Subject to completion, as filed with the Securities and Exchange Commission on March 25, 2019.

Registration No. 333-229173

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

# **AQUAMED TECHNOLOGIES, INC.**

(Exact name of Registrant as Specified in its Charter)

**Delaware** (State or other jurisdiction of incorporation or organization) **3841** (Primary Standard Industrial Classification Code Number) **26-4042544** (I.R.S. Employer Identification Number)

2150 Cabot Boulevard, West Suite B

Langhorne, Pennsylvania 19067 (215) 702-8550

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

David Johnson Chief Executive Officer

AquaMed Technologies, Inc. 2150 Cabot Boulevard, West Suite B

Langhorne, Pennsylvania 19067 (215) 702-8550

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With copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective and the satisfaction of all other conditions to the completion of the transactions described in the enclosed document have been satisfied or waived.

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.  $\Box$ 

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) 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.  $\Box$ 

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.  $\Box$ 

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.  $\Box$ 

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

Large accelerated filer 🗆	Accelerated filer $\Box$	Non-accelerated filer 🗵	Smaller reporting company 🗵
			Emerging growth company 🗵

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.  $\Box$ 

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 Securities and Exchange 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 issue 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 is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

#### Subject to Completion, dated March 25, 2019

#### PRELIMINARY PROSPECTUS

# 1,750,000 shares

# AquaMed Technologies, Inc.

# **Common Stock**

# (par value \$0.001 per share)

This prospectus is being furnished in connection with the planned distribution by Alliqua BioMedical, Inc. ("Alliqua"), on a *pro rata* basis to the holders of its common stock of all of the outstanding shares of its wholly-owned subsidiary AquaMed Technologies, Inc ("AquaMed" or "we," "our" and "us"). We refer to the distribution as the "Distribution." We expect that, immediately following the Distribution, pursuant to the Agreement and Plan of Merger dated as of November 27, 2018, as amended by Amendment No. 1 to Agreement and Plan of Merger, dated as of January 8, 2019 (the "Merger Agreement"), by and among AquaMed, AQ TOP, LLC ("Merger Sub") and TO Pharmaceuticals LLC ("TOP"), TOP will merge with and into Merger Sub with TOP as the surviving entity (the "Merger"), and following the Merger, will become a wholly owned subsidiary of AquaMed, subject to the terms and conditions in the Merger Agreement.

Each share of Alliqua common stock outstanding as of 5:00 p.m., New York City time, on the record date for the Distribution, which we refer to as the "Record Date," will entitle its holder to receive its *pro rata* portion of the AquaMed common stock. The distribution of shares will be made to a third-party distribution agent in book-entry form for the benefit of the holders of Alliqua common stock. Immediately following the Distribution, as consideration for the Merger, the current members of TOP and other third-party investors in AquaMed will receive approximately 90% of the total number of shares of AquaMed common stock outstanding immediately after the Merger and the Private Placement (as defined below) (on a fully diluted basis), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in such private placement and it is consummated on the terms currently proposed, before giving effect to any fees payable in equity to financial advisors or other intermediaries.

If you are a record holder of Alliqua common stock as of the close of business on which is the record date for the Distribution, you will be entitled to receive shares of AquaMed common stock for every one share of Alliqua common stock you hold on that date. Alliqua will distribute the shares of AquaMed common stock in book-entry form, which means that we will not issue physical stock certificates. As discussed under "The Transactions — When and How You Will Receive AquaMed Shares," if you sell your Alliqua common stock in the "regular-way" market after the record date and before the Distribution, you also will be selling your right to receive shares of AquaMed common stock in connection with the Distribution. Immediately following the Distribution, AquaMed and TOP will consummate the Merger.

The Distribution will be effective by 11:59 p.m., New York City time, on , 2019. Immediately after the Distribution, AquaMed will be an independent company.

Alliqua's stockholders are not required to vote on or take any other action in connection with the spin-off. We are not asking you for a proxy, and request that you do not send us a proxy. Alliqua stockholders will not be required to pay or otherwise provide any consideration for the shares of AquaMed common stock they receive in the spin-off, and they will not be required to surrender or exchange their shares of Alliqua common stock or take any other action in connection with the spin-off.

Alliqua currently owns all of the outstanding shares of AquaMed common stock. Accordingly, no trading market for AquaMed common stock currently exists. We expect trading of AquaMed common stock will begin on the first trading day after the Distribution Date. We intend to list AquaMed common stock on The Nasdaq Capital Market under the symbol "TOPP."

