per share.

May 2019 Public Offering of Common Stock

In May 2019, we completed a public offering of 1,227,167 shares of our common stock at a public offering price of \$2.35 per share, resulting in net proceeds of approximately \$2.55 million, after deducting the selling agent fee payable to Alexander Capital and other offering expenses payable by us (the "*May 2019 Public Offering*"). The May 2019 Public Offering was completed pursuant to our effective shelf registration statement on Form S-3 (File No. 333-225935) and the prospectus supplement was filed on May 9, 2019.

In connection with the May 2019 Public Offering, we entered into a Selling Agent Agreement with Alexander Capital, pursuant to which we paid to Alexander Capital (i) a cash fee equal to 7.0% of the aggregate gross proceeds of the May 2019 Public Offering, and (ii) issued to Alexander Capital 36,815 Selling Agent Warrants, an amount equal to 3.0% of the aggregate number of shares of common stock sold in the May 2019 Public Offering. We also reimbursed Alexander Capital for its expenses on a non-accountable basis in an amount equal to 1.0% of the gross proceeds of the May 2019 Offering and up to \$50,000 for other accountable expenses. The Selling Agent Warrants will become exercisable one year from the date of issuance, expire on May 9, 2024, and have an exercise price of \$2.82 per share.

Liquidity and Capital Resources

We have experienced net losses and negative cash flows from operations since our inception. As of March 31, 2019, we had cash of approximately \$414,000 and had an accumulated deficit of approximately \$52,178,000. We are dependent on obtaining, and are continuing to pursue, funding necessary to continue our operations from outside sources, including obtaining additional funding from the sale of securities. Without adequate funding, we may not be able to meet our obligations. We believe these conditions raise substantial doubt about our ability to continue as a going concern.

We have funded our operations to date primarily through the completion of our initial public offering in October 2016 (“*IPO*”), the issuance of debt and convertible debt securities, the issuance of common stock in various private placement transactions, and our public offerings in May 2018, April 2019, and May 2019. We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates. We will require additional financing to develop, prepare regulatory filings and obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities.

We are focused on expanding our product pipeline through collaborations, and also through potential acquisitions. We are continually evaluating potential asset acquisitions and business combinations. To finance such potential acquisitions, we may raise additional equity capital, incur additional debt, or both, which capital may not be available on a timely basis or on acceptable terms.

Cash Flows for the Three Months Ended March 31, 2019 and 2018

Net cash used in operating activities for the three months ended March 31, 2019 was \$2,627,797, which primarily reflected our net loss of \$4,660,755 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of \$578,403, non-cash stock-based compensation of \$511,335 due primarily to achievement of certain performance-based milestones associated with previously issued equity awards, non-cash restricted stock granted to employees/directors of \$296,285 due primarily to reaching certain performance-based milestones, non-cash restricted stock granted to a consultant in payment of accounts payable for \$60,000, accrued interest on convertible debt of \$24,658, and non-cash debt discount - warrants on convertible debt of \$29,104. Changes in assets and liabilities are due to an increase in other receivables of \$149,508, a decrease in prepaid expenses of \$172,886 due primarily to the expensing of prepaid insurance, an increase in right of use assets of \$289,830 due to the adoption of new lease accounting standards, an increase in deposits of \$4,125, an increase in accounts payable and accrued expenses of \$514,950 due primarily to increases in expenses as detailed below and an increase in other liabilities due to the adoption of new lease accounting standards.

Net cash used in operating activities for the three months ended March 31, 2018 was \$2,214,267, which primarily reflected our net loss of \$3,632,997 plus adjustments to reconcile net loss to net cash used in operating activities of depreciation and amortization expense of \$206,444, non-cash fair value adjustment of the contingent consideration of (\$10,000), non-cash stock-based compensation of \$29,018, non-cash restricted stock granted to employees/directors of \$113,700, non-cash debt discount - warrants on a 12% Senior Secured Original Issue Discount Convertible Debenture issued to Lincoln Park Capital in April 2017 (the “*LPC Debenture*”) of \$46,795, and a non-cash warrant modification expense of \$428,748. Changes in assets and liabilities are due to a decrease in other receivables of \$120,877 due primarily to the receipt of payments from our research partner Mayoly, a decrease in prepaid expenses of \$59,625 due primarily to the expensing of prepaid insurance, and an increase in accounts payable and accrued expenses of \$423,523 due primarily to increased research and development expense.

Net cash used in investing activities for the three months ended March 31, 2019 and 2018 was \$13,352 and \$29,521, respectively, which consisted of the purchase of property and equipment.

Net cash provided by financing activities for the three months ended March 31, 2019 was \$1,967,142, which consisted of \$2,000,000 from the issuance of the Notes to ADEC, \$61,590 received from a stockholder in relation to a warrant modification, offset by repayment of a note payable of \$94,448. Net cash provided by financing activities for the three months ended March 31, 2018 was \$2,245,701, which consisted of \$2,324,742 from the issuance of common stock from the exercise of previously issued common stock purchase warrants, offset by repayment of a note payable of \$79,041.

