As filed with the Securities and Exchange Commission on August 5, 2016

Registration No. 333-212511

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

AMENDMENT NO. 2
TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

AZURRX BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**2834**	**46-4993860**
(State or other jurisdiction of incorporation or organization)	(Primary standard industrial classification code number)	(I.R.S. employer identification number)

760 Parkside Avenue
Downstate Biotechnology Incubator, Suite 217
Brooklyn, New York 11226
(646) 699-7855

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Johan M. (Thijs) Spoor, President and Chief Executive Officer
AzurRx BioPharma, Inc.
760 Parkside Avenue
Downstate Biotechnology Incubator, Suite 217
Brooklyn, New York 11226
(646) 699-7855

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. £

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	x
(Do not check if smaller reporting company)			

CALCULATION OF REGISTRATION FEE

Title of Each Class of Security Being Registered	Proposed Maximum Aggregate Offering Price [(1)(2)]	Amount of Registration Fee [(3)]
Common Stock, $0.0001 par value	$ 17,250,000	$ 1,738.00

(1) Includes common stock that may be issued upon exercise of a 45-day option granted to the underwriters to cover over-allotments, if any.
(2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(3) $228 was paid in connection with this filing and the balance was previously paid. Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS **SUBJECT TO COMPLETION** **DATED AUGUST 5, 2016**

2,142,857 Shares

Common Stock

AZURRX BIOPHARMA, INC.

This is our initial public offering of common stock. No public market currently exists for our common stock. We anticipate the initial public offering price will be between $6.00 and $8.00 per share.

We are selling 2,142,857 shares of common stock.

We have applied to list the common stock on The NASDAQ Capital Market, or NASDAQ, under the symbol "AZRX."

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and, as such, may elect to comply with certain reduced reporting requirements after this offering. See "Prospectus Summary—Emerging Growth Company Status."

Investing in our securities involves a high degree of risk. You should carefully consider the risk factors beginning on page 6 of this prospectus before purchasing shares of our common stock.

	Price to Public	Underwriting Discounts and Commissions(1)	Proceeds to Us
Per Share	$ 7.00	$ 0.49	$ 6.51
Total	$ 15,000,000	$ 1,050,000	$ 13,950,000

(1) See "Underwriting" for additional information regarding underwriting compensation.

We have granted the underwriters the right to purchase an additional 321,429 shares of our common stock to cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to purchasers on ____, 2016.

WallachBeth Capital, LLC **Network 1 Financial Securities, Inc.**

The date of this prospectus is ____, 2016

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SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. For a more complete understanding of this offering, you should read the entire prospectus carefully, including the information under "Risk Factors" and our financial statements and the related notes included elsewhere in this prospectus before investing in our common stock.

In this prospectus, unless otherwise stated or the context otherwise requires, references 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 SAS, AzurRx BioPharma's wholly-owned subsidiary through which we conduct our European operations.

Our 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 without reaching the systemic circulation, i.e. the intestinal lumen, skin or mucosa. Our current product pipeline consists of two therapeutic proteins under development:

- MS1819 - an autologous (from the same organism) yeast recombinant lipase for exocrine pancreatic insufficiency (EPI) associated with chronic pancreatitis (CP) and cystic fibrosis (CF). A recombinant lipase is an enzyme that breaks up fat molecules, which is created from new combinations of genetic material in yeast.
- AZX1101 - a recombinant β-lactamase combination of bacterial origin for the prevention of hospital-acquired infections by resistant bacterial strains induced by parenteral administration of β-lactam antibiotics, as well as prevention of antibiotic-associated diarrhea (AAD). A recombinant β-lactamase is an enzyme that breaks up molecules with a beta-lactam ring as is often seen in antibiotics, which is created from new combinations of genetic material in yeast.

Our initial product, MS1819, is intended to treat patients suffering from EPI who are currently treated with porcine pancreatic extracts, or PPEs, which have been on the market since 1938. The PPE market is well established and growing with estimated sales of $880 million in the U.S. in 2015 (based on a 20% discount to IMS Health's 2015 prescription data) and has been growing for the past five years at a compound annual growth rate of 22% according to IMS Health 2009-2014 data. In spite of their long-term use, however, PPEs suffer from poor stability, formulation problems, possible transmission of conventional and non-conventional infectious agents due to their animal origins, possible adverse events at high doses in patients with CF and limited effectiveness. We believe that MS1819, if successfully developed and approved for commercialization, can address these shortcomings associated with PPEs.

Phase I/IIa testing of MS1819 was completed in March 2011 and we anticipate initiating a phase IIb clinical trial during the middle of 2016. We expect to use a substantial portion of the proceeds of this offering to conduct the necessary formulation work and validation and stabilization testing on the MS1819 capsules that will be used in future clinical studies, as well as to conduct the trial. While enrollment criteria and statistical considerations for the phase IIb clinical trial will be dependent on the outcome of discussions we expect to have with the U.S. Food and Drug Administration ("FDA"), we expect enrollment in this trial to last for up to 18 months depending on a number of factors, including but not limited to the number of clinical trial sites and local patient demographics. The trial is expected to have both an open-label and randomized component and we anticipate having initial results from the open-label, dose-escalation arm of the trial available approximately six months following the initiation of the trial.

Our second non-systemic biologic product under preclinical development, AZX1101, is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection (CDI) and antibiotic-associated diarrhea (AAD). CDIs are a leading type of hospital acquired infection (HAI) and are frequently associated with IV antibiotic treatment. Designed to be given orally and co-administered with a broad range of IV beta-lactam antibiotics (e.g., penicillins, cephalosporins and aminogycosides), AZX1101 is intended to protect the gut while the IV antibiotics fight the primary infection. AZX1101 is believed to have the potential to protect the gut from a broad spectrum of IV beta-lactam antibiotics. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. AZX1101's target market is significant and, according to IMS Health and CDM Hospital 2012 databases, represented by U.S. hospitals' purchases of approximately 118 million doses of IV beta-lactam antibiotics annually, which are administered to approximately 14 million patients. Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics.

We intend to use a portion of the proceeds of this offering to fund the additional preclinical studies needed to file an Investigational New Drug Application, or IND, with the FDA.

Emerging Growth Company Status

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act. As a result, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements that are applicable to other companies that are not emerging growth companies. Accordingly, we have included detailed compensation information for only our three most highly compensated executive officers and have not included a compensation discussion and analysis, or CD&A, of our executive compensation programs in this prospectus. In addition, for so long as we are an "emerging growth company," we will not be required to:

- engage an auditor to report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes–Oxley Act of 2002, or the Sarbanes–Oxley Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or the PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes;" or
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparison of the chief executive officer's compensation to median employee compensation.

In addition, the JOBS Act provides that an "emerging growth company" can use the extended transition period for complying with new or revised accounting standards.

We will remain an “emerging growth company” until the earliest to occur of:

- our reporting $1 billion or more in annual gross revenues;
- our issuance, in a three -year period, of more than $1 billion in non-convertible debt;
- the end of the fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million on the last business day of our second fiscal quarter; and
- March 31, 2021.

Our Corporate Information

We were incorporated on January 30, 2014 in the State of Delaware. In June 2014, we acquired 100% of the issued and outstanding capital stock of AzurRx BioPharma SAS (formerly ProteaBio Europe SAS), a company incorporated in October 2008 under the laws of France that had been a wholly-owned subsidiary of Protea Biosciences, Inc., or Protea Sub, in turn a wholly-owned subsidiary of Protea Biosciences Group, Inc., a publicly-traded company. Our principal executive offices are located at 760 Parkside Avenue, Downstate Biotechnology Incubator, Suite 217, Brooklyn, NY 11226. Our telephone number is 646-699-7855. We maintain a website at www.azurrx.com. The information contained on our website is not, and should not be interpreted to be, a part of this prospectus.

THE OFFERING

Common stock being offered by us	2,142,857 shares
Common stock to be outstanding immediately after this offering	10,813,945 shares [1]
Over-allotment option	321,429 shares
Use of proceeds	We intend to use the net proceeds from this offering to continue clinical development and testing of MS1819, to advance our preclinical AZX1101 program to pay back convertible debt notes note converted in the IPO and for working capital and other general corporate purposes.
Proposed NASDAQ trading symbol	"AZRX"
Risk factors	The securities offered by this prospectus are speculative and involve a high degree of risk and investors purchasing securities should not purchase the securities unless they can afford the loss of their entire investment. See "Risk Factors" beginning on page 6.

(1) The number of shares of our common stock to be outstanding immediately after this offering excludes:

- 1,092,800 shares of common stock issuable upon the exercise of outstanding options and warrants at a weighted average exercise price of $5.75 per share; and
- 1,081,395 shares reserved for issuance under our equity incentive plans.

Unless otherwise stated, all information in this prospectus assumes:

- the conversion of our outstanding shares of preferred stock into 878,171 shares of common stock;
- the conversion of our outstanding convertible notes into 2,642,160 shares of common stock immediately prior to the closing of this offering based on the assumed initial public offering price of $7.00 per share, the midpoint of the price range set forth on the cover page of this prospectus; and
- no exercise of the underwriters' over-allotment option to purchase additional shares.

SUMMARY CONSOLIDATED FINANCIAL AND OTHER DATA

The following table presents our summary consolidated historical financial data for the periods presented and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto included elsewhere in this prospectus. The consolidated statements of operations data for the fiscal years ended December 31, 2014 and 2015 are derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated statements of operations data for the three months ended March 31, 2016 and 2015 and the consolidated balance sheet data as of March 31, 2016 have been derived from our unaudited interim consolidated financial statements included elsewhere in this prospectus.

	01/30/14 (Date of Inception) through 12/31/14	01/01/15 through 12/31/15	Three Months Ended March 31, 2016 (unaudited)	Three Months Ended March 31, 2015 (unaudited)
Statements of Operations Data:				
Operating expenses	$ 2,329,106	$ 4,728,808	$ 1,347,216	$ 1,072,416
Loss from operations	(2,329,106)	(4,728,808)	(1,347,216)	(1,072,416)
Total other expense	(36,042)	(1,201,428)	$ (644,104)	(118,891)
Net loss	$ (2,365,148)	$ (5,930,236)	$ (1,991,320)	$ (1,191,307)
Net loss per share, basic and diluted	$ (0.67)	$ (1.63)	$ (0.42)	$ (0.33)

	As of December 31, 2015	As of December 31, 2014	As of March 31, 2016 Pro Forma (1) (unaudited)	As of March 31, 2016 Pro Forma As Adjusted (2)
Balance Sheet Data:				
Cash	$ 94,836	$ 581,668	$ 2,178,036	$ 15,062,178
Total assets	$ 6,575,753	$ 6,685,682	$ 8,167,821	$ 20,661,248
Total current liabilities	$ 2,430,855	$ 8,815,512	$ 2,295,827	$ 1,966,328
Total liabilities	$ 3,930,855	$ 10,315,512	$ 3,795,827	$ 3,466,328
Total stockholders' equity (deficit)	$ 2,644,898	$ (3,629,830)	$ 4,371,994	$ 17,194,920

(1) The pro forma balance sheet data as of March 31, 2016 reflects (i) the conversion of our outstanding shares of preferred stock into 878,171 shares of common stock that has no effect on Total stockholders' equity (deficit); (ii) the settlement in cash of other receivable for OID convertible debt of $150,000 that increases Cash by that amount but has no effect on Total assets; (iii) the conversion of $135,000 of convertible promissory notes into OID convertible notes that has no effect on Total current liabilities; (iv) the proceeds of $1,859,000 in additional OID convertible debt that increases Cash and Total current liabilities by that amount; and (v) the issuance of 2,642,160 shares of common stock immediately prior to the closing of this offering upon the mandatory conversion portion of OID convertible notes (based on the assumed initial public offering price of $7.00 per share, the midpoint of the price range set forth on the cover page of this prospectus that decreases Total current liabilities and Total liabilities by $9,791,501 and increases Total stockholders' equity (deficit) by that same amount.

(2) The pro forma as adjusted balance sheet data as of March 31, 2016 reflects the pro forma adjustments described in footnote (1) above as adjusted to give effect to (i) the receipt by us of the estimated net proceeds from this offering, based on an assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us of $2,150,000 that increases Cash by $13,240,715, increases Total assets by $12,850,000 and increases Total stockholders' equity (deficit) by $12,850,000; (ii) the grant of 107,143 warrants with a five-year life to the underwriters at 120% of the IPO price with an estimated value of $562,501 with no effect on Total stockholders' equity; and (iii) retiring in cash $356,573 of OID convertible debt and accreted interest not mandatorily converted at time of the IPO that decreases cash by $356,573, decreases Total current liabilities and Total liabilities by $329,499 and decreases Total stockholders' equity (deficit) by $27,074.

RISK FACTORS

You should carefully consider the risks described below and elsewhere in this report, which could materially and adversely affect our business, results of operations or financial condition. Our business faces significant risks and the risks described below may not be the only risks we face. Additional risks not presently known to us or that we currently believe are immaterial may materially affect our business, results of operations, or financial condition. If any of these risks occur, the trading price of our common stock could decline and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We are a development stage company and have a limited operating history upon which to base an investment decision.

We are a clinical development stage biopharmaceutical company. Since inception, we have engaged primarily in research and development activities, have not generated any revenues from product sales and have incurred significant net losses. As of March 31, 2016, we had an accumulated deficit of approximately $10.3 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations to date have been limited to organizing and staffing our company, acquiring, developing and securing the proprietary rights for, and undertaking pre-clinical development and clinical trials of our product candidates. These operations provide a limited basis for our stockholders and prospective investors to assess our ability to complete development of or commercialize any products and the advisability of investing in our securities.

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

Our two product candidates, MS1819 and AZX1101, are in the early stages of development and will require substantial further capital expenditures, development, testing, and regulatory clearances prior to commercialization. The development and regulatory approval process takes several years and it is not likely that either of such products, even if successfully developed and approved by the FDA or any comparable foreign regulatory authority, would be commercially available for at least four to five years or more. Of the large number of drugs in development, only a small percentage successfully completes the regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates, could result in the failure of our business and a loss of all of your investment in our company.

Any product candidates we advance into clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets, including Health Canada's Therapeutic Products Directorate, or the TPD, the European Medicines Agency, or the EMA. In the United States, we are not permitted to market our product candidates until we receive approval of a New Drug Application, or NDA, or Biologics License Application, or BLA, from the FDA. The process of obtaining such approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA, the TPD and/or the EMA can delay, limit or deny approval of a product candidate for many reasons, including, but not limited to:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate to their satisfaction that a product candidate is safe and effective for any indication;
- failure to accept clinical data from trials which are conducted outside their jurisdiction;
- the results of clinical trials may not meet the level of statistical significance required for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such agencies may disagree with our interpretation of data from preclinical studies or clinical trials;
- failure to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- changes in the approval policies or regulations of such agencies may significantly change in a manner rendering our clinical data insufficient for approval.

Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Our principal product candidate, MS1819 has only completed a phase I/IIa clinical trial, while our second product, AZX1101 has only been tested in a pre-clinical setting. Success in pre-clinical studies or early clinical trials does not mean that later clinical trials will be successful as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. We also may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates in clinical trials could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications and markets. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale. We have not yet completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent of adverse events, if any, that will be observed in patients who receive any of our product candidates. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain regulatory approval or commercialize such product or, if such product candidate is approved for marketing, future adverse events could cause us to withdraw such product from the market.

Delays in the commencement or completion of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval.

Although we intend to use the proceeds of this offering to commence a Phase II clinical trial for MS1819 in the second half of 2016 and to complete the preclinical work necessary to file an IND for AZX1101 by the first quarter of 2017, the commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial;
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues; and
- availability of cash.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results or difficulties in obtaining sufficient quantities of product manufactured in accordance with regulatory requirements.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with current Good Clinical Practices, or cGCPs, or other applicable foreign government guidelines governing the design, safety monitoring, quality assurance and ethical considerations associated with clinical studies. Clinical trials are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable Current Good Manufacturing Practices, or cGMPs, which are the FDA's regulations governing the design, monitoring and control of manufacturing processes and facilities. Clinical trials may be suspended by the FDA, other foreign governmental agencies, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

If we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

Because we in-licensed our product candidates from third parties, any dispute with our licensors or non-performance by us or by our licensors may adversely affect our ability to develop and commercialize the applicable product candidates.

Some of our product candidates, including related intellectual property rights, were in-licensed from third parties. Under the terms of our license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach by us. Our licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on our ability to generate cash in the future. These agreements generally require us to use diligent and reasonable efforts to develop and commercialize the product candidate. In the case of MS1819, Laboratoires Mayoly Spindler SAS, or Mayoly, licenses MS1819 from a third party and, accordingly, our rights to MS1819 are also subject to Mayoly's performance of its obligations to its licensor, any breach of which we may be required to remedy in order to preserve our rights.

If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partner regarding our rights or obligations under the license agreement, including any conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate may be adversely affected. Similarly, any such dispute or issue of non-performance between Mayoly and its licensor that we are unable to cure could adversely affect our ability to develop and commercialize MS1819. Any loss of our rights under our license agreements could delay or completely terminate our product development efforts for the affected product candidate.

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

From time to time, we may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. These relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to its other development activities. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and expect to continue to rely on third parties to produce commercial supplies of any approved product candidate, and our dependence on third party suppliers could adversely impact our business.

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The proprietary yeast strain used to manufacture MS1819 API is located in a storage facility maintained by Charles River Laboratories in Malvern, PA and such manufacturing is conducted by DSM Capua SPA in Italy. We are completely dependent on these third parties for product supply and our MS1819 development programs would be adversely affected by a significant interruption in our ability to receive such materials. Furthermore, our third-party suppliers will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable regulatory authorities in other jurisdictions to confirm such compliance. In the event that the FDA or such other authorities determine that our third-party suppliers have not complied with cGMP, our clinical trials could be terminated or subjected to a clinical hold until such time as we are able to obtain appropriate replacement material. Any delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

We do not expect to have the resources or capacity to commercially manufacture any of our proposed products, if approved, and will likely continue to be dependent upon third party manufacturers. Our dependence on third parties to manufacture and supply us with clinical trial materials and any approved products may adversely affect our ability to develop and commercialize our products on a timely basis or at all.

We rely on third parties to conduct our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our clinical development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We intend to use CROs to conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties will play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties upon which we rely for administration and conduct of our clinical trials will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, fail to adhere to our clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

We will face intense competition and may not be able to compete successfully.

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Our product candidates, if successfully developed and approved, will compete with established therapies, as well as new treatments that may be introduced by our competitors. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit management, scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. New developments, including the development of other biological and pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace. Developments by competitors may render our product candidates obsolete or noncompetitive. We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and patient registration for clinical trials and in identifying and in-licensing new product candidates.

Our success will depend upon intellectual property, proprietary technologies and regulatory market exclusivity periods, and we may be unable to protect our intellectual property.

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. Under our license agreement with Mayoly, enforcement of patents relating to MS1819 is the responsibility of Mayoly. If we or our licensors fail to appropriately prosecute and maintain patent protection for our product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide any competitive advantage;
- our competitors, many of which have substantially greater resources than we or our partners and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products; and
- we may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently. We may become subject to claims that we or consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates have wrongfully or inadvertently disclosed to us or used trade secrets or other proprietary information of their former employers or their other clients.

We intend to rely on market exclusivity periods that may not be or remain available to us.

We intend to rely on our ability to obtain and maintain a regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is currently 12 years from the date of marketing approval, reductions to this period have been proposed. This exclusivity period in Europe is currently 10 years from the date of marketing approval by the EMA. Once any regulatory period of exclusivity expires, depending on the status of our patent coverage and the nature of the product, we may not be able to prevent others from marketing products that are biosimilar to or interchangeable with our products, which would materially adversely affect us.

In addition, United States patent laws may change which could prevent or limit us from filing patent applications or patent claims to protect our products and/or technologies or limit the exclusivity periods that are available to patent holders. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law, and includes a number of significant changes to United States patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. These changes may favor larger and more established companies that have more resources to devote to patent application filing and prosecution. The United States Patent and Trademark Office is currently developing regulations and procedures to administer the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act will not become effective until one year or 18 months after its enactment. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend our issued patents.

If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market, distribute and sell any products we may successfully develop, we may not be able to effectively market and sell any such products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of any of our product candidates, and must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize any products that we may successfully develop. The establishment and development of a sales force, either by us or jointly with a partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch. If we, or our partners, are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may successfully develop, we will need to contract with third parties to market and sell such products. We may not be able to establish arrangements with third-parties on acceptable terms, if at all.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of hospitals and clinics and patients of the product as a safe and effective treatment;
- acceptance of the product by the target population;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable.

We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. While we have and intend to maintain product liability insurance relating to our clinical trials, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. We are unable to predict if we will be able to obtain or maintain product liability insurance for any products that may be approved for marketing. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to the testing and use of our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

If we fail to attract and retain key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.

We are dependent on our management team and clinical development personnel and our success will depend on their continued service, as well as our ability to attract and retain highly qualified personnel. In particular, the continued service of our senior management team, including Johan M. (Thijs) Spoor, our President and Chief Executive Officer, and Daniel Dupret, our Chief Scientific Officer, is critical to our success. The market for the services of qualified personnel in the pharmaceutical industry is highly competitive. The loss of service of any member of our senior management team or key personnel could prevent, impair or delay the implementation of our business plan, the successful conduct and completion of our planned clinical trials and the commercialization of any product candidates that we may successfully develop. We do not carry key man insurance for any member of our senior management team.

We use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We may use hazardous materials, including chemicals and biological agents and compounds, that could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any of our licensors, suppliers or collaborators infringe the third party's intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages, including the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

Healthcare reform and restrictions on reimbursements may limit our financial returns.

Our ability or the ability of our collaborators to commercialize any of our product candidates that we successfully develop may depend, in part, on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our product candidates to enable us or our collaborators to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are subject to federal, state, and foreign healthcare laws and regulations pertaining to fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal healthcare program anti-kickback law, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;

- the U.S. federal Health Insurance Portability and Accountability Act, or HIPAA, which prohibits, among other things, executing a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes requirements relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of March 31, 2016, we had twelve employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and international regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Risks Relating to our Finances, Capital Requirements and Other Financial Matters

We are a development stage company with a history of operating losses that are expected to continue and we are unable to predict the extent of future losses, whether we will generate significant revenues or whether we will achieve or sustain profitability.

We are a company in the development stage and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses since our inception, including losses of approximately $2,365,000, and $5,930,000 for the years ended December 31, 2014 and 2015, respectively, and $1,991,000 in the three months ended March 31, 2016. At March 31, 2016, we had an accumulated deficit of approximately $10,287,000. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, curtail or eliminate one or more of our research and development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2014 and 2015 and the three months ended March 31, 2016, we incurred research and development expenses of approximately $670,000, $1,398,000 and $686,000, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We believe that our cash on hand and the net proceeds from this offering will sustain our operations until January 2018 and that we will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals and potential commercialization. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our current financial condition raises substantial doubt about our ability to continue as a going concern.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration and licensing arrangements. Other than this offering, we currently have no other commitments or agreements relating to any of these types of transactions and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2015 and 2014 with respect to our ability to continue as a going concern. The existence of such a report may adversely affect our stock price and our ability to raise capital.