In reviewing this prospectus, you should carefully consider the matters described in the section titled *Risk Factors*" beginning on page <u>25</u> of this prospectus for a discussion of certain factors that should be considered by recipients of AquaMed common stock.

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

This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any securities.

The date of this prospectus is

, 2019.

# TABLE OF CONTENTS

INDUSTRY AND MARKET DATA	1
BASIS OF PRESENTATION	<u>1</u>
INTRODUCTION	<u>2</u>
<u>SUMMARY</u>	<u>3</u>
SUMMARY HISTORICAL FINANCIAL DATA OF AQUAMED	<u>22</u>
SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA OF TOP	<u>23</u>
UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS OF THE	
SURVIVING COMPANY	<u>24</u>
<u>RISK FACTORS</u>	<u>25</u>
CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS	<u>51</u>
THE TRANSACTIONS	<u>53</u>
THE MERGER AGREEMENT	<u>62</u>
THE ASSET CONTRIBUTION AND SEPARATION AGREEMENT AND ANCILLARY AGREEMENTS	<u>70</u>
MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE DISTRIBUTION	<u>73</u>
USE OF PROCEEDS	<u>74</u>
DETERMINATION OF OFFERING PRICE	<u>74</u>
DIVIDEND POLICY	<u>74</u>
CAPITALIZATION	<u>75</u>
SELECTED HISTORICAL FINANCIAL DATA FOR AQUAMED	<u>76</u>
SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA FOR TOP	<u>77</u>
UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS OF THE SURVIVING COMPANY	78
BUSINESS OF AQUAMED	84
BUSINESS OF TOP	88
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF	00
OPERATIONS OF AQUAMED	<u>112</u>
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF	
OPERATION OF TOP	<u>115</u>
LIQUIDITY AND CAPITAL RESOURCES FOLLOWING THE TRANSACTIONS	<u>120</u>
DESCRIPTION OF MATERIAL INDEBTEDNESS	<u>122</u>
MANAGEMENT OF THE COMPANY FOLLOWING THE TRANSACTIONS	<u>123</u>
EXECUTIVE COMPENSATION	128
CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS	131
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS, DIRECTORS AND EXECUTIVE	
<u>OFFICERS</u>	<u>133</u>
DESCRIPTION OF OUR CAPITAL STOCK	<u>135</u>
SHARES ELIGIBLE FOR FUTURE SALE	<u>140</u>
LEGAL MATTERS	<u>141</u>
EXPERTS	141
WHERE YOU CAN FIND MORE INFORMATION	141
INDEX TO FINANCIAL STATEMENTS	<u>F-1</u>

i

### INDUSTRY AND MARKET DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate is based on information from independent industry and research organizations, other thirdparty sources and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us upon reviewing such data and our knowledge of such industry and markets, which we believe to be reasonable. We did not commission any third-party data for use in connection with this prospectus. Such data involve uncertainties and risk and are subject to change due to a variety of factors, including those described under "Risk Factors."

# BASIS OF PRESENTATION

For the presented periods through July 13, 2018, T.O. Global LLC, a New York limited liability company ("TOG"), was the beneficial owner of all of the outstanding membership interests of TOP. All financial statements and financial information and all information with respect to the business and operations of TOP and its respective subsidiaries for periods prior to the consummation of the Merger, including under "Summary Historical Consolidated Financial Data of TOP," "Selected Historical Consolidated Financial Data for TOP," "Business of TOP" and "Management's Discussion and Analysis of Financial Condition and Plan of Operation of TOP" are presented on a consolidated basis for TOP and its respective subsidiaries, on a stand-alone basis from TOG. All references to "TOP" are to TO Pharmaceuticals LLC and its subsidiaries on a consolidated basis.

### INTRODUCTION

On November 28, 2018, Alliqua BioMedical, Inc. ("Alliqua") announced plans to separate its custom hydrogel and contract manufacturing business from Alliqua and to combine such business with TO Pharmaceuticals LLC ("TOP") and its subsidiaries pursuant to the Agreement and Plan of Merger (the "Merger Agreement") dated as of November 27, 2018. Prior to the Merger, Alliqua will distribute all of the shares of AquaMed common stock on a pro rata basis to the record holders of Alliqua common stock (the "Distribution"). Prior to the Distribution, Alliqua is undertaking a series of internal transactions, following which AquaMed will own all of the assets and liabilities of the custom hydrogel and contract manufacturing business. We refer to this series of internal transactions as the "Internal Reorganization," which is described in more detail under "The Asset Contribution and Separation Agreement and Ancillary Agreements." We refer to the Internal Reorganization and the Distribution collectively as the "Spin-Off."