Consolidated Results of Operations for the Three Months Ended March 31, 2019 and 2018

Research and development expenses were \$2,118,533 and \$1,678,029, respectively, for the three months ended March 31, 2019 and 2018, an increase of \$440,504, due primarily to the startup of a research and development function in the U.S. including expenses for our OPTION study that were not present in the same period in 2018. We expect research and development expenses to increase in future periods as our product candidates continue through clinical trials and we seek strategic collaborations.

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General and administrative (“G&A”) expenses were \$2,485,111 and \$1,916,333, respectively, for the three months ended March 31, 2019 and 2018, an increase of \$568,778. The increase for the three months ended March 31, 2019 as compared to the same period in 2018 was due primarily to an increase in non-cash restricted stock, stock-based compensation, and warrants granted accumulating to \$556,292 due primarily to achieving certain performance-based milestones related to such grants. We expect G&A expenses to increase going forward as we proceed closer to commercialization of our product candidates.

Fair value adjustment of our contingent consideration was \$0 and (\$10,000), respectively, for the three months ended March 31, 2019 and 2018. The difference in fair value adjustments in the three-month periods ended March 31, 2019 and 2018 is due to the contingent consideration being eliminated in 2018.

Interest expense was \$57,111 and \$48,635, respectively, for the three months ended March 31, 2019 and 2018, an increase of \$10,817. The higher interest expense is primarily due to the Notes issued to ADEC during the three months ended March 31, 2019.

Net loss was \$4,660,755 and \$3,632,997, respectively, for the three months ended March 31, 2019 and 2018. The higher net loss for the three months ended March 31, 2019 compared to the same period in 2018 is due to the changes in expenses as noted above.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended, (the “*Exchange Act*”) our Chief Executive Officer (“*CEO*”) and our Chief Financial Officer (“*CFO*”) conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our CEO and our CFO each concluded that our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act, (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms and (ii) is accumulated and communicated to our management, including our CEO and our CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in management’s evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report on Form 10-Q that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Our results of operations and financial condition are subject to numerous risks and uncertainties described in our Annual Report on Form 10-K for our fiscal year ended December 31, 2018, filed on April 1, 2019. You should carefully consider these risk factors in conjunction with the other information contained in this Quarterly Report. Should any of these risks materialize, our business, financial condition and future prospects could be negatively impacted. As of May 15, 2019, there have been no material changes to the disclosures made in the above referenced Form 10-K.

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ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(b)Exhibits

Exhibit No.	Description
4.1	Form of Selling Agent Warrant (incorporated by reference from Exhibit 4.1 filed with the Current Report on Form 8-K, filed April 3, 2019).
4.2	Form of Selling Agent Warrant (incorporated by reference from Exhibit 4.1 filed with the Current Report on Form 8-K, filed May 14, 2019).
10.1	Note Purchase Agreement, dated February 14, 2019 (incorporated by reference from Exhibit 10.1 filed with the Current Report on Form 8-K, filed February 20, 2019).
10.2	Senior Convertible Note A, dated February 14, 2019 (incorporated by reference from Exhibit 10.2 filed with the Current Report on Form 8-K, filed February 20, 2019).
10.3	Senior Convertible Note B, dated February 14, 2019 (incorporated by reference from Exhibit 10.3 filed with the Current Report on Form 8-K, filed February 20, 2019).
10.4	Form of Pledge Agreement, dated February 14, 2019 (incorporated by reference from Exhibit 10.4 filed with the Current Report on Form 8-K, filed February 20, 2019).
10.5	Warrant Amendment Agreement, dated February 14, 2019 (incorporated by reference from Exhibit 10.5 filed with the Current Report on Form 8-K, filed February 20, 2019).
10.6	Registration Rights Agreement, dated February 14, 2019 (incorporated by reference from Exhibit 10.6 filed with the Current Report on Form 8-K, filed February 20, 2019).
10.7#	Asset Purchase Agreement, by and between AzurRx BioPharma, Inc., AzurRx BioPharma SAS and Laboratoires Mayoly Spindler SAS, dated March 27, 2019 (incorporated by reference from Exhibit 10.25 filed with the Annual Report on Form 10-K, filed April 1, 2019).
10.8#	Patent License Agreement, by and between AzurRx BioPharma, Inc. and Laboratoires Mayoly Spindler SAS, dated March 27, 2019, (incorporated by reference from Exhibit 10.26 filed with the Annual Report on Form 10-K, filed April 1, 2019).
10.9	Selling Agent Agreement, by and between AzurRx BioPharma, Inc. and Alexander Capital, L.P., dated April 1, 2019 (incorporated by reference from Exhibit 10.1 filed with the Current Report on Form 8-K, filed April 3, 2019).
10.10	Selling Agent Agreement, by and between AzurRx BioPharma, Inc. and Alexander Capital, L.P., dated May 9, 2019 (incorporated by reference from Exhibit 10.1 filed with the Current Report on Form 8-K, filed May 14, 2019).
31.1	Certification of the Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of the Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of the Principal Executive Officer and Principal 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
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase

101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

Certain portions of this exhibit (indicated by “[****]”) have been omitted as the Company has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Company if publicly disclosed.

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.

AZURRX BIOPHARMA, INC.

By /s/ Johan M. (Thijs) Spoor
Johan M. (Thijs) Spoor
President and Chief Executive Officer
(Principal Executive Officer)

By /s/ Maged Shenouda
Maged Shenouda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 15, 2019