In their report dated June 15, 2016, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern. We have incurred losses and negative cash flows from operations since inception, have an accumulated deficit as of March 31, 2016 and require additional financing to fund future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Risks Associated with our Capital Stock and this Offering

We do not know whether an active, liquid and orderly trading market will develop for our common stock in the U.S.

Prior to this offering, there has been no public market for our common stock. Although we have applied for listing on The NASDAQ Capital Market, an active trading market for our shares may never develop or be sustained. The lack of an active or liquid market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable.

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Our stock price may experience substantial volatility as a result of a number of factors, including

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors or product manufacturers;

- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation;
- variations in our anticipated or actual operating results;
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations; foreign currency values and fluctuations; and
- overall economic conditions.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

Future sales of shares of our common stock by existing stockholders could depress the market price of our common stock.

Upon the closing of this offering, we will have an aggregate of 10,813,945 outstanding shares of common stock. The shares sold in this offering will be immediately tradable without restriction. 623,011 shares, or approximately 6% of our outstanding shares of common stock are currently restricted as a result of lock-up agreements. These shares will be available for sale into the public market 180 days following the date of this Prospectus, subject to certain exceptions and also to potential extensions under certain circumstances, and will be subject to volume and other sale restrictions. The representative of the underwriters may, in its sole discretion and at any time without notice, release all or any portion of the securities subject to lock-up agreements.

Also, in the future, we may issue additional securities in connection with investments and acquisitions. The amount of our common stock issued in connection with an investment or acquisition could constitute a material portion of our then outstanding stock. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Holders of approximately 5,331,108 shares, or 48%, of our common stock have registration rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders in the future. Once we register the shares for the holders of registration rights, they can be freely sold in the public market upon issuance, subject to the restrictions contained in the lock-up agreements. If a large number of these shares are sold in the public market, the sales could reduce the trading price of our common stock. See "Shares Eligible for Future Sale" for a more detailed description of sales that may occur in the future.

We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Provisions in our restated certificate of incorporation, our restated by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our restated certificate of incorporation, our restated by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our board of directors to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our board of directors.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the foregoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.

We intend to use the net proceeds from this offering for general corporate purposes and to continue preclinical and clinical development of our product candidates. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to utilize these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.

Because the public offering price per share of our common stock is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on an assumed public offering price of $7.00 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately $5.81 per share in the net tangible book value of the common stock. See the section entitled “Dilution” in this prospectus for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

We are eligible to be treated as an "emerging growth company," as defined in the JOBS Act, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this prospectus. We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds $700.0 million as of any March 31 before that time or if we have total annual gross revenue of $1.0 billion or more during any fiscal year before that time, after which, in each case, we would no longer be an emerging growth company as of the following December 31 or, if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If securities or industry analysts do not publish research or reports about our business, if they adversely change their recommendations regarding our shares or if our results of operations do not meet their expectations, our share price and trading volume could decline.

The trading market for our shares will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over these analysts. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our share price or trading volume to decline. Moreover, if one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our share price could decline.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the information in this prospectus contains forward-looking statements within the meaning of the federal securities laws. These statements include, among others, the following:

- the results of research and development activities;
- uncertainties relating to preclinical and clinical testing, financing and strategic agreements and relationships;
- the early stage of products under development;
- our need for substantial additional funds;
- government regulation;
- patent and intellectual property matters;
- dependence on third party manufacturers;
- competition; and
- foreign currency fluctuations.

These statements may be found under "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." Forward-looking statements typically are identified by the use of terms such as "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms, although some forward-looking statements are expressed differently. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above.

You should also consider carefully the statements under "Risk Factors" and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately $12,850,000, based on an assumed initial public offering price of $7.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus, and after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares, we estimate that we will receive an additional $2,092,500 million in net proceeds.

A $1.00 increase (decrease) in the assumed initial public offering price of $7.00 would increase (decrease) the net proceeds to us from this offering by $1,992,525.

We currently intend to use the net proceeds from this offering as follows:

- approximately $7,500,000 to continue clinical development and testing of MS1819;
- approximately $1,500,000 to advance our preclinical AZX1101 program;
- approximately $356,000 to repay convertible debt not being converted into shares of common stock in connection with this offering; and
- the balance, if any, for working capital and other general corporate purposes.

We believe that the proceeds allocated to the MS1819 program will be sufficient to enable us to conduct the necessary drug product formulation work, validation and stabilization testing and conduct the program. We expect that the proceeds allocated to AZX1101 will enable us to fund the additional preclinical studies and prepare the safety and toxicology data necessary to file an IND with the FDA; however, we will need to seek additional financing in order to pursue any clinical program.

The foregoing represents our best estimate of the allocation of the net proceeds of the offering during the next 12 to 18 months. This estimate is based on certain assumptions, including that no events occur which would cause us to abandon any particular efforts, that our research, development and testing activities will occur as projected, and that we do not enter into collaborations to fund a project separately. The amounts actually expended for each purpose may vary significantly in the event any of these assumptions prove inaccurate. We reserve the right to change our use of proceeds as unanticipated events may cause us to redirect our priorities and reallocate the proceeds accordingly. Pending specific utilization of the net proceeds as described above, we intend to invest the net proceeds of the offering in short-term investment grade and U.S. government securities.

DIVIDEND POLICY

We have never paid cash dividends on any of our capital stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2016:

- On an actual basis;
- the conversion of our outstanding shares of preferred stock into 878,171 shares of common stock on April 4, 2016 that decreases Preferred stock by $1,764,000, increases Common stock by $88, and increases Additional paid-in capital by $1,763,912; (ii) the proceeds of $1,859,000 in additional OID convertible debt that increases Notes payable by that amount; (iii) the issuance of 2,642,160 shares of common stock immediately prior to the closing of this offering upon the mandatory conversion portion of OID convertible notes (based on the assumed initial public offering price of $7.00 per share, the midpoint of the price range set forth on the cover page of this prospectus) that decreases Notes payable by $9,791,501, increases Common stock by $264, increases Additional paid-in capital by $10,577,454 and increases Accumulated deficit by $786,217; and (iv) the OID convertible debt beneficial conversion amount of $10,323,799 that increases Additional paid-in capital and Accumulated deficit by that amount;
- the receipt by us of the estimated net proceeds from this offering, based on an assumed initial public offering price of $7.00 per share, the midpoint of the range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us of $2,150,00 that increases Common stock by $214 and increases Additional paid-in capital by $12,849,786, (ii) the grant of 107,143 warrants with a five-year life to the underwriters at 120% of the price per share in this offering with an estimated value of $562,501 that has no effect on Total stockholders' (deficit) equity; and (iii) retiring in cash $356,573 of OID convertible debt and accrued interest not mandatorily converted at time of this offering which decreases Notes payable by $329,499 and increases Accumulated deficit by $27,074.

You should read this table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes included elsewhere in this prospectus.

	March 31, 2016 (unaudited)		
	Actual	Pro Forma	Pro forma As Adjusted
Notes payable (inclusive of current portion)	$ 7,460,503	$ 329,499	$ -
Stockholders' deficit:			
Preferred stock, $.0001 par value, 1,000,000 shares authorized; 36 shares issued and outstanding; 0; and 0	1,764,000	-	-
Common stock, $.0001 par value, 9,000,000 shares authorized; 5,150,757 shares issued and outstanding; 8,671,088 shares issued and outstanding, proforma; 10,813,945 shares issued and outstanding, as adjusted (1)	515	867	1,081
Additional paid-in capital	4,254,151	26,919,316	39,769,102
Accumulated deficit	(10,286,705)	(21,396,721)	(21,423,795)
Other comprehensive income	(1,151,468)	(1,151,468)	(1,151,468)
Total stockholders' (deficit) equity	(5,419,507)	4,371,994	17,194,920
Total capitalization	$ 2,040,996	$ 4,704,493	$ 17,194,920

(1) The number of shares to be outstanding immediately after this offering is based on 6,028,928 shares outstanding on August 4, 2016 , which excludes:

- 1,092,800 shares of common stock issuable upon the exercise of outstanding options and warrants at a weighted average exercise price of $5.75 per share; and,
- 1,081,395 shares reserved for issuance under our equity incentive plans.

DILUTION

"Net tangible book value" is total assets minus the sum of liabilities and intangible assets. "Net tangible book value per share" is net tangible book value divided by the total number of shares outstanding on March 31, 2016. After giving pro forma effect to (i) the conversion of our outstanding shares of preferred stock into 878,171 shares of common stock, and (ii) the issuance of 2,642,160 shares of common stock immediately prior to the closing of this offering upon the conversion of OID convertible notes (based on the midpoint of the price range set forth on the cover page of this prospectus), our pro forma net tangible book value on March 31, 2016 was approximately ($49,524), or ($0.01) per share.

After giving effect to our issuance and sale of 2,142,857 shares of common stock in this offering at an assumed initial public offering price of $7.00 per share, the mid-point of the estimated price range shown on the cover of this prospectus, after deducting the estimated underwriting discounts and offering expenses payable by us, the pro forma as adjusted net tangible book value as of March 31, 2016 would have been approximately $13 million, or $1.18 per share. This represents an immediate increase in pro forma net tangible book value of $1.19 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of $5.81 per share to investors purchasing shares of common stock in this offering at the assumed public offering price.

The following table illustrates this dilution:

Assumed public offering price per share		$ 7.00
Pro forma net tangible book value per share as of March 31, 2016	$ (0.01)	
Increase in pro forma net tangible book value per share attributable to the offering	1.18	
Pro forma as adjusted net tangible book value per share as of March 31, 2016 after the offering		1.19
Dilution per share to new investors in the offering		$ 5.81

A $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share would increase (decrease) the pro forma net tangible book value by approximately $2 million, the pro forma net tangible book value per share after this offering by $0.18 per share and the dilution in pro forma net tangible book value per share to investors in this offering by $0.18 per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and offering expenses payable by us. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to $1.50 per share, representing an immediate increase to existing stockholders of $1.50 per share and an immediate dilution of $5.50 per share to new investors. If any shares are issued in connection with outstanding options, you will experience further dilution.

The following table presents, on a pro forma basis as of March 31, 2016, the differences between the existing stockholders and the new investors purchasing our common stock in this offering with respect to the number of shares purchased from us, the total consideration paid or to be paid to us, which includes net proceeds received from the issuance of common stock, and the average price per share paid or to be paid to us at the public offering price of $7.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses:

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	8,671,088	80%	$ 15,847,502	51%	$ 1.83
New investors	2,142,857	20%	$ 15,000,000	49%	$ 7.00
Total	10,813,945	100%	$ 30,847,502	100%	

Assuming the underwriters' option to purchase additional shares is exercised in full, sales in this offering will reduce the percentage of shares held by existing stockholders to 78% and will increase the number of shares held by our new investors to 2,464,286 shares, or 22%, assuming no purchases of our common stock by existing stockholders in this offering.

SELECTED HISTORICAL FINANCIAL AND OPERATING DATA

The following table presents our selected historical financial data for the periods presented and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statement and notes thereto included elsewhere in this prospectus. The statements of operations data for the fiscal years ended December 31, 2014 and 2015 and the statements of financial condition data as of December 31, 2014 and 2015 are derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the three months ended March 31, 2015 and 2016 and the statements of financial condition data as of March 31, 2016 is derived from our unaudited financial statements included elsewhere in this prospectus.

	January 30, 2014 (Date of Inception) through December 31, 2014	Year Ending December 31, 2015	Three Months Ended March 31,	
			2015	2016
			(unaudited)	(unaudited)
Statements of Operations Data:				
Operating expenses	$ 2,329,106	$ 4,728,808	$ 1,072,416	$ 1,347,216
Loss from operations	$ (2,329,106)	$ (4,728,808)	$ (1,072,416)	$ (1,347,216)
Total other expense	$ (36,042)	$ (1,201,428)	$ (118,891)	$ (644,104)
Net loss	$ (2,365,148)	$ (5,930,236)	$ (1,191,307)	$ (1,991,320)
Net loss per share, basic and diluted	$ (0.67)	$ (1.63)	$ (0.33)	$ (0.42)

	As of December 31,		As of March 31,
	2014	2015	2016
			(unaudited)
Balance Sheet Data:			
Cash	$ 94,836	$ 581,668	$ 169,036
Total assets	$ 6,575,753	$ 6,685,682	$ 6,308,821
Total current liabilities	$ 2,430,855	$ 8,815,512	$ 10,228,328
Total liabilities	$ 3,930,855	$ 10,315,512	$ 11,728,328
Total stockholders' equity (deficit)	$ 2,644,898	$ (3,629,830)	$ (5,419,507)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our audited financial statements and the related notes thereto and other financial information appearing elsewhere in this prospectus.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, valuation of financial instruments and intangible assets, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition and operating results.

Intangible Assets

Our definite-lived intangible assets have a carrying value of approximately $2,513,000, $2,584,000, and $3,638,000 as of March 31, 2016, December 31, 2015 and 2014, respectively. These assets include in-process research and development and license agreements. These intangible assets were recorded at historical cost and are stated net of accumulated amortization.

The in process research and development and licenses are amortized over their remaining estimated useful lives, ranging from five to 12 years, based on the straight-line method. The estimated useful lives directly impact the amount of amortization expense recorded for these assets on a quarterly and annual basis.

In addition, we test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. Judgment is used in determining when these events and circumstances arise. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss. No events or circumstances arose in the three months ended March 31, 2016 and the years ended December 31, 2015 and 2014 that would indicate that the carrying value of any of our definite-lived intangible assets may not be recoverable.

Goodwill

Goodwill relates to the acquisition of ProteaBio Europe during 2014 and represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. As a result, the amount of goodwill is directly impacted by the estimates of the fair values of the assets acquired and liabilities assumed.

In addition, goodwill will be reviewed annually, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our review of goodwill on our one reporting unit. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss.

The carrying value of goodwill at March 31, 2016, December 31, 2015 and 2014 was approximately $1,908,000, $1,833,000, and $2,042,000, respectively. If actual results are not consistent with our estimates or assumptions, we may be exposed to an impairment charge that could be material.

Income Taxes

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact to the consolidated financial statements. We are subject to taxation in various U.S. and foreign jurisdictions and remain subject to examination by taxing jurisdictions for the calendar year 2013 and all subsequent periods due to the availability of net operating loss carryforwards. To the extent we prevail in matters for which a liability has been established, or are required to pay amounts in excess of our established liability, our effective income tax rate in a given financial statement period could be materially affected. An unfavorable tax settlement generally would require use of our cash and may result in an increase in our effective income tax rate in the period of resolution. A favorable tax settlement may reduce our effective income tax rate and would be recognized in the period of resolution.

Our effective income tax rate may be affected by changes in tax law, our level of earnings, and the results of tax audits.

Although we believe that the judgments and estimates discussed herein are reasonable, actual results could differ, and we may be exposed to losses or gains that could be material.

Jumpstart Our Business Startups Act of 2012

On April 5, 2012, the Jumpstart Our Business Startups Act of 2012 was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

General

To date, we have not generated any revenues from operations and at March 31, 2016, we had an accumulated deficit of approximately $10,287,000, primarily as a result of research and development (“R&D”) expenses and general and administrative (“G&A”) expenses. While we may in the future generate revenue from a variety of sources, including license fees, research and development payments in connection with strategic partnerships and/or government grants, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues or net income.

R&D Expenses

Conducting R&D is central to our business. R&D expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and annual payments related to in-licensed products and intellectual property;
- expenses incurred under agreements with clinical research organizations, investigative sites and consultants that conduct or provide other services relating to our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring clinical trial materials from third party manufacturers; and
- costs associated with non-clinical activities, patent filings and regulatory filings.

We expect to continue to incur substantial expenses related to our R&D activities for the foreseeable future as we continue product development. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our R&D expenses will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product.

G&A Expenses

G&A expenses consist principally of personnel-related costs, professional fees for legal, consulting and audit services, rent and other general operating expenses not otherwise included in R&D. We anticipate G&A expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded R&D activities;
- an expanding infrastructure and increased professional fees and other costs associated with the compliance with the Exchange Act, the Sarbanes-Oxley Act and stock exchange regulatory requirements and compliance; and
- business development and financing activities.

Liquidity and Capital Resources, March 31, 2016 and 2015

We have experienced net losses and negative cash flows from operations since our inception. As of March 31, 2016, we had sustained cumulative losses attributable to common stockholders of approximately $10,287,000. At March 31, 2016, we had cash and marketable securities of approximately $213,000.

We have funded our operations to date primarily through the issuance of debt and convertible debt securities. During the years ended December 31, 2015 and 2014 and the three months ended March 31, 2016, we funded our working capital requirements with the proceeds of short-term 8% promissory notes (the “Advance Notes”) and original issuance discount convertible notes (the “OID Notes”).

Through March 31, 2016, we had received aggregate gross proceeds of $896,000 from the issuance of Advance Notes, $761,000 of which had been repaid, leaving a principal balance of $135,000 outstanding. Payment of $33,790 of accrued interest on the $761,000 principal amount of Advance Notes repaid was made through the issuance of an aggregate of 5,242 shares of common stock.

Through March 31, 2016, we had received aggregate gross proceeds of $7,303,529 from the issuance of $7,961,445 principal amount of OID Notes. Subsequent to March 31, 2016 and through August 4, 2016, we received proceeds of $1,859,000 in additional OID Notes. These notes are due on November 4, 2016, are discounted at 92% of their face amount, have a conversion price of $4.65 per share, automatically convert into shares of our common stock upon the consummation of a public offering equal to the quotient obtained by dividing the principal amount multiplied by 1.25 by the lesser of (a) $4.65 or (b) the price per share or price per unit issued in this offering. The principal amount of the OID Notes, together with accrued interest, will convert into equity immediately prior to the consummation of this offering.

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 believe that our current cash and marketable securities are sufficient to fund operations until September 2016 without giving consideration to the proceeds of this offering based on our current business plan. Our current financial condition raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We will seek funds through additional equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us, we will be required to delay, curtail or eliminate one or more of our research and development programs.

Cash Flows for the Three Months Ended March 31, 2016 and 2015

Net cash used in operating activities for the three months ended March 31, 2016 was $636,546, which primarily reflected our net loss of $1,991,320 plus non-cash depreciation and amortization expense of $182,842, non-cash accreted interest on OID convertible debt and debt discount - warrants of $710,988, and an increase in accounts payable and accrued expenses of $511,274 due to our cash position, offset by an increase in prepaid expenses of $36,353 consisting primarily of finance and legal costs associated with the filing of the S-1. Net cash used in operating activities for the three months ended March 31, 2015 was $1,025,900, which primarily reflected our net loss of $1,191,307 plus non-cash depreciation and amortization expense of $186,229, non-cash accreted interest on OID convertible debt and debt discount - warrants of $133,478, offset by a decrease in accounts payable and accrued expenses of $135,283.

Net cash used in investing activities for the three months ended March 31, 2016 was $936 which consisted of the purchase of property and equipment. Net cash used in investing activities for the three months ended March 31, 2015 was $11,033, which consisted of the purchase of property and equipment.

Net cash provided by financing activities for the three months ended March 31, 2016 was $225,000, which consisted of the gross proceeds in connection with the issuance of OID convertible debt. Net cash provided by financing activities for the three months ended March 31, 2015 was $1,160,000, which consisted of the issuance of promissory notes of $270,000 and the gross proceeds in connection with the issuance of OID convertible debt of $1,140,000 offset by the repayment of promissory notes of $250,000.

Consolidated Results of Operations for the Three Months Ended March 31, 2016 and 2015

R&D expenses were $685,575 and $308,834, respectively, for the three months ended March 31, 2016 and 2015, an increase of $376,741. The increase in R&D is primarily due to costs associated with manufacturing additional batches of MS1819. We expect R&D expenses to increase in future periods as our product candidates continue through clinical trials and we seek strategic collaborations.

G&A expenses were $661,641 and $763,582, respectively, for the three months ended March 31, 2016 and 2015, a decrease of $101,941. The decrease was due primarily to a decrease in consulting fees. We expect G&A expenses to increase going forward as we proceed to advance our product candidates through the development and regulatory process.

Interest expense was $713,680 and $144,746, respectively, for the three months ended March 31, 2016 and 2015, an increase of $568,934. The increase was due to the higher level of outstanding OID convertible debt. Fair value adjustment of our warrants was $69,576 and $25,855, respectively, for the three months ended March 31, 2016 and 2015, an increase of $43,721. This increase was due to the higher level of warrant liability as a result of the higher level of outstanding OID convertible debt.

Net loss was $1,991,320 and $1,191,307 for the three months ended March 31, 2016 and 2015, respectively. The higher net loss for the three months ended March 31, 2016 versus the same period in 2015 is due to the higher expenses noted above.

Liquidity and Capital Resources, December 31, 2015 and 2014

We have experienced net losses and negative cash flows from operations since our inception. We have cumulative losses attributable to common stockholders of approximately $8,295,000 and $2,365,000, respectively, as of December 31, 2015 and 2014. We have financed our operations through issuances of equity and the proceeds of debt instruments. From the date of inception through December 31, 2014, we received gross proceeds of $859,490 from the sale of our common stock to private investors. From the date of inception through December 31, 2015, we received gross proceeds of $896,000 from the issuance of promissory notes. During this same period, we also repaid $761,000 of these promissory notes. From the date of inception through December 31, 2015, we received cash proceeds of $5,995,000 plus Marketable Securities from a noteholder with a fair value of $150,000 at date of issuance for total proceeds of $6,145,000 from the issuance of original issue discounted convertible debt.

At December 31, 2015 and 2014, we had cash and marketable securities of approximately $639,000 and $220,000, respectively. We have funded our operations to date primarily through the issuance of debt and convertible debt securities. During the years ended December 31, 2015 and 2014, we funded our working capital requirements with the proceeds of Advance Notes and OID Notes.

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 believe that our current cash and marketable securities are sufficient to fund operations until September 2016 without giving consideration to the proceeds of this offering based on our current business plan. Our current financial condition raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We will seek funds through additional equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us, we will be required to delay, curtail or eliminate one or more of our research and development programs.

Cash Flows for the Year Ended December 31, 2015 and the Period January 30, 2014 (Date of Inception) through December 31, 2014

Net cash used in operating activities for the year ended December 31, 2015 was $4,510,778, which primarily reflected our net loss of $5,930,236, plus non-cash expenses of $733,599 for depreciation and amortization, non-cash accreted interest expense due to the OID convertible debt and debt discount - warrants of $1,561,677, non-cash warrant expense of $218,337, and an increase of accounts payable and accrued expenses of $251,608 due to our limited cash position, offset by a non-cash fair value gain on warrant liability of $386,103, an increase in other receivables of $638,092 due to a higher French R & D tax credit in 2015 versus 2014 and an increase in prepaid expenses of $340,524 consisting primarily of finance and legal costs associated with the filing of the S-1. Net cash used in operating activities from January 30, 2014 (Date of Inception) through December 31, 2014 was $1,005,993, which primarily reflected our net loss of $2,365,148, offset by a non-cash fair value gain on the warrant liability of $1,368, non-cash expenses of $429,935 for depreciation and amortization, non-cash accreted interest expense due to the OID convertible debt and debt discount - warrants of $59,029, and a decrease of working capital of $871,559 due primarily to a decrease in accounts receivable of $356,252 as cash was collected from our European subsidiary's prior billings, an increase of accounts payable and accrued expenses of $563,089 due to our limited cash position, offset by an increase in other receivables of $50,595.