In this prospectus, unless otherwise noted or the context otherwise requires:

- "Alliqua" refers to Alliqua BioMedical, Inc. and its consolidated subsidiaries other than, for all periods following the Spin-Off, AquaMed and its consolidated subsidiaries;
- "AquaMed", "we", "our" and "us" refers to AquaMed Technologies, Inc. and its consolidated subsidiaries, including, with respect to periods following the consummation of the Spin-Off and the Merger, TOP and its consolidated subsidiaries;
- · "Merger Sub" refers to AQ TOP, LLC, a wholly owned subsidiary of AquaMed; and
- "TOP" refers to TO Pharmaceuticals LLC and its subsidiaries.

The Merger Agreement provides that, at closing, the following transactions will occur (in each case subject to the terms and conditions in the Merger Agreement): Merger Sub will merge with and into TOP (the "Merger"), with TOP surviving the Merger and becoming a wholly-owned subsidiary of AquaMed. Pursuant to and subject to the conditions in the Merger Agreement, the Merger will occur after the consummation by Alliqua of the Spin-Off. Following the Merger, AquaMed is expected to be renamed "TO Pharma Inc.," and the pre-Merger shareholders of Alliqua will own approximately 10% of the issued and outstanding shares of AquaMed, before giving effect to any fees payable in equity to financial advisors or other intermediaries or any issuances in respect of the Private Placement or other concurrent financing transaction in respect of greater than \$10 million of gross proceeds.

The consummation of the Merger is subject to, among other conditions:

- AquaMed shall have received binding commitments from third-party investors to consummate an equity financing of AquaMed in a minimum aggregate amount of \$10 million immediately prior to the effective time of the Merger, subject to waiver of such minimum amount by both parties (the "Private Placement");
- the Spin-Off having been consummated;
- the effectiveness of the registration statement of which this prospectus forms a part in connection with the Distribution;
- the approval for listing on the Nasdaq Capital Market of AquaMed common stock;
- the board of directors of AquaMed shall have received an independent third-party valuation of the shares of AquaMed common stock to be distributed in the Distribution;
- each of AquaMed and TOP shall have delivered audited financial statements to the other party;
- the accuracy of the parties' representations and warranties and the performance of their respective covenants contained in the Merger Agreement; and
- certain other customary conditions.

The Merger Agreement contains customary representations, warranties and covenants, including a requirement to use reasonable best efforts to consummate the Private Placement and the Merger prior to April 11, 2019.

#### SUMMARY

This summary highlights certain significant aspects of our business and is a summary of information contained elsewhere in this prospectus. This summary is not complete and you should carefully read this entire prospectus, including the information presented under the sections titled "Risk Factors," "Cautionary Statement Concerning Forward-Looking Statements," "Unaudited Pro Forma Condensed Combined Financial Statements of the Surviving Company," "Selected Historical Financial Data of AquaMed," "Selected Historical Consolidated Financial Data of TOP," "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed," "Management's Discussion and Analysis of Financial Condition and Plan of Operation of TOP," and the financial statements and the related notes thereto included elsewhere in this prospectus. This summary contains forward-looking statements that involve risks and uncertainties. Our actual results may differ significantly from results contemplated in the forward-looking statements as a result of various factors such as those set forth in the sections titled "Risk Factors" and "Cautionary Statement Concerning Forward-Looking Statements." When making an investment decision, you should also read the discussion under "Basis of Presentation," and "Introduction" for the definition of some of the terms used in this prospectus and other matters described in this prospectus. As used in this prospectus, references to "pro forma" or "on a pro forma basis" mean giving pro forma effect to the Spin-Off and Merger as described in "Unaudited Pro Forma Condensed Combined Financial Statements of the Surviving Company."

### Overview

After completing the Spin-Off and the Merger, we will be an independent, publicly traded company dedicated to discovering, developing and commercializing novel therapeutics based on TOP's proprietary cannabinoid product platform.

# The Transactions

#### **Overview**

On November 28, 2018, Alliqua announced plans for the complete legal and structural separation of its custom hydrogel and contract manufacturing business and the combination of AquaMed's business and the TOP businesses.