Net cash used in investing activities for the year ended December 31, 2015 was $24,380 consisting of purchases of property and equipment. Net cash used in investing activities from January 30, 2014 (Date of Inception) through December 31, 2014 was $751,955 consisting of $191,003 in purchases of property and equipment and $560,952 of the cash portion of the purchase of Protea Europe SAS.

Net cash provided by financing activities for the year ended December 31, 2015 was $5,021,353 consisting of gross proceeds of $5,395,000 in connection with the issuance of OID convertible debt, repayments of OID convertible debt of $117,947, gross proceeds from the issuance of promissory notes of $445,000, and the repayments of promissory notes of $701,000.

Net cash provided by financing activities from January 30, 2014 (Date of Inception) through December 31, 2014 was $1,850,491 consisting of gross proceeds of $859,491 for the sale of our common stock, gross proceeds of $600,000 in connection with the issuance of OID convertible debt, issuance of promissory notes of $451,000 offset by the repayments of promissory notes of $60,000.

Consolidated Results of Operations for the Year Ended December 31, 2015 and the Period January 30, 2014 (Date of Inception) through December 31, 2014 ("2014")

R&D expenses were $1,398,056 and $670,491, respectively, for the year ended December 31, 2015 and 2014, an increase of $727,565. The increase in R&D is primarily due to costs associated with manufacturing additional batches of MS1819 as well as increased R&D activities in France. We expect R&D expenses to increase in future periods as our product candidates continue through clinical trials and we seek strategic collaborations.

G&A expenses were $3,330,752 and $1,658,615, respectively, for the year ended December 31, 2015 and 2014, an increase of $1,672,137. The increase is primarily due to increased G&A expenses in the U.S. such as an increase in legal/investment banking/other professional consulting of $720,555, payroll expenses of $43,307, travel of $121,565, and warrant expense of $218,337 as well as an increase in amortization of $272,993. We expect G&A expenses to increase going forward as we proceed to advance our product candidates through the development and regulatory process.

Interest expense was $1,587,533 and $68,149, respectively, for the year ended December 31, 2015 and 2014, an increase of $1,519,384. The increase was due to the higher level of outstanding OID convertible debt. Fair value adjustment of our warrants was $386,103 and $1,368, respectively, for the year ended December 31, 2015 and 2014, an increase of $384,735. This increase was due to the valuation of the warrants liability at the end of each respective period as well as a higher level of warrant liability a result of the higher level of outstanding OID convertible debt.

Other income was $0 and $30,739, respectively, for the year ended December 31, 2015 and 2014. The other income in 2014 was primarily from Mayoly, our lipase development partner.

Net loss for the year ended December 31, 2015 was $5,930,236 compared to a net loss of $2,365,148 for 2014 as a result of the above.

Off-Balance Sheet Arrangements

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

DESCRIPTION OF THE BUSINESS

Overview

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 without reaching the systemic circulation, i.e. the intestinal lumen, skin or mucosa. Our current product pipeline consists of two therapeutic proteins under development:

- MS1819 - an autologous yeast recombinant lipase for exocrine pancreatic insufficiency (EPI) associated with chronic pancreatitis (CP) and cystic fibrosis (CF).
- AZX1101- a recombinant β-lactamase combination of bacterial origin for the prevention of hospital-acquired infections by resistant bacterial strains induced by parenteral administration of β-lactam antibiotics, as well as prevention of antibiotic-associated diarrhea (AAD).

Our initial product, MS1819, is intended to treat patients suffering from EPI who are currently treated with porcine pancreatic extracts, or PPEs, which have been on the market since 1938. The PPE market is well established and growing with estimated sales of $880 million in the U.S. in 2015 (based on a 20% discount to IMS Health's 2015 prescription data) and has been growing for the past five years at a compound annual growth rate of 22% according to IMS Health 2009-2014 data. In spite of their long-term use, however, PPEs suffer from poor stability, formulation problems, possible transmission of conventional and non-conventional infectious agents due to their animal origins, possible adverse events at high doses in patients with CF and limited effectiveness. We believe that MS1819, if successfully developed and approved for commercialization, can address these shortcomings associated with PPEs.

Phase 1 testing of MS1819 was completed in March 2011 and we expect to initiate a Phase II clinical trial during the middle of 2016. See "Product Programs-MS1819-Clinical Program" below. Our second non-systemic biologic product under preclinical development, AZX1101, is designed to protect the gut microbiome (gastrointestinal (GI) microflora) from the effects of certain commonly used intravenous (IV) antibiotics for the prevention of *C. difficile* infection (CDI) and antibiotic-associated diarrhea (AAD). CDIs are a leading type of hospital acquired infection (HAI) and are frequently associated with IV antibiotic treatment. Designed to be given orally and co-administered with a broad range of IV beta-lactam antibiotics (e.g., penicillins, cephalosporins and aminogycosides), AZX1101 is intended to protect the gut while the IV antibiotics fight the primary infection. AZX1101 is believed to have the potential to protect the gut from a broad spectrum of IV beta-lactam antibiotics. Beta-lactam antibiotics are a mainstay in hospital infection management and include the commonly used penicillin and cephalosporin classes of antibiotics. AZX1101's target market is significant and represented by annual U.S. hospitals purchases of approximately 118 million doses of IV beta-lactam antibiotics which are administered to approximately 14 million patients. Currently there are no approved treatments designed to protect the gut microbiome from the damaging effects of IV antibiotics. This worldwide market could represent a multi-billion-dollar opportunity for us. We intend to use a portion of the proceeds of this offering to fund the additional preclinical studies needed to file an Investigational New Drug Application, or IND, with the FDA.

Corporate History

On May 21, 2014, we entered into a stock purchase agreement (the "SPA") with Protea Biosciences Group, Inc. ("Protea Group") and its wholly-owned subsidiary, Protea Biosciences, Inc. ("Protea Sub" and, together with Protea Group, "Protea") to acquire 100% of the outstanding capital stock of AzurRx BioPharma SAS (formerly ProteaBio Europe SAS), a wholly-owned subsidiary of Protea Sub. On June 13, 2014, we completed the acquisition in exchange for the payment of $300,000 and the issuance of shares of our Series A convertible preferred stock (the "Series A Preferred") convertible into 33% of our outstanding common stock. Under the SPA, we are obligated to make certain milestone and royalty payments to Protea. See "Agreements and Collaborations" below.

Product Programs

We are currently engaged in research and development of two potential product candidates, MS1819 and AZX1101.

MS1819

MS1819 is the active pharmaceutical ingredient, or API, derived from *Yarrowia lipolytica*, an aerobic yeast naturally found in various foods such as cheese and olive oil that is widely used as a biocatalyst in several industrial processes. MS1819 is an acid-resistant secreted lipase naturally produced by *Yarrowia lipolytica,* known as LIP2, that we are developing through recombinant DNA technology for the treatment of exocrine pancreatic insufficiency, or EPI, associated with chronic pancreatitis (CP) and cystic fibrosis (CF). We obtained the exclusive right to commercialize MS1819 in the U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel pursuant to a sublicense from Laboratoires Mayoly Spindler SAS, or Mayoly, under a joint development agreement that also grants us joint commercialization rights for Brazil, Italy, China and Japan. See "Agreements and Collaborations."

Background

The pancreas is both an endocrine gland that produces several important hormones, including insulin, glucagon, and pancreatic polypeptide, as well as a digestive organ that secretes pancreatic juice containing digestive enzymes that assist the absorption of nutrients and digestion in the small intestine.

The targeted indication of MS1819 is the compensation of EPI, which is observed when the exocrine functions of the pancreas are below 10% of normal. The symptomatology of EPI is essentially due to pancreatic lipase deficiency, an enzyme that hydrolyses triglycerides into monoglycerides and free fatty acids. The pancreatic lipase enzymatic activity is hardly compensated by extrapancreatic mechanisms, because gastric lipase has nearly no lipolytic activity in the pH range of the intestine. On the other hand, when they are impaired, the pancreatic amylase and proteases (enzymes that break up starches and protein, respectively) activities can be, at least in part, compensated by the salivary amylase, the intestinal glycosidase, the gastric pepsin, and the intestinal peptidases, all of which are components of the gastric juice secreted by the stomach walls. In summary, lipid maldigestion due to lipase deficiency is responsible for weight loss, steatorrhea featured by greasy diarrhea, and fat-soluble vitamin deficiencies (i.e. A, D, E and K vitamins). In addition, EPI caused by chronic pancreatic disorders is also frequently associated with endocrine pancreatic insufficiency, resulting in diabetes mellitus sometimes called type IIIc.

CP, the most common cause of EPI, is a long-standing inflammation of the pancreas that alters its normal structure and functions. In the United States, its prevalence rate is of 42 cases per 100,000 inhabitants, resulting in approximately 132,000 cases. Approximately 60% of patients affected with CP display EPI, resulting in approximately 80,000 patients requiring substitution therapy in the U.S. In Western societies, CP is caused by chronic alcoholic consumption in approximately 55-80% of cases. Other relatively frequent etiologies include the genetic form of the disease that is inherited as an autosomal dominant condition with variable penetrance, pancreatic trauma and idiopathic causes. CP is frequently associated with episodes of acute inflammation in a previously injured pancreas, or as chronic damage with persistent pain, diabetes mellitus due to endocrine pancreatic insufficiency, or malabsorption caused by EPI. In addition to EPI symptoms, weight loss due to malabsorption and/or reduction in food intake due to pain related to food intake, are frequent.

CF, another frequent etiology of EPI, is a severe genetic disease associated with chronic morbidity and life-span decrease of most affected individuals. In most Caucasian populations, CF prevalence is of 7-8 cases per 100,000 inhabitants, but less common in other populations, resulting in approximately 30,000 affected individuals in the U.S. CF is inherited as monogenic autosomal recessive disease due to the defect at a single gene locus that encodes the Cystic Fibrosis Transmembrane Regulator protein (CFTR), a regulated chloride channel. Mutation of both alleles of this chloride channel gene results in the production of thick mucus, which causes a multisystem disease of the upper and lower respiratory tracts, digestive system, and the reproductive tract. The progressive destruction of the pancreas results in EPI that is responsible for malnutrition and contributes to significant morbidity and mortality. About 80-90% of patients with CF develop EPI, resulting in approximately 25,000-27,000 patients in the U.S. that require substitution therapy.

EPI can be also observed following pancreatic and gastric surgeries due to insufficient enzyme production or asynchronism between the entry of food into the small intestine and pancreatic juice with bile secretion, respectively. Other uncommon etiologies of EPI include intestinal disorders (e.g. severe celiac disease, small bowel resection, enteral artificial nutrition), pancreatic diseases (e.g. pancreatic trauma, severe acute pancreatitis with pancreatic necrosis, and pancreatic cancer), and other uncommon etiologies (e.g. Zollinger-Ellison syndrome, Shwachman-Diamond syndrome). Idiopathic EPI has been also reported in the elderly.

Current treatments for EPI stemming from CP and CF rely on porcine pancreatic extracts, or PPEs, which have been on the market since 1938. The PPE market is well established and growing with estimated sales in the U.S. of $880 million in 2015 and has been growing for the past 5 years at a compound annual growth rate of 22%. In spite of their long-term use, however, PPEs suffer from poor stability, formulation problems, possible transmission of conventional and non-conventional infectious agents due to their animal origins, possible adverse events at high doses in patients with CF and limited effectiveness.

We believe that MS1819 recombinant lipase is currently the only non-animal source product known to be in development for the treatment of CP and has the potential to address the shortcomings of PPEs.

History of the Program

In 1998, Mayoly, a European pharmaceutical company focusing primarily on gastroenterology disorders, launched a program for the discovery and characterization of novel lipases of non-animal origin that could be used in replacement therapy for EPI. The program was conducted in collaboration with INRA TRANSFERT, a subsidiary of the French academic laboratory, National Institute for Agricultural Research, or INRA. In 2000, Mayoly and INRA discovered that the yeast *Yarrowia lipolytica* secreted a lipase which was named LIP2. During the ensuing years, Mayoly investigated the *in vitro* enzymatic activities of LIP2 in collaboration with the Laboratory of Enzymology at Interfaces and Physiology of Lipolysis, or EIPL, a French public-funded research laboratory at the French National Scientific Research Centre laboratory, or CNR, which focuses on the physiology and molecular aspects of lipid digestion.

Pre-clinical Program

The efficacy of MS1819 has been investigated in normal minipigs, which are generally considered as a relevant model for digestive drug development when considering their physiological similarities with humans and their omnivore diet. Experimental pancreatitis was induced by pancreatic duct ligation, resulting in severe EPI with baseline coefficient of fat absorption, or CFA, around 60% post-ligature. CFA is a measurement obtained by quantifying the amount of fat ingested orally over a defined time period and subtracting the amount eliminated in the stool to ascertain the amount of fat absorbed by the body. Pigs were treated with either MS1819 or enteric-coated PPE, both administered as a single-daily dose.

At doses ranging from 10.5 to 211mg, MS1819 increases the CFA by +25 to +29% in comparison to baseline ($p<0.05$ at all doses), whereas the 2.5 mg dose had milder activity. Similar efficacy was observed in pigs receiving 100,000 U lipase of enteric-coated porcine pancreatic extract. These findings demonstrate the *in vivo* activity of MS1819 in a relevant *in vivo* model at a level similar to the PPEs at dosage of 10.5mg or greater. The results of a clinical trial are statistically significant if they are unlikely to have occurred by chance. Statistical significance of the trial results are typically based on widely used, conventional statistical methods that establishes the p-value of the results. A p-value of 0.05 or less is required to demonstrate statistical significance. As such, these CFA levels are considered to be statistically significant.

To date, two non-clinical toxicology studies have been conducted. Both show that MS1819 lipase is clinically well tolerated at levels up to 1000mg/kg in rats and 250 mg/kg in minipigs up to 13 weeks. MS1819 is therefore considered non-toxic in both rodent and non-rodent species up to a maximum feasible dose (MFD) of 1000 mg/kg/day in the rats over six months of administration.

Clinical Program

We believe that there are two principal therapeutic indications for EPI compensation by MS1819: (1) adult patients with CP or post-pancreatectomy and (2) children or young adults affected by cystic fibrosis. Because of their radically different pathophysiology, we intend to separately investigate each of these indications and have determined, based on market size and expected dose requirements, to pursue the indication for adults first.

During 2010 and 2011, a phase I/IIa clinical trial of MS1819 was conducted in conjunction with Mayoly in a single center in France. The study was an exploratory study mainly designed to investigate the safety of MS1819-FD (freeze-dried) and was a randomized, double blind, placebo controlled, parallel clinical trial in 12 patients affected with CP or pancreatectomy and severe EPI. This study was not designed, nor did it aim, to demonstrate statistically significant changes of CFA or steatorrhea under MS1819-FD. The primary endpoint of the study was defined as the relative change in steatorrhea (an established surrogate biomarker of EPI correction) in comparison to baseline. The study found that MS1819 was well tolerated with no serious adverse events. Only two adverse events were observed: constipation (2 patients out of 8 with MS1819) and hypoglycemia (2 patients out of 8 with MS1819, and 1 patient out of 4 with placebo). A non-statistically significant difference of the primary endpoint, possibly due to the small group size, was found between the two groups both in intention-to-treat, a group that included three patients who received the in-patient facility study diet but did not fulfill the protocol's inclusion criteria, and per-protocol analysis.

We are currently in the final stages of developing a protocol for a phase II multi-center dose escalation study in CP and pancreatectomy. This clinical trial is being designed to ascertain the active dose of MS1819 and to compare its efficacy with or in combination with PPEs and is expected to enroll approximately 15 patients. We have allocated a substantial portion of the proceeds of this offering to conduct the necessary formulation work and validation and stabilization testing on the MS1819 capsules that will be used in the Phase II study, as well as to sponsor and conduct the trial. We have identified a principal investigator and have identified CRO and clinical sites for the study. We expect to file an IND for the study as a result of interactions with the FDA. We expect to submit a U.S. IND by the third quarter of 2016. The U.S. trial is expected to be a placebo-crossover study in 30-60 patients with chronic pancreatitis. In parallel with the IND preparation, we expect to mitigate the dose escalation work in Australia and New Zealand.

AZX1101

AZX1101 is a recombinant-lactamase combination of bacterial origin under development for the prevention of hospital-acquired infections by resistant bacterial strains induced by parenteral administration of β-lactam antibiotics (known as nosocomial infections), as well as the prevention of antibiotic-associated diarrhea, or AAD. Nosocomial infections are a major health concern contributing to increased morbidity, mortality and cost. The Centers for Disease Control, or CDC has estimated that roughly 1.7 million hospital-associated infections (i.e. ~5% of the number of hospitalized patients), cause or contribute to 99,000 deaths each year in the U.S., with the annual cost ranging from $4.5 - $11 billion.

Our AZX1101 product candidate is at an early stage of preclinical development and will consist of a combination of two β-lactamases having complementary activity spectrum. We have selected two proteins from the screening of 22 candidate enzymes that show biochemical characteristics fitting with the application. The production processes of these two candidate proteins have been optimized and will be administrated to minipigs in order to evaluate efficacy. We intend to use a portion of the proceeds of this offering to conduct the first animal study and primary toxicology assessment of AZX1101 during the third quarter of 2016. The offering proceeds will not be sufficient to fund this program past these initial steps and, accordingly, even if the findings warrant further study, we will need to seek additional financing in order to pursue the AZX1101 program, which may not be available on acceptable terms, if at all.

Agreements and Collaborations

Stock Purchase Agreement

On May 21, 2014, we entered into the SPA with Protea to acquire 100% of the outstanding capital stock of ProteaBio Europe (the "Acquisition"). On June 13, 2014, we completed the acquisition in exchange for the payment to Protea of $600,000 and the issuance of shares of our Series A convertible preferred stock (the "Series A Preferred") convertible into 33% of our outstanding common stock. Pursuant to the SPA, Protea Sub assigned (i) to Protea Europe all of its rights, assets, know-how and intellectual property rights in connection with program PR1101 and those granted under that certain Joint Research and Development Agreement, by and among Protea Sub, Protea Europe and Mayoly, dated March 22, 2010 and (ii) to us all amounts, together with any right of reimbursement, due to Protea Sub in connection with outstanding shareholder loans.

Pursuant to the SPA, we are obligated to pay certain other contingent consideration upon the satisfaction of certain events, including (a) a one-time milestone payment of $2,000,000 due within (10) days of receipt of the first approval by the FDA of an NDA or BLA for a Business Product (as such term is defined in the SPA); (b) royalty payments equal to 2.5% of net sales of Business Product up to $100,000,000 and 1.5% of net sales of Business Product in excess of $100,000,000 and (c) ten percent (10%) of the Transaction Value (as defined in the SPA) received in connection with a sale or transfer of the pharmaceutical development business of Protea Europe.

Under the terms of the SPA, Protea has the right to designate one member of our board of directors, which right terminates upon the completion of this offering. Protea has exercised this right and Mr. Maged Shenouda sits on our Board.

Mayoly Agreement

Effective March 22, 2010, Protea and AzurRx SAS entered into a joint research and development agreement (the "2010 Agreement") with Mayoly pursuant to which Mayoly sublicensed certain of its exclusive rights to a genetically engineered yeast strain cell line on which our MS1819 is based that derive from a Usage and Cross-Licensing Agreement dated February 2, 2006 (the "INRA Agreement") between Mayoly and INRA, in charge of patent management acting for and on behalf of the National Centre of Scientific Research ("CNRS") and INRA.

Effective January 1, 2014, Protea entered into an amended and restated joint research and development agreement with Mayoly (the "Mayoly Agreement") pursuant to which Protea acquired the exclusive right to Mayoly patents and technology, with the right to sublicense, to develop, manufacture and commercialize human pharmaceuticals based on the MS1819 lipase within the following territories: U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel. The Mayoly Agreement further provides Mayoly the exclusive right to Protea's patents and technology, with the right to sublicense, to develop, manufacture and commercialize human pharmaceuticals based on the MS1819 lipase within the following territories: Mexico, Europe (excluding Italy, Portugal and Spain) and any other country not granted to us alone, or jointly with Mayoly. Rights to the following territories are held jointly with Mayoly: Brazil, Italy, Portugal, Spain, China and Japan. In addition, the Mayoly Agreement requires Protea to pay 70% of all development costs and requires each of the parties to use reasonable efforts to:

- devote sufficient personnel and facilities required for the performance of its assigned tasks;
- make available appropriately qualified personnel to supervise, analyze and report on the results obtained in the furtherance of the development program; and
- deploy such scientific, technical, financial and other resources as is necessary to conduct the development program.

Pursuant to the Mayoly Agreement, if Protea obtains marketing authorization in the U.S. during the development program, Protea is obligated to make a one-time milestone payment and pay Mayoly royalties on net product sales in the low single digits. If Protea does not obtain marketing authorization in the U.S. during the development program, but obtains such authorization thereafter, then Mayoly has the option to either request a license from Protea and pay 30% of our development costs, less the shared costs incurred by Mayoly and a royalty on net sales in the mid-teens, or Protea will pay Mayoly royalties on net product sales in the low single digits. If Mayoly receives EU marketing authorization after the development program concludes, then Protea may license the product from Mayoly for 70% of Mayoly's development costs, less the shared costs incurred by Protea and a royalty on net sales in the mid-teens. The agreement further provides that no royalties are payable by either party until all expenses incurred in connection with the development program since 2009 have been recovered. The Mayoly Agreement further grants Protea the right to cure any breach by Mayoly of its obligations under the INRA agreement. See "INRA Agreement" below. Unless earlier terminated in accordance with its terms, the Mayoly Agreement will expire, on a country by country basis, on the latest of (i) the expiration of any patent covered by the license, (ii) the duration of the legal protection of any intellectual property licensed under the agreement or (iii) the expiration of any applicable data exclusivity period. The latest expiration date of the current series of issued patents covered by the Mayoly Agreement is September 2028. See "Intellectual Property." Either party may terminate the agreement upon a material breach by the other party that remains uncured after 90 days' notice without prejudicing the rights of the terminating party. If the development program or license is terminated due to a material breach that is not cured, then the non-breaching party is free to develop, manufacture and commercialize the product, or grant a license to a third party to carry out such activities in the breaching parties territories or the joint territories. Further, the non-breaching party's net product sales will be subject to low single digit royalties. Finally, either party may terminate due to insolvency of the other party. In connection with the Acquisition, Protea, with the consent of INRA and CNRS, assigned all of its rights, title and interest in and to the Mayoly Agreement to AzurRx SAS.

INRA Agreement

In February 2006, INRA, acting on behalf of CNRS and Institut National de la Recherche Agronomique, entered into a Usage and Cross-licensing Agreement with Mayoly to specify their respective rights to the use of (1) French patent application no. FR9810900 (INRA CNRS patent application), (2) international patent application no. WO2000FR0001148 (Mayoly patent application) and (3) the technology and know-how associated with both patent applications.

The agreement covers extensions of both patent applications. Specifically, the INRA CNRS patent application encompasses application no. FR9810900 as well as PCT/FR99/02079 with national phase entry in the U.S. (no. 09/786,048, now US patent 6,582,951), Canada (no. 2,341,776) and Europe (no. 99.940.267.0, now EP 1 108 043 B1). The Mayoly patent application encompasses WO2000FR0001148 with the national phase entered in Europe (now EP 1 276 874 B1).

The agreement provides Mayoly with the world-wide use in human therapy, nutraceuticals, and cosmetology and provides INRA with world-wide (a) use of lipase as an enzymatic catalyst throughout this field, including the production of pharmaceuticals, and (b) treatment of the environment, food production processes, cleaning processes and other fields, excluding human therapies, neutraceuticals and cosmetology. The agreement provides for shared use in the production of lipase in the veterinary field (livestock and pets). As consideration for the agreement, Mayoly will pay INRA an annual lump sum of €5,000 until marketing. Upon marketing, Mayoly will pay INRA a lump sum of €100,000 and royalties on net sales of the product. Unless earlier terminated in accordance with its terms, the agreement with INRA expires upon the expiration of the patents in each country in which the license has been granted. The parties may terminate the agreement in the event the other party breaches its obligations therein, which termination shall become effective three months following written notice thereof to the breaching party. The breaching party shall have the right to cure such breach or default during such three month period.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

MS1819

The MS1819 program is protected by the following series of issued patents that we have licensed under the Mayoly Agreement covering the method for transformation of *Yarrowia lipolytica*, the sequence of the LIP2 enzyme and its production process:

- PCT/FR99/02079 patent family (including the patents EP1108043 B1, and US6582951) "Method for non-homologous transformation of *Yarrowia lipolytica*", concerns the integration of a gene of interest into the genome of a *Yarrowia* strain devoid of zeta sequences, by transforming said strain using a vector bearing zeta sequences. This modified strain is used for the current production process. This patent has been issued in the U.S., Canada, and validated in several European countries, including Austria, Belgium, Switzerland, Cyprus, Germany, Denmark, Spain, Finland, Great Britain, Greece, Ireland, France, Italy, Lithuania, Luxembourg, Netherlands, Portugal and Sweden. This patent expires September 1, 2019.

- PCT/FR2000/001148 patent family (including the patent EP1276874 B1) "Cloning and expressing an acid-resistant extracellular lipase of *Yarrowia lipolytica*" describes the coding sequences of acid-resistant extracellular lipases, in particular Candida *ernobii* or Yarrowia lipolytica yeasts and the production of said lipases in their recombinant form. This patent has been validated in several European countries, including Italy, France and Great Britain. This patent expires April 28, 2020; and

- PCT/FR2006/001352 patent family (including the patent EP2035556 and patent US8,334,130 and US8,834,867) "Method for producing lipase, transformed *Yarrowia lipolytica* cell capable of producing said lipase and their uses" describes a method for producing *Yarrowia lipolytica* acid-resistant recombinant lipase utilizing a culture medium without any products of animal origin or non-characterized mixtures such as tryptone, peptone or lactoserum, in addition to its uses. The European patents expire June 15, 2026, US patent 8,334,130 expires September 11, 2028, and US patent 8,834,867 expires September 15, 2026.

AZX1101

To date, we own one patent application covering different compositions which has been filed in France. This application was filed internationally (PCT) on October 13, 2015 as PCT/FR2015/052756 claiming priority to French patent application 1459935 dated October 16, 2014. This application was published as WO/2016/059341 titled "Hybrid Proteinaceous Molecule Capable Of Inhibiting At Least One Antibiotic And Pharmaceutical Composition Containing It." At present all PCT contracting states are designated. The term of patent protection available is typically 20 years from the filing date of the earliest international (PCT) application. Patents are territorial rights, meaning that the rights conferred are only applicable in the country or region in which a patent has been filed and granted, in accordance with the law of that country or region. Patent enforcement is only possible after a patent is granted and before the expiration of the patent term. Any patent issuing from PCT/FR2015/052756 will expire on October 13, 2035, unless the patent term is extended pursuant to specific laws of the granting country. We expect to file additional patent applications covering the production process and formulation of AZX1101 following completion of this offering.

Manufacturing

MS1819 API is obtained by fermentation in bioreactors using the engineered *Yarrowia lipolytica* strain. MS1819 is currently manufactured at a contract facility located in Capua Italy owned by DSM. The proprietary yeast cell line from which the API is derived is kept at a storage facility maintained by Charles River. Because the manufacturing process is fairly straightforward, we believe there are multiple alternative contract manufacturers capable of producing the product we need for clinical trials.

AZX1101 API production is still under development in-house. To date, the manufacturing process appears fairly straightforward with multiple options leading us to believe that there are multiple alternative contract manufacturers capable of producing the products we will need for clinical trials.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater financial and other resources, larger research and development staff and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies.

With respect to MS1819, we will compete with PPEs, a well-established market that is currently dominated by a few large pharmaceutical companies, including Abvie, Johnson & Johnson and Actavis plc. There are currently six PPE products that have been approved by the FDA for sale in the U.S. We believe our ability to compete in this market, if we are successful in developing and obtaining regulatory approval to market MS1819, will depend on our ability (or that of a corporate partner) to convince patients, their physicians, healthcare payors and the medical community of the benefits of using a non-animal based product to treat EPI, as well as by addressing other shortcomings associated with PPEs.

With respect to AZX1101, we are aware of only one beta-lactamase under active development by a US specialty pharmaceutical company for the treatment of *c. difficile* although the compounds being developed appear to have very limited efficacy to only specific classes of antibiotics rather than the large classes of antibiotics expected to be covered by our compound.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. To date, our research and development efforts have been conducted in France. We expect to continue to perform substantially all of our basic research activities in France in order to leverage our human capital expertise as well as to avail ourselves of tax credits awarded by the French government to research companies. We expect to conduct early stage development work in both France and the U.S. and late stage development work, including the MS1819 Phase II study and subsequent Phase 3 trial in the U.S. as North America is our principal target market for any products that we may successfully develop.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, the Public Health Services Act or the PHS Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, or NDAs, refusal to approve pending biologic license applications, or BLAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of either a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA for small molecule drugs, or a BLA is prepared and submitted for biologics. Section 351 of the PHS Act defines a biological product as a "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, … applicable to the prevention, treatment, or cure of a disease or condition of human beings." FDA regulations and policies have established that biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products (including cytokines and enzymes). Biological products subject to the PHS Act also meet the definition of drugs under FDC Act and therefore are regulated under provisions of both statutes. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or a BLA is substantial.

Once the submission is accepted for filing, the FDA begins an in-depth review. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA may refer applications for novel drug products, or drug products which present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices, or GMP — a quality system regulating manufacturing — is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug is safe and effective in the indication studied. The issuance of a biologics license is a determination that the product, the manufacturing process, and the manufacturing facilities meet applicable requirements to ensure the continued safety, purity and potency of the biologic product.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter (with the US license number, in the case of a biologic license) or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. The ANDA application also will not be approved until any non-patent exclusivity listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be submitted, unless the submission contains a Paragraph IV challenge to a listed patent — in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity during which the FDA cannot grant effective approval of an ANDA based on the approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use; the approval of which was required to be supported by new clinical trials conducted by, or for, the applicant.

The BPCIA

The Biologics Price Competition and Innovation Act (BPCIA) was enacted as part of the Affordable Care Act on March 23, 2010. The BPCIA creates an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. The objectives of the BPCIA are conceptually similar to those of the Hatch-Waxman Act, which established abbreviated pathways for the approval of small molecule drug products under the FDC Act. The implementation of an abbreviated licensure pathway for biological products can present challenges given the scientific and technical complexities that may be associated with the larger and typically more complex structure of biological products, as well as the processes by which such products are manufactured. Most biological products are produced in a living system such as a microorganism, or plant or animal cells, whereas small molecule drugs are typically manufactured through chemical synthesis.

A "biosimilar" product is a follow-on version of another biological product for which marketing approval is sought or has been obtained based on a demonstration that it is "biosimilar" to the original reference product. Section 351(k) of the PHS Act, added by the BPCIA, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. Section 351(i) defines biosimilarity to mean "that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components" and that "there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product". A 351(k) application must contain, among other things, information demonstrating that the biological product is biosimilar to a reference product based upon data derived from analytical studies, animal studies, and a clinical study or studies, unless the FDA determines, in its discretion, that certain studies are unnecessary. To meet the additional standard of "interchangeability," an applicant must provide sufficient information to demonstrate biosimilarity, and also to demonstrate that the biological product can be expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch. Biosimilar drugs are not generic drugs, which are shown to be the same as the reference product. However, biosimilar products that are also determined to be interchangeable may be substituted for the reference product without the intervention of the prescribing healthcare provider.

In many cases, biosimilars may be brought to market without conducting the full suite of clinical trials typically required of originators. The law establishes a period of 12 years of data exclusivity for reference products in order to preserve incentives for future innovation and outlines statutory criteria for science-based biosimilar approval standards that take into account patient safety considerations. Under this framework, data exclusivity protects the data in the innovator's regulatory application by prohibiting others, for a period of 12 years, from gaining FDA approval based in part on reliance on or reference to the innovator's data in their application to the FDA. Moreover, a biosimilar applicant cannot file their application until 4 years after the reference biological product was first licensed. The law does not change the duration of patents granted on biologic products, but does provide procedures for resolving patent disputes based on a biosimilar application.

The FDA maintains lists biological products, including any biosimilar and interchangeable biological products licensed by the FDA under the PHS Act in a book titled "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (the "Purple Book"). The Purple Book includes the date a biological product was licensed under 351(a) of the PHS Act and whether the FDA evaluated the biological product for reference product exclusivity. If the FDA has determined that a biological product is protected by a period of reference product exclusivity, the list will identify the date of first licensure and the date that reference product exclusivity (including any attached pediatric exclusivity) will expire. The list will not identify periods of orphan exclusivity and their expiration dates for biological products as those dates are available at the searchable database for Orphan Designated and/or Approved Products. The Purple Book also identifies whether a biological product licensed under section 351(k) of the PHS Act has been determined by the FDA to be biosimilar to or interchangeable with a reference biological product. Biosimilar and interchangeable biological products licensed under section 351(k) of the PHS Act are listed under the reference product to which biosimilarity or interchangeability was demonstrated.

Advertising and Promotion

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or supplement to same, before the change can be implemented. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA and BLA supplements as it does in reviewing NDAs and BLAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA or BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs, BLAs or supplements to same must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA and BLA holders a six-month extension of any exclusivity — patent or non-patent — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Physician Drug Samples

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling, and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce; or in return for; purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Foreign Regulatory Issues

Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by a comparable regulatory authority of a foreign country must generally be obtained prior to the commencement of marketing in that country. Although the time required to obtain such approval may be longer or shorter than that required for FDA approval, the requirements for FDA approval are among the most detailed in the world and FDA approval generally takes longer than foreign regulatory approvals.

Employees

As of August 4, 2016 , we had twelve full-time employees, of whom nine were employed by AzurRx SAS and located in France and three were employed by us and located in our office in Brooklyn, New York.

Properties

Our executive offices are located in approximately 687 square feet of office space at 760 Parkside Avenue, Downstate Biotechnology Incubator, Suite 217, Brooklyn, NY 11226 that we occupy under a lease expiring on December 31, 2016 with the option for multiple year renewals. The operations of AzurRx SAS are conducted at approximately 4,520 square feet of office space located at 290 chemin de Saint Dionisy, Jardin des Entreprises, 30980 Langlade, France, that we occupy under a 9-year lease expiring in December 24, 2020.

Legal Proceedings

As of the date hereof, we know of no material, existing or pending legal proceedings against us, nor are we the plaintiff in any material proceedings or pending litigation. There are no proceedings in which any of our directors, executive officers or affiliates, or any registered or beneficial shareholder, is an adverse party or has a material interest adverse to our interest. From time to time, we may be subject to various claims, legal actions and regulatory proceedings arising in the ordinary course of business.

Emerging Growth Company Status

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, which we refer to as the JOBS Act. As a result, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements that are applicable to other companies that are not emerging growth companies. Accordingly, we have included detailed compensation information for only our three most highly compensated executive officers and have not included a compensation discussion and analysis (CD&A) of our executive compensation programs in this prospectus. In addition, for so long as we are an "emerging growth company," we will not be required to:

- engage an auditor to report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes–Oxley Act of 2002 (the "Sarbanes–Oxley Act");
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board (the "PCAOB") regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

- submit certain executive compensation matters to shareholder advisory votes, such as "say-on-pay," "say-on-frequency," and "say-on-golden parachutes;" or
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparison of the chief executive officer's compensation to median employee compensation.

In addition, the JOBS Act provides that an "emerging growth company" can use the extended transition period for complying with new or revised accounting standards.

We will remain an "emerging growth company" until the earliest to occur of:

- our reporting $1 billion or more in annual gross revenues;
- our issuance, in a three year period, of more than $1 billion in non-convertible debt;
- the end of the fiscal year in which the market value of our common stock held by non-affiliates exceeds $700 million on the last business day of our second fiscal quarter; and
- June 30, 2021

DIRECTORS AND EXECUTIVE OFFICERS

The following table sets forth certain information about our executive officers, key employees and directors as of the date of this Registration Statement.

Name	Age	Position
Johan M. (Thijs) Spoor	44	President, Chief Executive Officer and Director
Daniel Dupret	60	Chief Scientific Officer
Edward J. Borkowski [1]	58	Chairman of the Board of Directors
Alastair Riddell [1]	67	Director
Maged Shenouda [1]	52	Director

(1) Member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee

Johan M. (Thijs) Spoor is our Chief Executive Officer since January 2016, President since April 2015, and Chairman from June 2014 to September 2015. From September 2010 until December 2015, he was the chief executive officer of FluoroPharma Medical, Inc. (OTC.QB: FPMI). He has served as chairman of the board of such company from June 2012 until December 2015, and still serves as a member of its board of directors. From December 2008 until February 2010, he worked at Oliver Wyman as a consultant to pharmaceutical and medical device companies. Mr. Spoor was an equity research analyst at J.P. Morgan from July 2007 through October 2008 and at Credit Suisse from November 2005 through July 2007, covering the biotechnology and medical device industries. Mr. Spoor also sits on the board of directors of MetaStat, Inc. (MTST). He holds a Pharmacy degree from the University of Toronto as well as an M.B.A. from Columbia University. We believe that Mr. Spoor's background in pharmacy, finance and accounting and as a healthcare research analyst, as well as his experience at both large and small healthcare companies, provides him with a broad familiarity of the range of issues confronting our company, which makes him a qualified member of our board.

Daniel Dupret has served as President of AzurRx SAS since its formation in 2007 and as Chief Scientific Officer of our company since the Acquisition. Previously, Dr. Dupret founded Proteus SA in 1998 and served as its President and CEO from 1998 to 2007. He founded Appligene SA in 1985 and served as its CSO, then President and CEO until 1998. From 1982 to 1985, he served as Project leader at Transgene SA. In parallel to his biotechnology career, Daniel Dupret served as an advisor for the French government and the European commission in connection with grant commission and funding of early-stage biotechnology companies. From 2003 to 2007, he served as President of the Board of the University of Nîmes.

Edward J. Borkowski joined our board of directors in May 2015 and was appointed Chairman of our board of directors in September 2015. In May 2015, Mr. Borkowski joined the board of Concordia Healthcare. In February 2016, he joined Concordia as its Executive Vice President and continues to serve on its board of directors. Between September 2013 and February 2016, Mr Borkowski was the Chief Financial Officer of Amerigen Pharmaceuticals, an early stage, private, generic pharmaceutical company. From May 2012 to June 2013, Mr. Borkowski served as the Chief Financial Officer of ConvaTec Inc., a private global medical products and technologies company. From January 2011 to May 2012, Mr. Borkowski served as a consultant and advisor to several investment and private equity firms relating to investing in the medical technology and generic pharmaceutical industry. From May 2009 to December 2010, Mr. Borkowski served as the Chief Financial Officer of CareFusion Corporation, a global healthcare company focused on pharmaceutical dispensing equipment, infusion pumps, ventilators and surgical instruments. From 2002 through 2009, Mr. Borkowski was the Chief Financial Officer of Mylan Labs, one of the largest generic and specialty pharmaceutical companies in the world. Mr. Borkowski received his M.B.A. from Rutgers University and his B.S. from Allegheny College. He is also a Certified Public Accountant and a member of the AICPA and NYSSCPA. We believe that Mr. Borkowski's industry specific extensive management experience provides him with a broad and deep understanding of our business and our competitors' efforts, which makes him a qualified member of our board.

Alastair Riddell joined our board of directors in September 2015. Since September 2012, Dr. Riddell has served as the Chairman of Definigen Ltd. and has served as the Chairman of both Silence Therapeutics Ltd. since November 2013 and Procure Therapeutics from October 2009 to November 2012. From 2007 to 2009, he served as the Chief Executive Officer of Stem Cell Sciences, Inc. and from 2005 to 2007, he served as the Chief Executive Officer of Paradigm Therapeutics. From 1998 to 2005, Dr. Riddell served as the Chief Executive Officer of Pharmagene Laboratories Ltd. We believe that Dr. Riddell's background as a medical doctor with experience in a variety of hospital specialties coupled with his experience in the life sciences industry, directing all phases of clinical trials, before moving to sales, marketing and general management, makes him a qualified member of our board.

Maged Shenouda joined our board of directors in October 2015. Mr. Shenouda, a financial professional in the biotechnology industry, was the head of Business Development at Retrofin, Inc. from January 2014 until November 2014. From January 2012 until September 2013, he served as Head of East Coast Operations for the Blueprint Life Science Group. Prior thereto, Mr. Shenouda was a financial analyst, first at UBS from January 2004 until March 2010 and Stifel Nicolaus from June 2010 until November 2011. He currently serves on the board of directors of Protea and was appointed to our board as Protea's designee pursuant to the terms of the SPA.

CORPORATE GOVERNANCE

Director Independence

The board of directors has reviewed the independence of our directors based on the listing standards of the NASDAQ. Based on this review, the board of directors determined that each of Messrs. Borkowski, Shenouda and Riddell are independent within the meaning of the NASDAQ rules. In making this determination, our board of directors considered the relationships that each of these non-employee directors has with us and all other facts and circumstances our board of directors deemed relevant in determining their independence. As required under applicable NASDAQ rules, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present.

Board Committees

Our board of directors has established the following three standing committees: audit committee; compensation committee; and nominating and governance committee, or nominating committee. Our board of directors has adopted written charters for each of these committees. Upon completion of this offering, copies of the charters will be available on our website. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

The audit committee is responsible for, among other matters:

- appointing, compensating, retaining, evaluating, terminating, and overseeing our independent registered public accounting firm;
- discussing with our independent registered public accounting firm the independence of its members from its management;
- reviewing with our independent registered public accounting firm the scope and results of their audit;
- approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the interim and annual financial statements that we file with the SEC;
- reviewing and monitoring our accounting principles, accounting policies, financial and accounting controls, and compliance with legal and regulatory requirements;
- coordinating the oversight by our board of directors of our code of business conduct and our disclosure controls and procedures
- establishing procedures for the confidential and/or anonymous submission of concerns regarding accounting, internal controls or auditing matters; and
- reviewing and approving related-person transactions.

Our audit committee consists of Messrs. Borkowski, Shenouda and Riddell, with Mr. Borkowski serving as the chairman. The NASDAQ rules require us to have one independent audit committee member upon the listing of our common stock, a majority of independent directors within 90 days of the date of this prospectus and all independent audit committee members within one year of the date of this prospectus. Our board of directors has affirmatively determined that Messrs. Borkowski and Riddell meet the definition of "independent director" for purposes of serving on an audit committee under Rule 10A-3 and NASDAQ rules. Our board of directors has determined that Mr. Borkowski qualifies as an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K.

Compensation Committee

The compensation committee is responsible for, among other matters:

- reviewing key employee compensation goals, policies, plans and programs;
- reviewing and approving the compensation of our directors and executive officers;
- reviewing and approving employment agreements and other similar arrangements between us and our executive officers; and
- appointing and overseeing any compensation consultants or advisors.

Our compensation committee consists of Messrs. Borkowski, Shenouda and Riddell, with Dr. Riddell serving as the chairman.

Nominating Committee

The purpose of the nominating committee is to assist the board in identifying qualified individuals to become board members, in determining the composition of the board and in monitoring the process to assess board effectiveness. Our nominating committee consists of Messrs. Borkowski, Shenouda and Riddell, with Mr. Borkowski serving as the chairman.

Board Leadership Structure

Currently, our principal executive officer is Johan M. (Thijs) Spoor and our chairman of the board is Edward J. Borkowski.

Risk Oversight

Our board of directors will oversee a company-wide approach to risk management. Our board of directors will determine the appropriate risk level for us generally, assess the specific risks faced by us and review the steps taken by management to manage those risks. While our board of directors will have ultimate oversight responsibility for the risk management process, its committees will oversee risk in certain specified areas.

Specifically, our compensation committee will be responsible for overseeing the management of risks relating to our executive compensation plans and arrangements, and the incentives created by the compensation awards it administers. Our audit committee will oversee management of enterprise risks and financial risks, as well as potential conflicts of interests. Our board of directors will be responsible for overseeing the management of risks associated with the independence of our board of directors.

Code of Business Conduct and Ethics

Our board of directors adopted a code of business conduct and ethics that applies to our directors, officers and employees. Upon completion of this offering, a copy of this code will be available on our website. We intend to disclose on our website any amendments to the Code of Business Conduct and Ethics and any waivers of the Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions.

EXECUTIVE COMPENSATION

Summary Compensation Table

The following table provides information regarding the compensation paid during the years ended December 31, 2015 and 2014 to our principal executive officer, principal financial officer and certain of our other executive officers, who are collectively referred to as "named executive officers" elsewhere in this prospectus.

Name and Principal Position	Year	Salary	Bonus	Equity Awards	All Other Compensation	Total
Johan M. (Thijs) Spoor, President and Chief Operating Officer	2015	$ 478,400	-0-	-0-	-0-	$ 478,400
	2014	$ 139,100	-0-	-0-	-0-	$ 139,100
Daniel Dupret, Chief Scientific Officer	2015	$ 204,675	-0-	-0-	-0-	$ 204,675
	2014	$ 229,174	-0-	-0-	-0-	$ 229,174

Potential Payments Upon Termination or Change in Control

If we terminate Mr. Spoor's employment other than for cause, we will pay him twelve (12) months of his base salary as severance. In the event of termination by us without cause or by Mr. Spoor for good reason in connection with a change of control, the Company will pay him eighteen (18) months of his base salary as severance.

If we terminate Dr. Dupret's employment other than for cause, the Company will pay him twelve (12) months of his base salary as severance.

Overview of Our Fiscal 2015 Executive Compensation

Elements of Compensation

Our executive compensation program consisted of the following components of compensation in 2014:

Base Salary. Each named executive officer receives a base salary for the expertise, skills, knowledge and experience he offers to our management team. Base salaries are periodically adjusted to reflect:

- The nature, responsibilities, and duties of the officer's position;
- The officer's expertise, demonstrated leadership ability, and prior performance;
- The officer's salary history and total compensation, including annual cash incentive awards and annual equity incentive awards; and
- The competitiveness of the officer's base salary.

Each named executive officer's base salary for fiscal 2014 is listed in the 2014 Summary Compensation Table.

Employment Agreement

Effective as of January 1, 2016, we entered into an employment agreement with Mr. Spoor to serve as our president and chief executive officer for a term of three years. The employment agreement with Mr. Spoor provides for a base annual salary of $350,000, increasing to $425,000 upon completion of this offering and listing of our common stock on The NASDAQ Stock Market or NYSE MKT, and subject an annual milestone bonus, at the sole discretion of the board of directors based on his attainment of certain financial, clinical development, and/or business milestones to be established annually by our board of directors or compensation committee. The employment agreement is terminable by either party at any time. In the event of termination by us without cause or by Mr. Spoor for good reason not in connection with a change of control, as those terms are defined in the agreement, he is entitled to twelve (12) months' severance payable over such period. In the event of termination by us without cause or by Mr. Spoor for good reason in connection with a change of control, as those terms are defined in the agreement, he will receive his eighteen (18) months' severance.

Subject to any required consents from third parties, on or as promptly as practicable following the effective date, Mr. Spoor shall be issued 100,000 shares of restricted stock that vest as follows: (i) 50,000 upon the first commercial sale in the United States of MS1819, and (ii) 50,000 upon our total market capitalization exceeding $1 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the Board.

In addition, subject to any required consents from third parties, on or as promptly as practicable following the effective date, Mr. Spoor shall also be granted ten-year options to be governed by the terms of the 2014 Incentive Plan to purchase 380,000 shares of common stock, which options will vest as follows: (i) 100,000 upon consummation of this offering, (ii) 50,000 upon initiation of a Phase II clinical trial in the United States for MS1819, (iii) 50,000 completion of a Phase II clinical trial in the United States for MS1819, (iv) 100,000 upon initiation of a Phase III clinical trial in the United States for MS1819, (v) 50,000 upon initiation of a Phase I clinical trial in the United States for any product other than MS1819, and (vi) 30,000 upon the determination of a majority of our board. The employment agreement contains standard confidential and proprietary information, and one-year non-competition and non-solicitation provisions.

On June 8, 2016, the Board clarified Mr. Spoor's agreement as follows: the 380,000 options described have neither been granted nor priced, the options will be granted at a future date to be determined by the Board, and the options will be priced at that future date when they are granted.

Outstanding Equity Incentive Awards At Fiscal Year-End

There were no outstanding equity awards held by our named executive officers as of December 31, 2015 and 2014.

Warrant Exercises and Stock Vested

No officers or directors exercised warrants and no stock vested during the years ended December 31, 2015 and 2014.

Non-Executive Director Compensation

Edward Borkowski was paid $90,000 in 2015 as a financial consultant. In July 2016, we issued 45,000 shares of restricted stock to Mr. Borkowski and 30,000 shares of restricted stock to each of Messrs. Shenouda and Riddell. The shares of restricted stock vest as follows: (i) 50% upon the first commercial sale in the United States of MS1819, and (ii) 50% upon our total market capitalization exceeding $1 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the Board.

Compensation Committee Interlocks and Insider Participation

None of our officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors.

Amended and Restated 2014 Omnibus Equity Incentive Plan

Our board of directors and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan (the "2014 Plan"). The 2014 Plan is a comprehensive incentive compensation plan under which we can grant equity-based and other incentive awards to our officers, employees, directors, consultants and advisers. The purpose of the 2014 Plan is to help us attract, motivate and retain such persons with awards under the 2014 Plan and thereby enhance shareholder value.

Administration. The 2014 Plan is administered by the board, and upon consummation of this offering will be administered by the compensation committee of the board, which shall consist of three members of the board, each of whom is a "non-employee director" within the meaning of Rule 16b-3 promulgated under the Exchange Act and an "outside director" within the meaning of Code Section 162(m). Among other things, the compensation committee has complete discretion, subject to the express limits of the 2014 Plan, to determine the directors, employees and nonemployee consultants to be granted an award, the type of award to be granted the terms and conditions of the award, the form of payment to be made and/or the number of shares of common stock subject to each award, the exercise price of each option and base price of each stock appreciation right ("SAR"), the term of each award, the vesting schedule for an award, whether to accelerate vesting, the value of the common stock underlying the award, and the required withholding, if any. The compensation committee may amend, modify or terminate any outstanding award, provided that the participant's consent to such action is required if the action would impair the participant's rights or entitlements with respect to that award. The compensation committee is also authorized to construe the award agreements, and may prescribe rules relating to the 2014 Plan. Notwithstanding the foregoing, the compensation committee does not have any authority to grant or modify an award under the 2014 Plan with terms or conditions that would cause the grant, vesting or exercise thereof to be considered nonqualified "deferred compensation" subject to Code Section 409A.

Grant of Awards; Shares Available for Awards. The 2014 Plan provides for the grant of stock options, SARs, performance share awards, performance unit awards, distribution equivalent right awards, restricted stock awards, restricted stock unit awards and unrestricted stock awards to non-employee directors, officers, employees and nonemployee consultants of AzurRx or its affiliates. The aggregate number of shares of common stock that may be issued under the 2014 Plan shall not exceed ten percent (10%) of the issued and outstanding shares of common stock on an as converted basis (the "As Converted Shares") on a rolling basis. For calculation purposes, the As Converted Shares shall include all shares of common stock and all shares of common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but shall not include any shares of common stock issuable upon the exercise of options, warrants and other convertible securities issued pursuant to the 2014 Plan. The number of authorized shares of common stock reserved for issuance under the Plan shall automatically be increased concurrently with our issuance of fully paid and non-assessable shares of As Converted Shares. Shares shall be deemed to have been issued under the 2014 Plan solely to the extent actually issued and delivered pursuant to an award. If any award expires, is cancelled, or terminates unexercised or is forfeited, the number of shares subject thereto is again available for grant under the 2014 Plan.

The number of shares of common stock for which awards may be granted under the 2014 Plan to a participant who is an employee in any calendar year is limited to 300,000 shares. Future new hires and additional non-employee directors and/or consultants would be eligible to participate in the 2014 Plan as well. The number of stock options and/or shares of restricted stock to be granted to executives and directors cannot be determined at this time as the grant of stock options and/or shares of restricted stock is dependent upon various factors such as hiring requirements and job performance.

Stock Options. The 2014 Plan provides for either "incentive stock options" ("ISOs"), which are intended to meet the requirements for special federal income tax treatment under the Code, or "nonqualified stock options" ("NQSOs"). Stock options may be granted on such terms and conditions as the compensation committee may determine; provided, however, that the per share exercise price under a stock option may not be less than the fair market value of a share of common stock on the date of grant and the term of the stock option may not exceed 10 years (110% of such value and five years in the case of an ISO granted to an employee who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of capital stock of our Company or a parent or subsidiary of our Company). ISOs may only be granted to employees. In addition, the aggregate fair market value of common stock covered by one or more ISOs (determined at the time of grant), which are exercisable for the first time by an employee during any calendar year may not exceed $100,000. Any excess is treated as a NQSO.

Stock Appreciation Rights. A SAR entitles the participant, upon exercise, to receive an amount, in cash or stock or a combination thereof, equal to the increase in the fair market value of the underlying common stock between the date of grant and the date of exercise. SARs may be granted in tandem with, or independently of, stock options granted under the 2014 Plan. A SAR granted in tandem with a stock option (i) is exercisable only at such times, and to the extent, that the related stock option is exercisable in accordance with the procedure for exercise of the related stock option; (ii) terminates upon termination or exercise of the related stock option (likewise, the common stock option granted in tandem with a SAR terminates upon exercise of the SAR); (iii) is transferable only with the related stock option; and (iv) if the related stock option is an ISO, may be exercised only when the value of the stock subject to the stock option exceeds the exercise price of the stock option. A SAR that is not granted in tandem with a stock option is exercisable at such times as the compensation committee may specify.

Performance Shares and Performance Unit Awards. Performance share and performance unit awards entitle the participant to receive cash or shares of common stock upon the attainment of specified performance goals. In the case of performance units, the right to acquire the units is denominated in cash values.

Distribution Equivalent Right Awards. A distribution equivalent right award entitles the participant to receive bookkeeping credits, cash payments and/or common stock distributions equal in amount to the distributions that would have been made to the participant had the participant held a specified number of shares of common stock during the period the participant held the distribution equivalent right. A distribution equivalent right may be awarded as a component of another award under the 2014 Plan, where, if so awarded, such distribution equivalent right will expire or be forfeited by the participant under the same conditions as under such other award.

Restricted Stock Awards and Restricted Stock Unit Awards. A restricted stock award is a grant or sale of common stock to the participant, subject to our right to repurchase all or part of the shares at their purchase price (or to require forfeiture of such shares if issued to the participant at no cost) in the event that conditions specified by the compensation committee in the award are not satisfied prior to the end of the time period during which the shares subject to the award may be repurchased by or forfeited to us. Our restricted stock unit entitles the participant to receive a cash payment equal to the fair market value of a share of common stock for each restricted stock unit subject to such restricted stock unit award, if the participant satisfies the applicable vesting requirement.

Unrestricted Stock Awards. An unrestricted stock award is a grant or sale of shares of our common stock to the participant that is not subject to transfer, forfeiture or other restrictions, in consideration for past services rendered to AzurRx or an affiliate or for other valid consideration.

Change-in-Control Provisions. In connection with the grant of an award, the compensation committee may provide that, in the event of a change in control, such award will become fully vested and immediately exercisable.

Amendment and Termination. The compensation committee may adopt, amend and rescind rules relating to the administration of the 2014 Plan, and amend, suspend or terminate the 2014 Plan, but no such amendment or termination will be made that materially and adversely impairs the rights of any participant with respect to any award received thereby under the 2014 Plan without the participant's consent, other than amendments that are necessary to permit the granting of awards in compliance with applicable laws. We have attempted to structure the 2014 Plan so that remuneration attributable to stock options and other awards will not be subject to the deduction limitation contained in Code Section 162(m).

CERTAIN RELATIONSHIPS AND RELATED-PARTY TRANSACTIONS

We were party to an agreement with JIST Consulting ("JIST"), a company controlled by Johan M. Spoor, our CEO, President and member of our board of directors, to provide Mr. Spoor's services as a consultant for business strategy, financial modeling, and fundraising. During the years ended December 31, 2015 and 2014, we incurred $478,400 and $139,100, respectively, of expenses to JIST. As of March 31, 2016, we had $508,300 in accounts payable to JIST. Mr. Spoor received no other compensation from us other than reimbursement of related travel expenses.

We were party to an agreement with Rigby-Hutton Management Services ("RHMS") to provide our former President, Christine Rigby-Hutton. During the years ended December 31, 2015 and 2014, we incurred $27,750 and $99,142, respectively, of expenses to RHMS. As of March 31, 2016, we had $38,453 in accounts payable to RHMS. Ms. Rigby-Hutton resigned effective April 20, 2015.

On May 21, 2014, we entered into the SPA with Protea in connection with the Acquisition. Pursuant to the SPA, we issued to Protea 100 shares of our Series A Preferred convertible into 33% of our outstanding common stock. See the section entitled "Description of the Business, Agreements" above.

On August 31, 2014, January 31, 2015, February 28, 2015 and May 31, 2015, we issued promissory notes to Matthew Balk and his affiliates in the aggregate principal amount of $236,000. These notes have been repaid in full as to $50,000 on November 11, 2014, $111,000 on April 3, 2015, and $75,000 on August 7, 2015. Mr. Balk holds voting and dispositive power over the shares held by Pelican Partners LLC, which owns 40%, 47%, and 64%, respectively, of the outstanding common stock of the Company as of March 31, 2016 and December 31, 2015 and 2014.

In July 2014, we issued promissory notes to Johan M. (Thijs) Spoor, our president, chief operating officer and chairman of the board, in the aggregate principal amount of $10,000. These notes were repaid in full as to $5,000 on October 17, 2014 and $5,000 on November 10, 2014.

From October 1, 2015 through December 31, 2015, the Company used the services of Edward Borkowski, a member of the Board of Directors and the Company's audit committee chair, as a financial consultant. Expense recorded in general and administrative expense in the accompanying statements of operations related to Mr. Borkowski for the year ended December 31, 2015 was $90,000. As of March 31, 2016, we had $90,000 in accounts payable to Mr. Borkowski. Mr. Borkowski received no other compensation from the Company other than reimbursement of related travel expenses. On October 14, 2014 and March 12, 2015, the Company issued original issue discounted convertible notes to Edward Borkowski, a director and the Company's audit committee chair, in the aggregate principal amount of $300,000. The notes will automatically convert into shares of the Company's common stock upon the consummation of this offering at a conversion price equal to the principal amount divided by the lesser of $6.45 per share or the per share price of the Company's common stock in this offering, multiplied by 80%. Mr. Borkowski has signed an exchange agreement related to these notes as detailed in Note 10 to our financial statements below.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of our common stock as of August 4, 2016 , and as adjusted to reflect the sale of common stock being offered in this offering by:

- each person, or group of affiliated persons, known to us to own beneficially more than 5% of our common stock;
- each of our current directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

The information in the following table has been presented in accordance with the rules of the SEC. Under such rules, beneficial ownership of a class of capital stock includes any shares of such class as to which a person, directly or indirectly, has or shares voting power or investment power and also any shares as to which a person has the right to acquire such voting or investment power within 60 days through the exercise of any stock option, warrant or other right. If two or more persons share voting power or investment power with respect to specific securities, each such person is deemed to be the beneficial owner of such securities. Except as we otherwise indicate below and under applicable community property laws, we believe that the beneficial owners of the common stock listed below, based on information they have furnished to us, have sole voting and investment power with respect to the shares shown. Except as otherwise indicated, each stockholder named in the table is assumed to have sole voting and investment power with respect to the number of shares listed opposite the stockholder's name.

The calculations of beneficial ownership in this table are based on 6,028,928 shares of common stock outstanding at August 4, 2016.

Name and Address of Beneficial Owner [1]	Shares Beneficially Owned	Percentage Total Voting Power Prior to Offering	Percentage Total Voting Power After This Offering
Daniel Dupret	0	*	*
Johan M. (Thijs) Spoor [2]	339,885	6%	3%
Alastair Riddell	10,000	*	*
Edward J. Borkowski [3]	280,486	5%	3%
Maged Shenouda	20,000	*	*
Pelican Partners LLC [4]	1,803,146	30%	17%
Richard Melnick [5]	911,962	15%	8%
Jason Adelman [6]	560,243	9%	5%
Burke Ross [7]	1,804,866	25%	16 %
ADEC Private Equity Investment, LLC [8]	1,304,866	18%	11%
EBR Ventures, LLC [9]	500,000	8%	5%
All directors and executive officers as a group (5 persons)	650,371	11%	6%

* Less than 1%.

(1) Unless otherwise indicated, the address of such individual is c/o AzurRx BioPharma, Inc., 760 Parkside Avenue, Downstate Biotechnology Incubator, Suite 217, Brooklyn, NY 11226.

(2) Includes 300,000 shares issuable pursuant to options granted by third parties at an exercise price of $1.00 per share and 39,851 shares held in a trust for the benefit of Mr. Spoor's minor children.

(3) Includes 103,126 shares issuable upon conversion of OID notes and 27,360 shares issuable upon the exercise of warrants.

(4) The address of such individual is P.O. Box 2422, Westport, CT 06880.

(5) The address of such individual is 28 Gothic Ave., Crested Butte, CO 81224.

(6) The address of such individual is 30 E. 72nd St., 5th Floor, New York, NY 10021.

(7) Includes 1,031,268 shares issuable upon conversion of OID notes and 273,598 shares issuable upon the exercise of warrants held by ADEC Private Equity Investment, LLC and 500,000 shares of common stock held by EBR Ventures, LLC.

(8) Includes 1,031,268 shares issuable upon conversion of OID notes and 273,598 shares issuable upon the exercise of warrants. Burke Ross has voting and dispositive power over the shares held by such entity. The address of such entity is c/o SCS Financial, 919 Third Ave., 30th Floor, New York, NY 10022.

(9) Burke Ross has voting and dispositive power over the shares held by such entity. The address of such entity is 172 South Ocean Blvd., Palm Beach, FL 33480.

DESCRIPTION OF SECURITIES

General

Our amended and restated certificate of incorporation authorizes the issuance of up to 100,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

Common Stock

As of August 4, 2016 , there were 6,028,928 shares of common stock outstanding and 1,092,800 shares of common stock subject to outstanding warrants. An additional 2,642,160 shares of common stock will be issued immediately prior to the closing of this offering upon the conversion of outstanding convertible notes. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights.

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that are outstanding or that we may designate and issue in the future.

Preferred Stock

Our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

Convertible Notes

Commencing on October 10, 2014, through a series of transactions, we issued original issue 15% discounted convertible notes to various investors. On March 31, 2016, the holders of all but $300,000 in principal signed exchange agreements rolling the principal amount into new original issue 8% discounted convertible notes due on November 4, 2016, modifying the conversion price to $4.65 per share. The aggregate gross proceeds received in connection with these notes as of August 4, 2016 was $9,042,529. The notes will automatically convert into shares of our common stock upon the consummation of this offering equal to the quotient obtained by dividing the principal amount, multiplied by 1.25, by the lesser of (a) $4.65 or (b) the price per share or price per unit issued in this offering (2,642,160 shares).

Options

We currently do not have any outstanding options to purchase shares of our common stock or other securities.

Warrants

In connection with our private placement of our original issue discounted convertible notes, we issued five-year warrants (the "Warrants") to purchase an aggregate of 950,360 shares of our common stock at exercise prices ranging from $5.58 to $7.37 per share. In addition, we issued warrants to purchase an aggregate of 142,440 shares of our common stock to placement agents in connection with this private placement.

Transfer Agent

The transfer agent for our common stock is Transhare Corporation, 4626 South Broadway, Englewood, Colorado 80113, Tel: (303) 662-1112.

Listing

We have applied to have our common stock listed on The NASDAQ Capital Market under the symbol "AZRX."

Holders

As of August 4, 2016 , there were 6,028,928 shares of common stock outstanding, which were held by approximately 46 stockholders of record.

Registration Rights

Pursuant to the SPA with Protea, we granted registration rights to Protea to include the shares of common stock issuable upon conversion of the Series A Preferred in registration statements that we may file for ourselves or other stockholders in the future. We also agreed with the holders of our outstanding OID notes and warrants issued in connection therewith that we file a registration statement providing for the resale of the shares of common stock underlying such notes and warrants no later than sixty (60) days following the effective date of this offering (subject to any underwriter lock-ups). In addition, we granted certain registration rights in connection with the issuance of the warrants issued to our placement agent in connection with a previous private placement. We will pay all of the expenses associated with each of such registrations.

Delaware Anti-Takeover Law

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers upon consummation of this offering. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a "business combination" with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an "interested stockholder");
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A "business combination" includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our board of directors approves the transaction that made the stockholder an "interested stockholder," prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market for our common stock existed, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market could adversely affect prevailing market prices of our common stock from time to time and could impair our future ability to raise equity capital in the future. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Based upon the number of shares outstanding as of August 4, 2016, upon the closing of this offering, we will have outstanding an aggregate of 10,813,945 shares of common stock, assuming no exercise of the underwriters' over-allotment option and no exercise of outstanding options, after giving effect to the conversion of (i) all outstanding shares of our preferred stock into 878,171 shares of common stock and (ii) the issuance of 2,642,160 shares of common stock upon the conversion of outstanding convertible notes immediately prior to the closing of this offering. All of the shares sold in this offering by us will be freely tradable without restrictions or further registration under the Securities Act, unless held by our affiliates, as that term is defined under Rule 144 under the Securities Act, or subject to lock-up agreements. The remaining shares of common stock outstanding upon the closing of this offering are restricted securities as defined in Rule 144. Restricted securities may be sold in the U.S. public market only if registered or if they qualify for an exemption from registration, including by reason of Rule 144 or Rule 701 under the Securities Act, which rules are summarized below. These remaining shares will generally become available for sale in the public market as follows:

- no shares will be eligible for sale in the public market on the date of this prospectus; and
- approximately 10,813,945 shares will be eligible for sale in the public market upon expiration of lock-up agreements 181 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations of Rule 144 and Rule 701.

As of August 4, 2016 , of the 1,092,800 shares of common stock issuable upon exercise of outstanding options and warrants, approximately 1,092,800 shares will be vested and eligible for sale 181 days after the date of this prospectus.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, the shares of common stock reserved for future issuance under our 2014 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements, a registration statement under the Securities Act or an exemption from registration, including Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

In general, a person who has beneficially owned restricted shares of our common stock for at least six months would be entitled to sell their securities provided that (1) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, (2) we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale and (3) we are current in our Exchange Act reporting at the time of sale.

Persons who have beneficially owned restricted shares of our common stock for at least six months, but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 108,139 shares immediately after the closing of this offering based on the number of common shares outstanding as of August 4, 2016 .
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

In general, under Rule 701, a person who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been one of our affiliates during the immediately preceding 90 days may sell these shares in reliance upon Rule 144, but without being required to comply with the notice, manner of sale, public information requirements or volume limitation provisions of Rule 144. Rule 701 also permits affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701. As of August 4, 2016, no shares of our outstanding common stock had been issued in reliance on Rule 701 as a result of exercises of stock options and issuance of restricted stock. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

Following this offering, we intend to file with the SEC a registration statement on Form S-8 under the Securities Act to register the offer and sale of shares of our common stock that are issuable pursuant to our 2014 Plan. Shares covered by this registration statement will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Arrangements

We, all of our directors and executive officers have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, subject to certain exceptions, we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock. These agreements are described in the section of this prospectus titled "Underwriting."

Registration Rights

Pursuant to the SPA with Protea, we granted registration rights to Protea to include the shares of common stock issuable upon conversion of the Series A Preferred in registration statements that we may file for ourselves or other stockholders in the future. We also agreed with the holders of our outstanding OID notes and warrants issued in connection therewith that we file a registration statement providing for the resale of the shares of common stock underlying such notes and warrants no later than sixty (60) days following the effective date of this offering (subject to any underwriter lock-ups). In addition, we granted certain registration rights in connection with the issuance of the warrants issued to our placement agent in connection with a previous private placement. We will pay all of the expenses associated with each of such registrations. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Our Restated Certificate of Incorporation and Amended and Restated Bylaws, subject to the provisions of Delaware Law, contain provisions which allow the corporation to indemnify any person against liabilities and other expenses incurred as the result of defending or administering any pending or anticipated legal issue in connection with service to us if it is determined that person acted in good faith and in a manner which he reasonably believed was in the best interest of the corporation. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

UNDERWRITING

WallachBeth Capital, LLC and Network 1 Securities, Inc. are acting as the co-book-running managers of the offering, and we have entered into an underwriting agreement, dated July 13, 2016, with them as underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters and the underwriters have agreed to purchase from us, at the public offering price per share less the underwriting discounts set forth on the cover page of this prospectus.

The underwriters are committed to purchase all the shares of common stock offered by us other than those covered by the option to purchase additional shares described below, if they purchase any shares. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-allotment Option

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of 321,429 additional shares (15% of the shares sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise all or part of this option, it will purchase shares covered by the option at the public offering price per share that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be $17,250,000 and the total net proceeds, before expenses, to us will be $16,042,500.

Discount

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	$ 7.00	$ 15,000,000	$ 17,250,000
Underwriting discount (7%)	$ 0.49	$ 1,050,000	$ 1,207,500
Proceeds, before expenses, to us	$ 6.51	$ 13,950,000	$ 16,042,500

The underwriters propose to offer the shares offered by us to the public at the public offering price per share set forth on the cover of this prospectus. In addition, the underwriters may offer some of the shares to other securities dealers at such price less a concession of $[_____] per share. If all of the shares offered by us are not sold at the public offering price per share, the underwriters may change the offering price per share and other selling terms by means of a supplement to this prospectus.

We will pay the out-of-pocket accountable expenses of the underwriters in connection with this offering. The underwriting agreement, however, provides that in the event the offering is terminated, any advance expense deposits paid to the underwriters will be returned to the extent that offering expenses are not actually incurred in accordance with FINRA Rule 5110(f)(2)(C).

We have agreed to pay the underwriters' non-accountable expenses allowance equal to 1% of the public offering price of the shares (excluding shares that we may sell to the underwriters to cover over-allotments). We have also agreed to pay the underwriters' expenses relating to the offering, including (a) all filing fees incurred in clearing this offering with FINRA; (b) up to $5,000 of fees, expenses and disbursements relating to background checks of our officers and directors; (c) all fees, expenses and disbursements relating to the registration, qualification or exemption of securities offered under the securities laws of foreign jurisdictions designated by the underwriters; (d) stock transfer and/or stamp taxes, if any, payable upon the transfer of shares of our common stock to the underwriters; (e) $21,775 for the underwriters' use of Ipreo's book-building, prospectus tracking and compliance software for this offering; (f) up to $20,000 of the underwriters' actual accountable road show expenses for the offering; and (g) up to $100,000 for the fees of the underwriters' counsel.

We estimate that the total expenses of the offering payable by us, excluding underwriting discounts and commissions, will be approximately $750,000.

Discretionary Accounts

The underwriters do not intend to confirm sales of the securities offered hereby to any accounts over which they have discretionary authority.

Lock-Up Agreements

Pursuant to certain "lock-up" agreements, we, our executive officers and directors have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic risk of ownership of, directly or indirectly, engage in any short selling of any common stock or securities convertible into or exchangeable or exercisable for any common stock, whether currently owned or subsequently acquired, without the prior written consent of the underwriters, for a period of 180 days from the date of effectiveness of the offering.

The lock-up period described in the preceding paragraph will be automatically extended if: (1) during the last 17 days of the restricted period, we issue an earnings release or announce material news or a material event; or (2) prior to the expiration of the lock-up period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the date of the earnings release, unless the underwriters waive this extension in writing; provided, however, that this lock-up period extension shall not apply to the extent that FINRA has amended or repealed NASD Rule 2711(f)(4), or has otherwise provided written interpretive guidance regarding such rule, in each case, so as to eliminate the prohibition of any broker, dealer, or member of a national securities association from publishing or distributing any research report, with respect to the securities of an emerging growth company (as defined in the JOBS Act) prior to or after the expiration of any agreement between the broker, dealer, or member of a national securities association and the emerging growth company or its stockholders that restricts or prohibits the sale of securities held by the emerging growth company or its stockholders after the initial public offering date.

Underwriter Warrants

We have agreed to issue to the underwriters warrants to purchase up to a total of 107,143 shares of common stock. The warrants are exercisable at $8.40 per share (120% of the public offering price) commencing on a date which is one year from the effective date of the offering under this prospectus supplement and expiring on a date which is no more than five (5) years from the effective date of the offering in compliance with FINRA Rule 5110(f)(2)(G). The warrants have been deemed compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The underwriters (or their permitted assignees under the Rule) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will it engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from effectiveness. In addition, the warrants provide for registration rights upon request, in certain cases. We will bear all fees and expenses attendant to registering the securities issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be adjusted in certain circumstances including in the event of a stock dividend, extraordinary cash dividend or our recapitalization, reorganization, merger or consolidation. However, the warrant exercise price or underlying shares will not be adjusted for issuances of shares of common stock at a price below the warrant exercise price.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by the underwriters, if any, participating in this offering and the underwriters participating in this offering may distribute prospectuses electronically. The underwriters may agree to allocate a number of shares for sale to its online brokerage account holders. Internet distributions will be allocated by the underwriters that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or the underwriters in their capacity as underwriters, and should not be relied upon by investors.

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

- Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of shares in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared with the price at which they may purchase shares through exercise of the over- allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

- Penalty bids permits the underwriters to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our shares of common stock or preventing or retarding a decline in the market price of our shares of common stock. As a result, the price of our common stock or warrants in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The NASDAQ Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive Market Making

In connection with this offering, the underwriters may engage in passive market making transactions in our common stock on The NASDAQ Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, then that bid must then be lowered when specified purchase limits are exceeded.

Other Relationships

The underwriters and their respective affiliates may, in the future provide various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. However, except as disclosed in this prospectus, we have no present arrangements with the underwriters for any further services.

Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the shares of our common stock offered hereby has been passed upon for us by Loeb & Loeb LLP, New York, NY. Cozen O'Connor, New York, NY, is acting as counsel to the underwriters.

EXPERTS

WeiserMazars LLP, an independent registered public accounting firm, has audited the financial statements of AzurRx BioPharma, Inc. as of December 31, 2015 and 2014 and for the year ended December 31, 2015 and the period from January 30, 2014 (date of inception) through December 31, 2014 and the statements of operations and comprehensive loss and cash flows for the period from January 1, 2014 through May 31, 2014 for Protea Europe SAS (predecessor) included in this prospectus and registration statement as set forth in its reports, which are included in this prospectus and registration statement. The report for AzurRx BioPharma, Inc. includes an explanatory paragraph about the existence of substantial doubt concerning its ability to continue as a going concern. Such financial statements have been so included in reliance on the reports of WeiserMazars, LLP, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, which includes amendments and exhibits, under the Securities Act and the rules and regulations under the Securities Act for the registration of common stock being offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information that is in the registration statement and its exhibits and schedules. Certain portions of the registration statement have been omitted as allowed by the rules and regulations of the SEC. Statements in this prospectus that summarize documents are not necessarily complete, and in each case you should refer to the copy of the document filed as an exhibit to the registration statement. You may read and copy the registration statement, including exhibits and schedules filed with it, and reports or other information we may file with the SEC at the public reference facilities of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference rooms. In addition, the registration statement and other public filings can be obtained from the SEC's internet site at www.sec.gov.

Upon completion of this offering, we will become subject to information and periodic reporting requirements of the Exchange Act and we will file annual, quarterly and current reports, proxy statements, and other information with the SEC.

AzurRx BioPharma, Inc.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of AzurRx BioPharma, Inc.

We have audited the accompanying consolidated balance sheets of AzurRx BioPharma, Inc. (the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (deficit), and cash flows for the year ended December 31, 2015 and for the period January 30, 2014 (date of inception) through December 31, 2014. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2015 and 2014, and the consolidated results of their operations and their consolidated cash flows for the year ended December 31, 2015 and for the period January 30, 2014 (date of inception) through December 31, 2014, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred significant operating losses and negative cash flows from operations since inception. The Company also had a working capital deficiency of $6,748,152 and an accumulated deficit of $8,295,384 at December 31, 2015. The Company is dependent on obtaining necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue their operations. These conditions raise substantial doubt about its ability to continue as a going concern. Management's plans regarding those matters also are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to that matter.

As described in Note 1, the consolidated balance sheet as of December 31, 2014 and the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows for the period January 30, 2014 (date of inception) through December 31, 2014 have been restated to correct a misstatement.

/s/ WeiserMazars LLP
Edison, New Jersey

June 15, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of AzurRx BioPharma, Inc.

We have audited the accompanying statements of operations and comprehensive loss and cash flows of Protea Europe SAS (the "Company") (Predecessor to AzurRx BioPharma SAS) for the period from January 1, 2014 through May 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements of the Company referred to above present fairly, in all material respects, the results of its operations and its cash flows for the period from January 1, 2014 through May 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ WeiserMazars LLP
Edison, New Jersey
June 15, 2016

AZURRX BIOPHARMA, INC.
Consolidated Balance Sheets

	12/31/14 (Restated)	12/31/15	03/31/16 (Unaudited)
ASSETS			
Current Assets:			
Cash	$ 94,836	$ 581,668	$ 169,036
Marketable securities	125,070	56,850	44,343
Other receivables	428,752	1,074,858	1,084,043
Prepaid expenses	14,796	353,984	390,715
Total Current Assets	663,454	2,067,360	1,688,137
Property, equipment, and leasehold improvements, net	211,725	176,319	172,958
Other Assets:			
In process research & development, net	422,104	345,678	351,337
License agreements, net	3,215,701	2,238,105	2,161,986
Goodwill	2,042,454	1,832,579	1,908,195
Deposits	20,315	25,641	26,208
Total Other Assets	5,700,574	4,442,003	4,447,726
Total Assets	$ 6,575,753	$ 6,685,682	$ 6,308,821
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)			
Current Liabilities:			
Accounts payable and accrued expenses	$ 1,003,544	$ 781,985	$ 1,325,697
Accounts payable and accrued expenses - related party	219,530	636,753	636,753
Convertible promissory notes	391,000	135,000	135,000
Convertible debt	661,285	6,442,372	7,325,503
Warrant liability	146,376	818,216	801,497
Interest payable	9,120	1,186	3,878
Total Current Liabilities	2,430,855	8,815,512	10,228,328
Contingent consideration	1,500,000	1,500,000	1,500,000
Total Liabilities	3,930,855	10,315,512	11,728,328
Stockholders' Equity (Deficit):			
Convertible preferred stock - Par value $0.0001 per share; 1,000,000 shares authorized; 36 shares outstanding as of March 31, 2016; 71 shares outstanding as of December 31, 2015; 100 shares outstanding as of December 31, 2014; liquidation preference approximates par value at March 31, 2016, December 31, 2015 and 2014	4,900,000	3,479,000	1,764,000
Common stock - Par value $0.0001 per share; 9,000,000 shares authorized; 5,150,757 shares outstanding as of March 31, 2016; 4,296,979 shares outstanding as of December 31, 2015; 3,584,321 shares outstanding as of December 31, 2014	358	430	515
Additional paid in capital	859,133	2,532,188	4,254,151
Accumulated deficit	(2,365,148)	(8,295,384)	(10,286,705)
Accumulated other comprehensive (loss) income	(749,445)	(1,346,064)	(1,151,468)
Total Stockholders' Equity (Deficit)	2,644,898	(3,629,830)	(5,419,507)
Total Liabilities and Stockholders' Equity (Deficit)	$ 6,575,753	$ 6,685,682	$ 6,308,821

See accompanying notes to consolidated financial statements

See accompanying notes to consolidated financial statements

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

	01/01/14 through 05/31/14 Protea Europe SAS (Predecessor)	01/30/14 (Date of Inception) through 12/31/14 (1) Consolidated (Restated)	Year Ended 12/31/15 Consolidated	3 Months Ended 03/31/16 Consolidated (Unaudited)	3 Months Ended 03/31/15 Consolidated (Unaudited)
Research and development expenses	$ 380,132	$ 670,491	$ 1,398,056	$ 685,575	$ 308,834
General & administrative expenses	207,074	1,658,615	3,330,752	661,641	763,582
Loss from operations	(587,206)	(2,329,106)	(4,728,808)	(1,347,216)	(1,072,416)
Other:					
Interest expense	-	(68,149)	(1,587,533)	(713,680)	(144,746)
Fair value adjustment, warrants	-	1,368	386,105	69,576	25,855
Other income	-	30,739	-	-	-
Total other	-	(36,042)	(1,201,428)	(644,104)	(118,891)
Loss before income taxes	(587,206)	(2,365,148)	(5,930,236)	(1,991,320)	(1,191,307)
Income taxes	-	-	-	-	-
Net loss	$ (587,206)	$ (2,365,148)	$ (5,930,236)	$ (1,991,320)	$ (1,191,307)
Other comprehensive income (loss):					
Foreign currency translation adjustment	$ 2,179	$ (749,445)	$ (596,619)	$ 194,596	$ (675,857)
Total comprehensive loss	$ (585,027)	$ (3,114,593)	$ (6,526,855)	$ (1,796,724)	$ (1,867,164)
Basic and diluted weighted average shares outstanding	4,000	(2) 3,540,196	3,627,133	4,725,879	3,584,321
Loss per share - basic and diluted	$ (146.80)	$ (0.67)	$ (1.63)	$ (0.42)	$ (0.33)

(1) - Includes Protea Europe SAS from date of acquisition, see Note 2
(2) - All shares owned by former parent

See accompanying notes to consolidated financial statements

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

	Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total
	Shares	Amount	Shares	Amount				
Balance, January 30, 2014 (Date of Inception), AzurRx	-	$ -	-	$ -	$ -	$ -	$ -	$ -
Common stock issued			3,584,321	358	859,133			859,491
Acquisition of Protea Europe SAS	100	4,900,000						4,900,000
Foreign currency translation adjustment							(749,445)	(749,445)
Net loss						(2,365,148)		(2,365,148)
Balance, December 31, 2014 (Restated)	**100**	**4,900,000**	**3,584,321**	**358**	**859,133**	**(2,365,148)**	**(749,445)**	**2,644,898**
Common stock issued			5,242	1	33,789			33,790
Preferred stock converted into common stock	(29)	(1,421,000)	707,416	71	1,420,929			-
Warrants issued to investment bankers					218,337			218,337
Foreign currency translation adjustment							(596,619)	(596,619)
Net loss						(5,930,236)		(5,930,236)
Balance, December 31, 2015	**71**	**$ 3,479,000**	**4,296,979**	**$ 430**	**$ 2,532,188**	**$ (8,295,384)**	**$ (1,346,064)**	**$ (3,629,830)**
(unaudited)								
Preferred stock converted into common stock	(35)	(1,715,000)	853,778	85	1,714,915			-
Warrants issued to investment bankers					7,048			7,048
Foreign currency translation adjustment							194,596	194,596
Net loss						(1,991,320)		(1,991,320)
Balance, March 31, 2016	**36**	**$ 1,764,000**	**5,150,757**	**$ 515**	**$ 4,254,151**	**$ (10,286,705)**	**$ (1,151,468)**	**$ (5,419,507)**

See accompanying notes to consolidated financial statements

AZURRX BIOPHARMA, INC.
Consolidated Statements of Cash Flows

	01/01/14 through 05/31/14 Protea Europe SAS (Predecessor)	01/30/14 (Date of Inception) through 12/31/14 (1) Consolidated (Restated)	Year Ended 12/31/15 Consolidated	3 Months Ended 03/31/16 Consolidated (Unaudited)	3 Months Ended 03/31/15 Consolidated (Unaudited)
Cash flows from operating activities:					
Net loss	$ (587,206)	$ (2,365,148)	$ (5,930,236)	$ (1,991,320)	$ (1,191,307)
Adjustments to reconcile net loss to net cash used in operating activities:					
Depreciation	4,153	11,113	41,784	10,845	10,902
Amortization	-	418,822	691,815	171,997	175,327
Fair value adjustment, warrants	-	(1,368)	(386,103)	(69,576)	(25,855)
Warrant expense	-	-	218,337	7,048	-
Interest expense settled with issuances of common stock	-	-	33,790	-	-
Accreted interest on convertible debt	-	27,893	749,262	348,610	63,167
Accreted interest on debt discount - warrants	-	31,136	812,415	362,378	70,311
Changes in assets and liabilities, net of effects of acquisition:					
Accounts receivable	-	356,252	-	-	-
Other receivables	6,204	(50,595)	(638,092)	45,859	(5,092)
Prepaid expenses	(10,696)	(1,307)	(340,524)	(36,353)	662
Deposits	-	(5,000)	(6,900)	-	-
Accounts payable and accrued expenses	31,839	563,089	251,608	511,274	(135,283)
Interest payable	-	9,120	(7,934)	2,692	11,268
Due to related party	549,307	-	-	-	-
Net cash used in operating activities	(6,399)	(1,005,993)	(4,510,778)	(636,546)	(1,025,900)
Cash flows from investing activities:					
Purchase of property and equipment	-	(191,003)	(24,380)	(936)	(11,033)
Acquisition of Protea Europe SAS, net of cash acquired	-	(560,952)	-	-	-
Net cash used in investing activities	-	(751,955)	(24,380)	(936)	(11,033)
Cash flows from financing activities:					
Issuances of common stock	-	859,491	-	-	-
Issuances of convertible promissory notes	-	451,000	445,000	-	270,000
Repayments of convertible promissory notes	-	(60,000)	(701,000)	-	(250,000)
Issuances of convertible debt	-	600,000	5,395,000	225,000	1,140,000
Repayments of convertible debt	-	-	(117,647)	-	-
Net cash provided by financing activities	-	1,850,491	5,021,353	225,000	1,160,000
Effect of exchange rate changes on cash	(2,788)	2,293	637	(150)	(9,702)
(Decrease) increase in cash	(6,399)	92,543	486,195	(412,482)	123,067
Cash, beginning balance	48,235	-	94,836	581,668	94,836
Cash, ending balance	$ 39,048	$ 94,836	$ 581,668	$ 169,036	$ 208,201
Supplemental disclosures of cash flow information:					
Cash paid for interest	$ -	$ -	$ -	$ -	$ -
Cash paid for income taxes	$ -	$ -	$ -	$ -	$ -
Non-cash investing and financing activities:					
Shares issued for purchase of Protea Europe SAS	$ -	$ 4,900,000	$ -	$ -	$ -
Contingent consideration related to purchase of Protea Europe SAS acquisition	$ -	$ 1,500,000	$ -	$ -	$ -
Receipt of marketable securities in exchange for issuance of convertible debt to investor	$ -	$ 150,000	$ -	$ -	$ -
Issuance of 5,242 shares of common stock as payment of interest on convertible promissory notes	$ -	$ -	$ 33,790	$ -	$ -
Conversion of preferred shares into common shares by Protea	$ -	$ -	$ 1,421,000	$ 1,715,000	$ -

(1) - Includes Protea Europe SAS from date of acquisition, see Note 2

See accompanying notes to consolidated financial statements

Notes to Consolidated Financial Statements, AzurRx Biopharma Inc., March 31, 2016, December 31, 2015 and 2014 (Information pertaining to the three month periods ended March 31, 2016 and 2015 are unaudited)

Note 1 - The Company, Basis of Presentation, and Significant Accounting Policies

The Company

AzurRx Biopharma, Inc. ("AzurRx", the "Company", 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 BioPharma SAS (formerly ProteaBio Europe SAS), a company incorporated in October 2008 under the laws of France that had been a wholly-owned subsidiary of Protea Biosciences, Inc., or Protea Sub, in turn a wholly-owned subsidiary of Protea Biosciences Group, Inc., a publicly-traded company.

AzurRx, through its AzurRx Europe SAS subsidiary, 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 without reaching the systemic circulation, i.e. the intestinal lumen, skin or mucosa. The Company's current product pipeline consists of two therapeutic proteins under development:

- MS1819 - a recombinant (synthetic) lipase, an enzyme derived from a specialized yeast, which breaks apart fats. Lipases are required to treat patients whose pancreases don't work anymore in a condition known as exocrine pancreatic insufficiency (EPI) which usually arises from chronic pancreatitis (CP) or cystic fibrosis (CF).

- AZ1101- a recombinant (synthetic) enzyme which is being developed to prevent hospital-acquired infections which come from resistant bacterial strains caused by parenteral (intra-venous) administration of β-lactam antibiotics, as well as prevention of antibiotic-associated diarrhea (AAD).

Basis of Presentation and Principles of Consolidation

The financial statements for the period January 1, 2014 through May 31, 2014 include only the accounts of Protea Europe SAS ("Predecessor"). There were no material transactions between June 1, 2014 and June 13, 2014 on the accounts of the Predecessor so the Company assumed May 31, 2014 as the acquisition date for financial statement presentation purposes. For the period January 30, 2014 (date of inception) through May 31, 2014, general & administrative expenses and net loss for the U.S. parent company were $176,456. The financial statements for the periods January 30, 2014 (date of inception) through December 31, 2014; January 1 through December 31, 2015; and January 1, 2016 through March 31, 2016 and 2015 include the accounts of AzurRx and its wholly-owned subsidiary, AzurRx Europe SAS (collectively, the "Company"). Intercompany transactions and balances have been eliminated upon consolidation.

At December 31, 2014 and the year then ended, the Company has recorded a prior period adjustment relating to their property, equipment and leasehold improvements, intangible assets, and goodwill in regards to its consolidation of its French acquired subsidiary. The impact of these adjustments are as follows:

Financial Statement Item	As Previously Reported	As Adjusted	Change
Consolidated Balance Sheet			
Property, equipment, and leasehold improvements, net	$ 222,662	$ 211,725	$ 10,937
Total Other assets	$ 6,391,503	$ 5,700,574	$ 690,929
Total Assets	$ 7,277,619	$ 6,575,753	$ 701,866
Accumulated deficit	$ (2,406,922)	$ (2,365,148)	$ (41,774)
Accumulated other comprehensive loss	$ (5,805)	$ (749,445)	$ 743,640
Total Stockholders' Equity (Deficit)	$ 3,346,764	$ 2,644,898	$ 701,866
Consolidated Statement of Operations and Comprehensive Loss			
Loss from operations	$ (2,370,880)	$ (2,329,106)	$ (41,774)
Net loss	$ (2,406,922)	$ (2,365,148)	$ (41,774)
Foreign currency translation adjustment	$ (9,343)	$ (749,445)	$ 740,102
Total comprehensive loss	$ (2,416,265)	$ (3,114,593)	$ 698,328
Loss per share - basic and diluted	$ (0.68)	$ (0.67)	$ (0.01)
Consolidated Statement of Cash Flows			
Net loss	$ (2,406,922)	$ (2,365,148)	$ (41,774)
Amortization	$ 460,596	$ 418,822	$ 41,774

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operations since inception, had a working capital deficiency at March 31, 2016 and December 31, 2015 of approximately $8,540,000 and $6,748,000, respectively, and had an accumulated deficit at March 31, 2016 and December 31, 2015 of approximately $10,287,000 and $8,295,000, respectively. The Company is dependent on obtaining necessary funding from outside sources, including obtaining additional funding from the sale of securities in order to continue their operations. These conditions raise substantial doubt about its ability to 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

Use of Estimates
The accompanying consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America, 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.

Concentration of Risks
Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and available for sale marketable securities. The Company primarily maintains its cash balances with financial institutions in federally-insured accounts. The Company may from time to time have cash in banks in excess of FDIC insurance limits. The Company has not experienced any losses to date resulting from this practice. The Company's investments in Marketable Securities are comprised of a single investment in a publicly traded stock received as payment from an investor for his $150,000 investment in the Company's Original Issue Convertible Debt. The investor has agreed to make up any shortfall from sales of these securities while any gain is for the account of the Company. As of March 31, 2016, the market value of these Marketable Securities are $44,343 and an associated Other Receivable of $105,657 was recorded. As of December 31, 2015, the market value of these Marketable Securities are $56,850 and an associated Other Receivable of $93,150 was recorded. As of December 31, 2014, the market value of these Marketable Securities are $125,070 and an associated Other Receivable of $24,930 was recorded. See Note 3 below.

Property, Equipment, and Leasehold Improvements
Property, equipment and leasehold improvements are carried on the cost basis and depreciated over the estimated useful lives of the related assets using the straight-line method. For financial statement purposes, depreciation expense is provided using the straight-line method over the estimated useful lives of the assets as follows:

LaboratoryEquipment	5 years
ComputerEquipment	5 years
OfficeEquipment	7-8 years
LeaseholdImprovements	Term of lease or estimated useful life of the assets; whichever is shorter

Expenditures for maintenance and repairs are charged to operations as incurred while renewals and betterments are capitalized.

Goodwill and Intangible Assets
Goodwill represents the excess of the purchase price of the acquired business over the fair value of amounts assigned to assets acquired and liabilities assumed. Goodwill and other intangible assets with indefinite useful lives are reviewed for impairment annually or more frequently if events or circumstances indicate impairment may be present. Any excess in carrying value over the estimated fair value is charged to results of operations.

Intangible assets subject to amortization consist of in process research and development and license agreements reported at the fair value at date of the acquisition less accumulated amortization. Amortization expense is provided using the straight-line method over the estimated useful lives of the assets as follows:

InProcess Research & Development	12 years
LicenseAgreements	5 years

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.

Fair Value Measurements

The Company follows Accounting Standards Codification ("ASC") Topic 820-10, Fair Value Measurements and Disclosures ("ASC 820"), which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use.

At March 31, 2016, December 31, 2015 and 2014, the Company had Level 2 instruments consisting of marketable securities of common stock in a thinly-traded public company received as payment from an investor for $150,000 of the Company's Original Issue Discounted Convertible Note, see Notes 3 and 10 below.

At March 31, 2016, December 31, 2015 and 2014, the Company had Level 3 instruments consisting of the Company's common stock warrant liability related to the Company's convertible debt, see Note 10 and contingent consideration in connection with the Protea Europe SAS acquisition, see Note 6.

The carrying amounts of the Company's financial instruments, including accounts payable, and accrued liabilities, approximate fair value due to their short maturities.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis:

	Fair Value Measurements at Reporting Date Using			
	Total	**Level 1**	**Level 2**	**Level 3**
As of March 31, 2016 (Unaudited):				
Marketable Securities	$ 44,343	$ -	$ 44,343	$ -
Warrant Liability	$ 801,497	$ -	$ -	$ 801,497
Contingent Consideration	$ 1,500,000	$ -	$ -	$ 1,500,000
As of December 31, 2015:				
Marketable Securities	$ 56,850	$ -	$ 56,850	$ -
Warrant Liability	$ 818,216	$ -	$ -	$ 818,216
Contingent Consideration	$ 1,500,000	$ -	$ -	$ 1,500,000
As of December 31, 2014:				
Marketable Securities	$ 125,070	$ -	$ 125,070	$ -
Warrant Liability	$ 146,376	$ -	$ -	$ 146,376
Contingent Consideration	$ 1,500,000	$ -	$ -	$ 1,500,000

The following table provides a reconciliation of the fair value of liabilities using Level 3 significant unobservable inputs:

	Warrant Liability	**Contingent Consideration**
Date of Inception (January 30, 2014)	$ -	$ -
Protea Europe SAS acquisition	-	1,500,000
Issuance of warrants	147,744	-
Change in fair value	(1,368)	-
Balance at December 31, 2014	146,376	1,500,000
Issuance of warrants	1,057,943	-
Change in fair value	(386,105)	-
Balance at December 31, 2015	818,214	1,500,000
Issuance of warrants	52,859	-
Change in fair value	(69,576)	-
Balance at March 31, 2016	$ 801,497	$ 1,500,000

The warrant liability above relates to the Company's original issued discounted convertible notes, see Note 10 below.

The fair values of the outstanding warrants were measured by the Company using a Binomial Option Pricing model. Inputs used to determine estimated fair value of the warrant liabilities at March 31, 2016, December 31, 2015 and 2014 include the estimated fair value of the underlying stock at the valuation date ($1.77, $2.16 and $3.09, respectively), the estimated term in years of the warrants (5.49, 4.90 and 5.34, respectively), risk-free interest rates (1.28%, 1.72% and 1.69%, respectively), expected dividends (zero) and the expected volatility (117.5%, 98% and 93%, respectively) of the underlying stock. The significant unobservable inputs used in the fair value measurement of the warrant liabilities are the fair value of the underlying stock at the valuation date and the estimated term of the warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The contingent consideration was valued by the Company using a series of Black-Scholes Option Pricing Models ("BSM"). Significant unobservable inputs used in the calculations included projected net sales over a 9-year period discounted by the Company's weighted average cost of capital of 33.7%, the contractual hurdle amount of $100 million that replaces the strike price input in the traditional BSM, an asset volatility of 90% that replaces the equity volatility in the traditional BSM, risk-free rates ranging from 1.5% to 2.7%, and an option-adjusted spread of 0.5% that is applied to these payments to account for the payer's risk and arrive at a present value of the expected payment. As the next sales forecast becomes less uncertain, liability may lower in value. If the volatility increases, then the liability value may increase.

The fair value of the Company's other receivables, convertible debt, and loans payable are as follows:

		Fair Value Measured at Reporting Date Using			
	Carrying Amount	Level 1	Level 2	Level 3	Fair Value
As of March 31, 2016 (Unaudited).:					
Other Receivables	$ 1,084,043	$ -	$ -	$ 1,084,043	$ 1,084,043
Convertible Debt	$ 7,325,503			$ 7,325,503	$ 7,325,503
Convertible Promissory Notes	$ 135,000	$ -	$ -	$ 135,000	$ 135,000
As of December 31, 2015:					
Other Receivables	$ 1,074,858	$ -	$ -	$ 1,074,858	$ 1,074,858
Convertible Debt	$ 6,442,372			$ 6,442,372	$ 6,442,372
Convertible Promissory Notes	$ 135,000	$ -	$ -	$ 135,000	$ 135,000
As of December 31, 2014:					
Other Receivables	$ 428,752	$ -	$ -	$ 428,752	$ 428,752
Convertible Debt	$ 661,285	$ -	$ -	$ 661,285	$ 661,285
Convertible Promissory Notes	$ 391,000	$ -	$ -	$ 391,000	$ 391,000

The fair value of Other Receivables approximates carrying value as these consist primarily of French R & D tax credits that are normally received within 9 months of year end.

The fair value of Convertible Debt and Loans Payable approximates carrying value due to the terms of such instruments and applicable interest rates.

Stock-based Compensation

The Company's board of directors and stockholders have adopted and approved the Amended and Restated 2014 Omnibus Equity Incentive Plan which took effect on May 12, 2014. Although the Company did not grant any stock options under the Plan during the three months ended March 31, 2016 and the years ended December 31, 2015 and 2014, the Company will account for its stock-based compensation awards in accordance with ASC Topic 718, Compensation—Stock Compensation ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For stock options granted to employees and to members of the board of directors for their services on the board of directors, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, the Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period.

Income Taxes

Income taxes are recorded in accordance with ASC 740, Accounting for Income Taxes ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. The Company determines its deferred tax assets and liabilities based on differences between financial reporting and tax bases of assets and liabilities, which are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of March 31, 2016, December 31, 2015 and 2014, the Company does not have any significant uncertain tax positions. All tax years are still open for audit.

Impairment of Long-lived Assets
The Company periodically evaluates its long-lived assets for potential impairment in accordance with ASC Topic 360, Property, Plant and Equipment ("ASC 360"). Potential impairment is assessed when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends and product development cycles. If impairments are identified, assets are written down to their estimated fair value. The Company has not recognized any impairment charges through March 31, 2016.

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 year-end exchange rates. Income and expense items are translated at average rates of exchange prevailing during the year. Gains and losses from translation adjustments are accumulated in a separate component of shareholders' equity (deficit).

Collaboration Agreements
As more fully discussed in Note 14, the Company has joint research collaboration agreements with Laboratoires Mayoly Spindler SAS and INRA TRANSFERT. Any payments due from our collaboration partners is recorded as a reduction in research and development expenses.

Subsequent Events
The Company considered events or transactions occurring after the balance sheet date but prior to the date the consolidated financial statements are available to be issued for potential recognition or disclosure in its consolidated financial statements.

Note 3 - Marketable Securities

At March 31, 2016, December 31, 2015 and 2014, the Company had $44,343, $56,850 and $125,070, respectively, of common stock in a public company. These available for sale securities are recorded at fair value and were received as payment from an investor for $150,000 of the Company's Original Issue Discounted Convertible Notes. The investor has agreed to make up any shortfall between the value of the Marketable Securities when converted to cash and the face amount of his Convertible Note.

The Marketable Securities fair value was based on Level 2 inputs.

Note 4 - Other Receivables

Other Receivables consisted of the following:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
Research & development tax credits	$ 950,482	$ 912,818	$ 380,247
Investor subscription	105,657	93,150	24,930
Other	27,904	68,880	23,575
	$ 1,084,043	$ 1,074,848	$ 428,752

The research & development tax credits are refundable tax credits for research conducted in France. The Investor subscription is related to an investor's agreement to make up any shortfall between the Marketable Securities given for his Convertible Debt, see Note 3. The make-whole provision is a deemed "put" measured at fair value due to its relationship in connection with the Marketable Securities. The Company follows the guidance in ASC 815-25-35-6 and records the change in fair values of both the Marketable Securities and the "put" in earnings. Due to the correlation of these instruments, the change in fair values completely offset and net to zero. Other is primarily amounts due from collaboration partner Mayoly, see Note 14.

Note 5 - Property, Equipment, and Leasehold Improvements

Property, equipment and leasehold improvements consisted of the following:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
Laboratory Equipment	$ 154,709	$ 148,578	$ 155,703
Computer Equipment	17,986	16,733	11,105
Office Equipment	29,906	29,057	22,048
Leasehold Improvements	29,163	28,008	31,215
	231,764	222,376	220,071
Less accumulated depreciation	(58,806)	(46,057)	(8,346)
	$ 172,958	$ 176,319	$ 211,725

Depreciation expense for the three months ended March 31, 2016 and 2015 was $10,845 and $10,902, respectively. Depreciation expense for the years ended December 31, 2015 and 2014 was $41,784 and $11,113, respectively. Depreciation expense is included in General and Administrative ("G & A") expenses.

Note 6 - Acquisition

On March 19, 2014, AzurRx entered into a Memo of Understanding with Protea Biosciences Group, Inc. ("Protea Group") and its wholly-owned subsidiary, Protea Biosciences, Inc. ("Protea Sub" and, together with Protea Group, "Protea") to acquire 100% of the outstanding capital stock of AzurRx BioPharma SAS (formerly ProteaBio Europe SAS), a wholly-owned subsidiary of Protea Sub, a company engaged in the research and development of non-systemic biologics for the treatment of patients with gastrointestinal disorders in exchange for a non-refundable deposit of $300,000. On May 21, 2014, the Company entered into a stock purchase agreement (the "SPA") with Protea for this acquisition. On June 13, 2014, the Company completed the acquisition in exchange for a payment of $300,000 and the issuance of shares of its Series A convertible preferred stock (the "Series A Preferred"). Pursuant to the SPA, the Company is obligated to pay Protea certain other Contingent Consideration in U.S. dollars upon the satisfaction of certain events, including (a) a one-time milestone payment of $2,000,000 due within (10) days of receipt of the first approval by the Food and Drug Administration ("FDA") of a New Drug Application ("NDA") or Biologic License Application ("BLA") for a Business Product (as such term is defined in the SPA); (b) royalty payments equal to 2.5% of net sales of Business Product up to $100,000,000 and 1.5% of net sales of Business Product in excess of $100,000,000 and (c) ten percent (10%) of the Transaction Value (as defined in the SPA) received in connection with a sale or transfer of the pharmaceutical development business of Protea Europe. The total consideration was $7,000,000, which consisted of $600,000 cash, the fair value of the 100 shares of Class A Preferred stock issued to Protea, and the fair value of the Contingent Consideration described above.

The estimated useful lives of the intangible assets acquired are described in Note 2, "Significant Accounting Policies, *Goodwill and Intangible Assets"*.

Goodwill related to this acquisition is 100% deductible for U.S. federal income tax purposes.

Acquisition costs in connection with this acquisition were approximately $118,000 and are included in operating expenses.

The acquisition was accounted for as a business combination and, accordingly, the purchase price was allocated to the identified tangible and intangible assets acquired less the liabilities assumed, based on fair value.

The purchase price was determined as following:

Purchase price:		
Fair value of Class A preferred stock issued to seller	$	4,900,000
Cash		600,000
Fair value of the contingent consideration		1,500,000
Total purchase price	$	7,000,000

The Class A Preferred Stock was valued using the Option Pricing Method. Significant unobservable inputs used in this calculation included the Company's total equity value at June 13, 2014 of $34.8 million, the exercise price of $0.01 for the first breakpoint, for each closed form option model an expected term of four years, volatility of 90%, and an interpolated risk-free rate of 1.32%.

See Note 2, ***Fair Value Measurements*** above for the explanation of the valuation method and significant inputs used to value the Contingent Consideration.

The following table summarizes the allocation of the purchase price to the estimated fair value of the assets acquired and the liabilities assumed as of the date of the acquisition:

Net assets acquired were allocated as follows:		
Cash	$	39,045
Accounts receivable		291,740
Other receivable		424,384
Prepaid expenses and other current assets		15,202
Property and equipment		45,381
Other long-term assets		17,157
In process research and development		495,829
License agreements		4,045,064
Goodwill		2,290,892
Accounts payable and accrued expenses		(664,694)
Total purchase price	$	7,000,000

The following is the proforma income statement as if both companies had been consolidated for the full applicable periods presented (unaudited):

	Year Ended 12/31/14
Research and development expenses	$ 1,050,623
General & administrative expenses	1,865,689
Loss from operations	(2,916,312)
Interest expense	(68,149)
Fair value adjustment, warrants	1,368
Other income	30,739
Total other	(36,042)
Loss before income taxes	(2,952,354)
Income taxes	-
Net loss	$ (2,952,354)
Basic and diluted weighted average shares outstanding	3,540,196
Loss per share - basic and diluted	$ (0.83)

Note 7 - Intangible Assets and Goodwill

Intangible assets are as follows:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
In Process Research & Development	$ 413,000	$ 396,634	$ 442,058
Less accumulated amortization	(61,663)	(50,956)	(19,954)
	$ 351,337	$ 345,678	$ 422,104
License Agreements	$ 3,369,329	$ 3,235,814	$ 3,606,394
Less accumulated amortization	(1,207,343)	(997,709)	(390,693)
	$ 2,161,986	$ 2,238,105	$ 3,215,701

Amortization expense for the three months ended March 31, 2016 and 2015 was $171,997 and $175,327, respectively. Amortization expense for the years ended December 31, 2015 and 2014 was $691,815 and $418,822, respectively. Amortization expense is included in G & A expenses.

As of March 31, 2016, amortization expense is expected to be $708,282 per year for the next three years and two months and $34,417 per year for the next year and 10 months after that.

Goodwill is as follows:

	Goodwill
Date of Inception (January 30, 2014)	$ -
Protea Europe SAS acquisition	2,290,892
Foreign currency translation	(248,438)
Balance at December 31, 2014	2,042,454
Foreign currency translation	(209,875)
Balance at December 31, 2015	1,832,579
Foreign currency translation	75,616
Balance at March 31, 2016 (unaudited)	$ 1,908,195

Note 8 - Accounts Payable

Accounts payable and accrued expenses consisted of the following:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
Trade payables	$ 916,563	$ 409,407	$ 825,574
Accrued expenses	139,721	174,210	4,197
Accrued payroll	269,413	198,368	173,773
	$ 1,325,697	$ 781,985	$ 1,003,544

Note 9 - Convertible Promissory Notes

Commencing on July 22, 2014 and through April 3, 2015, the Company, through a series of transactions with various investors, raised $896,000 through the sale of its convertible promissory notes with various maturity dates that can be extended by the Company. The maturity dates ranged from August 31, 2014 through May 31, 2015. All maturity dates have been extended by the Company. Through December 31, 2015, the Company entered into transactions in which noteholders were voluntarily repaid $761,000 and shares were issued to such noteholders in lieu of interest payments. As of December 31, 2014, the Company raised $451,000 through the sale of these convertible promissory notes and repaid $60,000 of these notes. The notes bear interest at 8% per annum and are convertible into Common Stock of the Company at $6.45 per share at the investors' discretion as long as the notes are outstanding. As of March 31, 2016, December 31, 2015 and 2014, the Company had $135,000, $135,000 and $391,000, respectively, of these notes outstanding.

Interest expense for the three months ended March 31, 2016 and 2015 incurred in connection with the promissory notes was $2,693 and $11,268, respectively. Interest expense for the years ended December 31, 2015 and 2014 incurred in connection with the promissory notes was $25,856 and $9,120, respectively. On August 7, 2015, 5,242 shares of the Company's common stock were issued in payment of $33,790 of accrued interest payable on these notes. Interest payable at March, 31, 2016, December 31, 2015 and 2014 in connection with these notes was $3,878, $1,186 and $9,120, respectively.

Note 10 - Original Issue Discounted Convertible Notes

Commencing on October 10, 2014, the Company, through a series of transactions, issued original issue discounted convertible notes to several investors at 85% of the principal amount of the notes. The notes do not otherwise bear interest. The notes are convertible into shares of the Company's common stock at the principal amount divided by the lesser of $6.45 per share or the per share price of the Common Stock representing the pre-money valuation immediately prior to any shares sold in the Company's initial public offering ("IPO"), multiplied by 80% (the "Convertible Shares"). Additionally, separate warrants to purchase shares of the Company's common stock equal to 50% of the number of Convertible Shares at the lesser of $7.37 per share or at a 20% discount to the pre-money IPO valuation of the Company were issued in conjunction with these notes. The warrants are exercisable for five years beginning six months after the issue date. If the pre-money IPO valuation of the Company is less than $43,750,000, then the number of Warrant Shares (herein defined as the underlying common stock shares) will be recalculated as follows: New Number of Warrant Shares = Existing Warrant Shares * [43,750,000/(IPO valuation*80%)]. The Company did not recognize any amounts associated with the beneficial conversion feature at the dates of issuances of such notes due to the unsatisfied condition associated with the pre-money valuation. If, and when, the pre-money valuation is determined, the Company may be required to recognize the value of the beneficial conversion feature, if any, in earnings.

The notes had nine-month terms with principal and interest due starting July 10, 2015. The holders of the notes may demand payment in cash before the maturity date within thirty (30) trading days of the Company's initial public offering. If, on the maturity date, the principal amount of any note remains unpaid, the Company shall pay to the note holder a one-time default penalty of 5% of the total amount unpaid on the maturity date. The Company, however, shall still be required to repay the note holder the principal balance and interest on the principal balance, which shall accrue at the default interest rate equal to the lesser of 18% per annum or the maximum rate permitted under applicable law. As of December 31, 2015, $2,105,882 in principal amount of these notes are in default due to being past their maturity dates.

On March 31, 2016, the holders of all but $300,000 in principal signed exchange agreements nullifying the default provisions and rolling the principal amount into new original issue discounted convertible notes at 92% of the principal amount of the notes due on November 4, 2016, modifying the conversion price to $4.65 per share, and modifying the strike price of the warrants down to the lesser of (i) $5.58 or (ii) a 15% premium to the price per share or unit issued in the IPO or in connection with a public listing. As a result of these exchange agreements, as of December 31, 2015, the Company has not recorded any of the default provisions for all but $300,000 in principal of these notes. The aggregate gross proceeds received in connection with these notes through March 31, 2016, December 31, 2015 and 2014 was $7,303,529, $6,145,000 and $750,000, respectively. Through June 13, 2016, gross proceeds of $700,000 were received from the issuance of additional original issue discounted convertible notes.

The Company accounted for the warrant feature of the notes based upon the fair value of the warrants on the date of issuance. The effect of the warrant modifications is reflected in the fair value adjustment at March 31, 2016 noted below. The Company recorded a warrant liability related to the warrants at March 31, 2016, December 31, 2015 and December 31, 2014 of $1,251,066, $1,205,687, and $147,744, respectively. The warrant liability was adjusted to the fair value at March 31, 2016 of $801,497 by recording a fair value adjustment of $69,576 at March 31, 2016. The warrant liability was adjusted to the fair value at December 31, 2015 of $818,216 by recording a fair value adjustment of $386,105 at December 31, 2015 and the warrant liability was adjusted to the fair value at December 31, 2014 of $146,376 by recording a fair value adjustment of $1,368 at December 31, 2014.

For the three month periods ended March 31, 2016 and 2015, the Company recorded $710,988 and $133,479, respectively, of interest expense related to the original issue discount and warrant features of these notes. For the three months ended March 31, 2016 and 2015, $348,610 and $63,167, respectively, of these amounts were accreted interest expense related to the original issue discount feature of the notes that also increased the outstanding balance of the convertible debt by the same amount. For the three months ended March 31, 2016 and 2015, $362,378 and $70,311, respectively, of these amounts were amortization of the debt discount related to the warrant features of the convertible debt.

For the years ended December 31, 2015 and 2014, the Company recorded $1,561,677 and $59,029, respectively, of interest expense related to the original issue discount and warrant features of these notes. For the years ended December 31, 2015 and 2014, $749,262 and $27,893, respectively, of these amounts were accreted interest expense related to the original issue discount feature of the notes that also increased the outstanding balance of the convertible debt by the same amount. For the years ended December 31, 2015 and 2014, $812,415 and $31,136, respectively, of these amounts were amortization of the debt discount related to the warrant features of the convertible debt.

Convertible Debt consisted of:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
Convertible Debt	$ 7,303,529	$ 6,145,000	$ 750,000
Accreted Interest	74,589	659,508	27,893
Debt Discount - Warrants	(52,615)	(362,136)	(116,608)
	$ 7,325,503	$ 6,442,372	$ 661,285

Note 11 - Equity

The Company has authorized 9,000,000 shares of its common stock, $0.0001 par value and 1,000,000 shares of preferred stock, $0.0001 par value.

Common Stock
At March 31, 2016, December 31, 2015 and 2014, the Company had issued and outstanding 5,150,757, 4,296,979 and 3,584,321, respectively, shares of its common stock.

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. The 2014 Plan permits the Company to award stock options (both incentive stock options and non-qualified stock options), stock appreciation rights, restricted stock, restricted stock units, performance stock awards, performance unit awards, unrestricted stock awards, distribution equivalent rights to the Company's officers, employees, directors, consultants and advisers. The maximum number of shares of common stock that may be issued pursuant to awards under the 2014 Plan is ten percent (10%) of the issued and outstanding shares of the Company's common stock on an "as converted" basis on a rolling basis. The "as converted" shares include all shares of the Company's common stock and all shares of the Company's common stock issuable upon the conversion of outstanding preferred stock and other convertible securities, but do not include any shares of common stock issuable upon the exercise of options and other convertible securities issued pursuant to the Plan. During the three months ended March 31, 2016 and the years ended December 31, 2015 and 2014, the Company did not grant any stock options under the Plan.

Series A Convertible Preferred Stock
Pursuant to the SPA with the Protea Group, on June 13, 2014, the Company issued 100 shares of Series A Convertible Preferred Stock ("Series A").

The terms of the Series A are described below:

Voting
The Series A preferred stock holders are entitled to vote, together with the holders of common stock as one class, on all matters to which holders of common stock shall be entitled to vote, in the same manner and with the same effect as the common stock holders with the same number of votes per share that equals the number of shares of common stock into which the Series A preferred stock is convertible at the time of such vote.

Dividends
The holders of the Series A Preferred shall be entitled to receive dividends, when, as, and if declared by the Board, ratably with any declaration or payment of any dividend on common stock. To date there have been no dividends declared or paid by the Board of Directors.

Liquidation
The holders of the Series A shall be entitled to receive, before and in preference to, any distribution of any assets of the Company to the holders of common stock, an amount equal to $0.0001 per share, plus any declared but unpaid dividends. The liquidation preference as of March 31, 2016, December 31, 2015 and 2014 approximates par value.

Conversion
The Series A is convertible into 33% of the issued and outstanding shares of common stock on a fully diluted basis, assuming the conversion, exercise, or exchange for shares of common stock of all convertible securities issued and outstanding immediately prior to such conversion, including the Series A Preferred stock, all outstanding warrants and options, and all outstanding convertible debt, notes, debentures, or any other securities which are convertible, exercisable, or exchangeable for shares of common stock. The Series A Convertible Preferred Stock is subject to mandatory conversion upon the occurrence of certain triggering events including a public offering coupled with an equity-linked financing with an offering price that values the Company prior to consummation of such financing at not less than $12,000,000 and the aggregate gross proceeds to the Company (before deduction of underwriting discounts and registration expenses) are not less than $6,000,000. The Company did not recognize any amounts associated with the beneficial conversion feature at the date of issuance of such convertible preferred shares due to the unsatisfied condition associated with the pre-money valuation. If, and when, the pre-money valuation is determined, the Company may be required to recognize the value of the beneficial conversion feature, if any, in earnings.

During the three months ended March 31, 2016, Protea Group converted 35 shares of Series A Convertible Preferred Stock into 853,778 shares of commons stock. During the year ended December 31, 2015, Protea Group converted 29 shares of Series A Convertible Preferred Stock into 707,416 shares of commons stock. During the year ended December 31, 2014, no shares were converted. In April 2016, Protea Group converted the balance of 36 shares of Series A Convertible Preferred Stock into 878,171 shares of common stock.

Note 12 - Warrants

Stock warrant transactions for the period from January 30, 2014 (date of inception) through March 31, 2016 were as follows:

	Warrants	Exercise Price Per Share	Weighted Average Exercise Price
Warrants issued and exercisable at January 30, 2014	**-**	**-**	**-**
Granted during the year	68,400	$ 7.37	$ 7.37
Expired during the year	-	-	-
Exercised during the year	-	-	-
Warrants issued and exercisable at December 31, 2014	**68,400**	**$ 7.37**	**$ 7.37**
Granted during the year	594,074	$ 7.37	$ 7.37
Expired during the year	-	-	-
Exercised during the year	-	-	-
Warrants issued and exercisable at December 31, 2015	**662,474**	**$ 7.37**	**$ 7.37**
Granted during the year	44,705	$ 5.58	$ 5.58
Expired during the year	-	-	-
Exercised during the year	-	-	-
Warrants issued and exercisable at March 31, 2016 (unaudited)	**707,179**	**$ 5.58 - $7.37**	**$ 5.84**

Exercise Price		Number of Shares Under Warrants	Weighted Average Remaining Contract Life in Years		Weighted Average Exercise Price
$	5.58	605,127	4.72	$	5.58
$	7.37	102,052	4.70	$	7.37
Total warrants		**707,179**	**4.72**	**$**	**5.84**

Per the terms of exchange agreements executed on March 31, 2016 with certain holders of the Company's Original Issue Discounted Convertible Notes, the associated warrants had their exercise price adjusted to $5.58 per share with no other adjustments made to the warrants, see Note 10 above.

During the three months ended March 31, 2016, 5,259 immediately vesting warrants were issued to investment bankers in association with the placement of original issue discounted convertible notes with a value of $7,048, using the same valuation used to value the warrants issued in connection with the original issue discounted convertible notes, see Note 10 above. This amount was included in G & A expenses.

During the year ended December 31, 2015, 102,052 immediately vesting warrants were issued to investment bankers in association with the placement of original issue discounted convertible notes with a value of $218,337, using the same valuation used to value the warrants issued in connection with the original issue discounted convertible notes, see Note 10 above. This amount was included in G & A expenses.

During the year ended December 31, 2014, no such warrants were issued.

Through June 13, 2016, 122,721 warrants were issued to investors and 11,688 warrants were issued to placement agents in connection with the issuance of $700,000 of additional original issue discounted convertible notes.

Note 13 - Interest Expense

During the three months ended March 31, 2016 and 2015, the Company incurred $713,680 and $144,746, respectively, of interest expense. During the three months ended March 31, 2016 and 2015, $710,988 and $133,479, respectively, of this amount was in connection with the Convertible Notes issued by the Company in the form of accretion of original issue debt discount and amortization of the debt discount related to the warrants. During the three months ended March 31, 2016 and 2015, the Company also incurred $2,693 and $11,268, respectively, of interest expense in connection with the promissory notes issued by the Company.

During the years ended December 31, 2015 and 2014, the Company incurred $1,587,533 and $68,149, respectively, of interest expense. During the years ended December 31, 2015 and 2014, $1,561,677 and $59,029, respectively, of this amount was in connection with the Convertible Notes issued by the Company in the form of accretion of original issue debt discount and amortization of the debt discount related to the warrants. During the years ended December 31, 2015 and 2014, the Company also incurred $25,856 and $9,120, respectively, of interest expense in connection with the promissory notes issued by the Company.

Note 14 - Agreements

Mayoly Agreement

On March 22, 2010, the Predecessor entered into a joint research and development agreement (the "2010 Agreement") with Laboratoires Mayoly Spindler SAS ("Mayoly") with no consideration exchanged, pursuant to which Mayoly sublicensed certain of its exclusive rights to a genetically engineered yeast strain cell line on which MS1819 is based that derive from a Usage and Cross-Licensing Agreement dated February 2, 2006 (the "INRA Agreement") between Mayoly and INRA TRANSFERT, a subsidiary of the National Institute for Agricultural Research ("INRA") in charge of patent management acting for and on behalf of the National Centre of Scientific Research ("CNRS") and INRA.

Effective January 1, 2014, the Predecessor entered into an amended and restated joint research and development agreement with Mayoly (the "Mayoly Agreement") with no consideration exchanged, pursuant to which the Predecessor acquired the exclusive right, with the right to sublicense, to commercialize human pharmaceuticals based on the MS1819 lipase within the following territories: U.S. and Canada, South America (excluding Brazil), Asia (excluding China and Japan), Australia, New Zealand and Israel. Rights to the following territories are held jointly with Mayoly: Brazil, Italy, Portugal, Spain, China and Japan. The Mayoly Agreement requires the Predecessor to pay 70% of all development costs and requires each of the parties to use reasonable efforts to:

- devote sufficient personnel and facilities required for the performance of its assigned tasks;
- make available appropriately qualified personnel to supervise, analyze and report on the results obtained in the furtherance of the development program; and
- deploy such scientific, technical, financial and other resources as is necessary to conduct the development program.

The Agreement grants the Predecessor the right to cure any breach by Mayoly of its obligations under the INRA agreement. In connection with the Acquisition, the Predecessor, with the consent of INRA and CNRS, assigned all of it rights, title and interest in and to the 2014 Agreement to the AzurRx Europe SAS.

The Agreement includes a €1,000,000 payment due to Mayoly upon the U.S. FDA approval of MS1819.

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.

Employment Agreement
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. The Company may terminate Mr. Spoor's employment at any time and for any reason, or for no reason. Mr. Spoor may terminate his 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 shall automatically increase to $425,000 upon (i) consummation of the Company's initial public offering which results in the listing of the Company's common stock on The NASDAQ Stock Market or NYSE MKT, or (ii) consummation of a merger or consolidation of the Company with or into any other corporation or corporations, or a sale of all or substantially all of the assets of the Company, or the effectuation by the Company of a transaction or series of related transactions in which more than 50% of the voting shares of the Company is disposed of or conveyed, and in each such case the Company becomes a public reporting company which results in the listing of the Company's shares (or shares of the Company's parent company) on The NASDAQ Stock Market or NYSE MKT (the "Public Event"). At the sole discretion of the Board 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 or the Compensation Committee.

In addition, Mr. Spoor shall be issued 100,000 shares of common stock, which vest as follows: (i) 50,000 Restricted Shares upon the first commercial sale in the United States of MS1819, and (ii) 50,000 Restricted Shares upon the total market capitalization of the Company exceeding $1 billion dollars for 20 consecutive trading days, in each case subject to the earlier determination of a majority of the Board. In the event of a Change of Control (defined), all of the Restricted Shares shall vest in full. The estimated fair value at the date of grant was $216,000. Mr. Spoor shall also be issued 380,000 10-year stock options pursuant to the Company's Amended and Restated Stock Option Plan, which options shall vest as follows so long as the Executive is serving as Chief Executive Officer or President at such time: (i) 100,000 of such stock options shall vest upon consummation of the Public Event, (ii) 50,000 of such stock options shall vest upon the Company initiating a Phase II clinical trial in the United States for MS1819 (i.e., upon the first individual enrolled in the trial), (iii) 50,000 of such stock options shall vest upon the Company completing a Phase II clinical trial in the United States for MS1819, (iv) 100,000 of such stock options shall vest upon the Company initiating a Phase III clinical trial in the United States for MS1819, (v) 50,000 of such stock options shall vest upon the Company initiating a Phase I clinical trial in the United States for any product other than MS1819, and (vi) 30,000 of such stock options shall vest upon the determination of a majority of the Board.

On June 8, 2016, the Board clarified Mr. Spoor's agreement as follows: the 380,000 options described have neither been granted nor priced since certain key provisions, particularly the underlying strike price, have not been determined. The options will be granted at a future date to be determined by the Board, and the options will be priced at that future date when they are granted.

If the Company terminates Mr. Spoor's employment other than for cause, or he terminates for good reason, as both terms are defined in the agreement, the Company will pay him twelve (12) months of his base salary as severance. If the Company terminates Mr. Spoor's employment other than for cause, or he terminates for good reason, in connection with a Change of Control, the Company will pay him eighteen (18) months of his base salary in lump sum as severance. Upon termination of Mr. Spoor's employment, the Company may impose a restrictive covenant on him for up to twelve (12) months, provided that the Company must continue his severance payments to continue the covenant beyond nine (9) months.

Note 15 - 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, 2016, December 31, 2015 and 2014, the Company had gross deferred tax assets of approximately $2,901,000, $2,412,000 and $645,000, 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 $2,901,000, $2,412,000 and $645,000, respectively, has been established at March 31, 2016, December 31, 2015 and 2014.

The significant components of the Company's net deferred tax assets (liabilities) consisted of:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
Gross deferred tax assets:			
Net operating loss carry-forwards	$ 2,901,000	$ 2,412,000	$ 645,000
Deferred tax asset valuation allowance	(2,901,000)	(2,412,000)	(645,000)
Net deferred tax asset	$ -	$ -	$ -

Income taxes computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	March 31, 2016 (Unaudited)	December 31, 2015	December 31, 2014
Income taxes benefit (expense) at statutory rate	34%	34%	34%
State income tax, net of federal benefit	11%	11%	11%
Change in valuation allowance	(45%)	(45%)	(45%)
	0%	0%	0%

At March 31, 2016, the Company has gross net operating loss carry-forwards for U.S. federal and state income tax purposes of approximately $6,405,000 and $6,402,000, respectively, which expire in the year 2036. The net increase in the valuation allowance for the three months ended March 31, 2016 was approximately $489,000.

At December 31, 2015, the Company has gross net operating loss carry-forwards for U.S. federal and state income tax purposes of approximately $5,325,000 and $5,322,000, respectively, which expire in the year 2035. The net increase in the valuation allowance for the year ended December 31, 2015 was approximately $1,767,000.

At December 31, 2014, the Company has gross net operating loss carry-forwards for U.S. federal and state income tax purposes of approximately $1,425,000 and $1,422,000, respectively, which expire in the year 2034. The net increase in the valuation allowance for the year ended December 31, 2014 was approximately $645,000.

The Company acquired a French subsidiary during 2014. The operations of the subsidiary are not taxed in the United States and this is not considered in the tax provision. At December 31, 2015 and 2014, the Company has approximately $5,052,000 and $2,722,000, respectively, in net operating losses which it can carryforward indefinitely to offset against future French income.

ASC 740 prescribes recognition threshold and measurement attributes for the financial statement recognition and measurement of uncertain tax positions taken or expected to be taken in a tax return. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. At March 31, 2016, December 31, 2015 and 2014, the Company had taken no uncertain tax positions that would require disclosure under ASC 740.

Note 16 - 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.

For the three months ended March 31, 2016, diluted net loss per share did not include the effect of 707,179 shares of common stock issuable upon the exercise of outstanding warrants; 1,194,364 shares of common stock issuable upon the conversion of promissory notes and convertible debt; and 878,171 shares of common stock issuable upon the conversion of the Series A preferred stock, as their effect would be anti-dilutive.

For the three months ended March 31, 2015, diluted net loss per share did not include the effect of 172,367 shares of common stock issuable upon the exercise of outstanding warrants; 408,454 shares of common stock issuable upon the conversion of promissory notes and convertible debt; and 2,439,365 shares of common stock issuable upon the conversion of the Series A preferred stock, as their effect would be anti-dilutive.

For the year ended December 31, 2015, diluted net loss per share did not include the effect of 662,474 shares of common stock issuable upon the exercise of outstanding warrants; 1,141,769 shares of common stock issuable upon the conversion of promissory notes and convertible debt; and 1,731,949 shares of common stock issuable upon the conversion of the Series A preferred stock, as their effect would be anti-dilutive.

For the period of inception (January 30, 2014) through December 31, 2014, diluted net loss per share did not include the effect of 68,400 shares of common stock issuable upon the exercise of outstanding warrants, 197,419 shares of common stock issuable upon the conversion of promissory notes and convertible debt, and 1,896,620 shares of common stock issuable upon the conversion of the Series A preferred stock, as their effect would be anti-dilutive.

Note 17 - Related Party Transactions

During the years ended December 31, 2015 and 2014, the Company employed the services of JIST Consulting ("JIST"), a company controlled by Johan M. Spoor, the Company's President and a Director, as a consultant for business strategy, financial modeling, and fundraising. Expense recorded in general and administrative expense in the accompanying statements of operations related to JIST for the years ended December 31, 2015 and 2014 was $478,400 and $139,100, respectively. Included in accounts payable at March 31, 2016, December 31, 2015 and is $508,300, $508,300, and $139,100, respectively, for JIST relating to Mr. Spoor's services. Mr. Spoor received no other compensation from the Company other than reimbursement of related travel expenses.

During the years ended December 31, 2015 and 2014, the Company's President, Christine Rigby-Hutton, was employed through Rigby-Hutton Management Services ("RHMS"). Expense recorded in general and administrative expense in the accompanying statements of operations related to RHMS for the years ended December 31, 2015 and 2014 was $27,750 and $99,142, respectively. Included in accounts payable at March 31, 2016, December 31, 2015 and 2014 is $38,453, $38,453 and $80,430, respectively, for RHMS for Ms. Rigby-Hutton's services. Ms. Rigby-Hutton received no other compensation from the Company other than reimbursement of related travel expenses. Ms. Rigby-Hutton resigned from the Company effective April 20, 2015.

From October 1, 2015 through December 31, 2015, the Company used the services of Edward Borkowski, a member of the Board of Directors and the Company's audit committee chair, as a financial consultant. Expense recorded in general and administrative expense in the accompanying statements of operations related to Mr. Borkowski for the year ended December 31, 2015 was $90,000. Included in accounts payable at March 31, 2016 and December 31, 2015 is $90,000 for Mr. Borkowski's services. Mr. Borkowski received no other compensation from the Company other than reimbursement of related travel expenses. On October 14, 2014 and March 12, 2015, the Company issued original issue discounted convertible notes to Edward Borkowski, a director and the Company's audit committee chair, in the aggregate principal amount of $300,000. The notes will automatically convert into shares of the Company's common stock upon the consummation of this offering at a conversion price equal to the principal amount divided by the lesser of $6.45 per share or the per share price of the Company's common stock in this offering, multiplied by 80%. Mr. Borkowski has signed an exchange agreement related to these notes as detailed in Note 10 above.

On August 31, 2014, January 31, 2015, February 28, 2015 and May 31, 2015, the Company issued promissory notes to Matthew Balk and his affiliates in the aggregate principal amount of $236,000. These notes have been repaid in full as to $50,000 on November 11, 2014, $111,000 on April 3, 2015, and $75,000 on August 7, 2015. Mr. Balk holds voting and dispositive power over the shares held by Pelican Partners LLC, which owns 40%, 47%, and 64%, respectively, of the outstanding common stock of the Company as of March 31, 2016 and December 31, 2015 and 2014.

In July 2014, the Company issued promissory notes to Johan M. (Thijs) Spoor, the Company's President, Chief Operating Officer and Chairman of the Board, in the aggregate principal amount of $10,000. These notes were repaid in full as to $5,000 on October 17, 2014 and $5,000 on November 10, 2014.

AZURRX BIOPHARMA, INC.

2,142,857 Shares

Common Stock

PROSPECTUS

WallachBeth Capital, LLC **Network 1 Financial Securities, Inc.**

Through and including ???????, 2016 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to a dealers' obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or membership.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the various expenses, all of which will be borne by the registrant, in connection with the sale and distribution of the securities being registered, other than the underwriting discounts and commissions. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee.

SEC registration fee	$	1,510.50
FINRA fees	$	3,950.00
Printing and engraving expenses	$	5,000.00
Accounting fees and expenses	$	425,000.00
Legal fees and expenses	$	300,000.00
Miscellaneous	$	14,579.50
Total	$	750,000.00

Item 14. Indemnification of Directors and Officers.

Amended and Restated Bylaws

Pursuant to our bylaws, our directors and officers will be indemnified to the fullest extent allowed under the laws of the State of Delaware for their actions in their capacity as our directors and officers.

We must indemnify any person made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative ("Proceeding") by reason of the fact that he is or was a director, against judgments, penalties, fines, settlements and reasonable expenses (including attorney's fees) ("Expenses") actually and reasonably incurred by him in connection with such Proceeding if: (a) he conducted himself in good faith, and: (i) in the case of conduct in his own official capacity with us, he reasonably believed his conduct to be in our best interests, or (ii) in all other cases, he reasonably believes his conduct to be at least not opposed to our best interests; and (b) in the case of any criminal Proceeding, he had no reasonable cause to believe his conduct was unlawful.

We must indemnify any person made a party to any Proceeding by or in the right of us, by reason of the fact that he is or was a director, against reasonable expenses actually incurred by him in connection with such proceeding if he conducted himself in good faith, and: (a) in the case of conduct in his official capacity with us, he reasonably believed his conduct to be in our best interests; or (b) in all other cases, he reasonably believed his conduct to be at least not opposed to our best interests; provided that no such indemnification may be made in respect of any proceeding in which such person shall have been adjudged to be liable to us.

No indemnification will be made by unless authorized in the specific case after a determination that indemnification of the director is permissible in the circumstances because he has met the applicable standard of conduct.

Reasonable expenses incurred by a director who is party to a proceeding may be paid or reimbursed by us in advance of the final disposition of such Proceeding in certain cases.

We have the power to purchase and maintain insurance on behalf of any person who is or was our director, officer, employee, or agent or is or was serving at our request as an officer, employee or agent of another corporation, partnership, joint venture, trust, other enterprise, or employee benefit plan against any liability asserted against him and incurred by him in any such capacity or arising out of his status as such, whether or not we would have the power to indemnify him against such liability under the provisions of the amended and restated bylaws.

Delaware Law

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

Indemnification Agreements

As permitted by the Delaware General Corporation Law, we have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all expenses (including attorneys' fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of us or any of our affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or preceding that may result in a claim for indemnification.

We have an insurance policy covering its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Item 15. Recent Sales of Unregistered Securities.

The information below lists all of the securities sold by us during the past three years which were not registered under the Securities Act:

Between January 30, 2014 and September 2015, we sold 100 shares of Series A Convertible Preferred Stock and 3,584,321 shares of common stock.

Commencing on July 22, 2014, the Company, through a series of transactions with various investors, raised $896,000 through the issuance and sale of its promissory notes.

Commencing on October 10, 2014, the Company, through a series of transactions with various investors, raised $9,162,526 through the issuance and sale of its original issue discounted convertible notes and warrants to purchase an aggregate of 2,128,683 shares of common stock.

In July 2016, the Company issued an aggregate of 105,000 shares of restricted stock to the Company's non-executive members of its board of directors.

These securities were issued pursuant to the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder, in reliance on the recipient's status as an "accredited investor" as defined in Rule 501(a) of Regulation D, except for the restricted stock grants which were issued pursuant to Rule 701 or Rule 506.

Item 16. Exhibits and Financial Statement Schedules.

(a) The following exhibits are filed as part of this Registration Statement:

1.1	Form of Underwriting Agreement**
3.1	Amended and Restated Certificate of Incorporation of the Registrant**
3.2	Amended and Restated Bylaws of the Registrant**
4.1	Form of Common Stock Certificate**
4.2	Form of Investor Warrant**
4.3	Form of Underwriter Warrant
5.1	Opinion of Loeb & Loeb LLP regarding legality**
10.1	Stock Purchase Agreement dated May 21, 2014 between the Registrant, Protea Biosciences Group, Inc. and its wholly-owned subsidiary, Protea Biosciences, Inc.**
10.2	Amended and Restated Joint Research and Development Agreement dated January 1, 2014 between the Registrant and Mayoly+**
10.3	Amended and Restated AzurRx BioPharma, Inc. 2014 Omnibus Equity Incentive Plan**
10.4	Employment Agreement between the Registrant and Mr. Spoor**
14.1	Code of Ethics of AzurRx BioPharma, Inc. Applicable To Directors, Officers And Employees**
21.1	Subsidiaries of the Registrant**
23.1	Consent of WeiserMazars LLP, independent registered public accounting firm
23.2	Consent of Loeb & Loeb LLP (included in Exhibit 5.1)**
24.1	Power of Attorney (included on signature page)**

** Previously filed.

+ Confidential treatment has been granted with respect to portions of this exhibit.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement or amendment thereto to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Brooklyn, New York, on August 5, 2016 .

AZURRX BIOPHARMA, INC.

By: /s/ Johan M. (Thijs) Spoor
Name: Johan M. (Thijs) Spoor
Title: President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Johan M. (Thijs) Spoor Johan M. (Thijs) Spoor	President, Chief Executive Officer and Director (principal executive officer and principal financial and accounting officer)	August 5, 2016
* Edward J. Borkowski	Chairman of the Board of Directors	August 5, 2016
* Alastair Riddell	Director	August 5, 2016
* Maged Shenouda	Director	August 5, 2016

* /s/ Johan M. (Thijs) Spoor
Attorney-in-fact