To effectuate the separation, Alliqua is undertaking the Internal Reorganization described under "The Asset Contribution and Separation Agreement and Ancillary Agreements." After giving effect to the Internal Reorganization, we will hold all of the assets and liabilities related to the custom hydrogel and contract manufacturing business.

Following the Internal Reorganization, Alliqua will distribute all of its equity interest in us, consisting of all of the outstanding shares of our common stock, to the record holders of Alliqua common stock on a pro rata basis.

Following the Spin-Off, under the Merger Agreement and in accordance with Delaware law, Merger Sub will merge with and into TOP, with TOP surviving the Merger. As a result of the Merger, TOP will become a wholly owned subsidiary of AquaMed. For details of the structure of the transaction, see "The Merger Agreement."

# **Transaction Rationale**

The board of directors of Alliqua considered the following potential benefits in deciding to pursue the Spin-Off and Merger:

 Stockholder Value. On October 11, 2018, Alliqua signed an Agreement and Plan of Merger and Reorganization (the "Adynxx Merger Agreement") with Adynxx, Inc. ("Adynxx") and Embark Merger Sub, Inc. ("Embark"), a wholly-owned subsidiary of Alliqua. Pursuant to the Adynxx Merger Agreement, Embark will merge with and into Adynxx, with Adynxx continuing as the surviving corporation, and the former Adynxx stockholders will own approximately 86% of Alliqua's outstanding equity after the transaction (the "Adynxx Merger"). AquaMed's custom

hydrogels contract manufacturing business is not synergistic with the potential combined operations of Alliqua and Adynxx. In addition, under the terms of the Adynxx Merger Agreement, Alliqua is required to use its commercially reasonable efforts to spin-off AquaMed's custom hydrogels business. We believe the Spin-Off and the Merger will provide greater value to Alliqua stockholders than if the AquaMed business remained a part of Alliqua following the closing of the Adynxx Merger as the combination of AquaMed and TOP will create an independent, publicly traded company dedicated to discovering, developing and commercializing novel therapeutics based on TOP's proprietary cannabinoid-based product platform and serving customers in the cannabinoid pharmaceutical therapy industry.

- *Strategic Focus and Flexibility*. Following the Spin-Off and Merger, we will be better able to dedicate financial and human capital resources to pursue appropriate growth opportunities and execute strategic plans best suited to our business than if we remained a part of Alliqua or as an independent company without the business combination with TOP.
- Strategic Positioning in Industry. The combination of AquaMed and TOP is a strategic move to position
  the combined company as an independent, publicly traded cannabinoid pharmaceutical therapy-based
  company. The combination of AquaMed and TOP is expected to provide opportunities for the combined
  company to leverage its unique ability to create novel therapeutics based on TOP's proprietary
  cannabinoid-based product platform in a number of U.S. Food and Drug Administration (the "FDA")regulated clinical indications, including a hydrogel product.
- Management Incentives. The Spin-Off will enable AquaMed to create incentives for its management and employees that are more closely tied to its business performance and stockholder expectations. AquaMed's equity-based compensation arrangements will more closely align the interests of AquaMed's management and employees with the interests of its stockholders and should increase AquaMed's ability to attract and retain personnel.
- Capital Structure and Stockholder Flexibility. The segments in which Alliqua and AquaMed expect to
  operate have historically had different growth profiles and cash flow dynamics. The Spin-Off will allow
  Alliqua and AquaMed to separately manage their capital strategies and cost structures and will allow
  investors to make independent investment decisions with respect to Alliqua and AquaMed, including the
  ability for AquaMed to achieve alignment with a more natural stockholder base. Investment in one or the
  other company may appeal to investors with different goals, strategies, interests and concerns.

The board of directors of Alliqua also considered and balanced against the potential benefits of the Spin-Off and Merger a number of potentially adverse factors concerning the Spin-Off and Merger, including the following:

- the fact that, although we will continue to exercise control and supervision over our operations prior to
  closing, the Merger Agreement prohibits us from taking a number of actions relating to the conduct of its
  business prior to the closing without TOP's consent, which may delay or prevent us from undertaking
  business opportunities that may arise during the pendency of the transactions, whether or not the Spin-Off
  and/or Merger is completed;
- the fact that immediately following the Transactions, the current members of TOP and the third- party
  investors that participate in the Private Placement are expected to hold approximately 90% of the total
  number of shares of AquaMed common stock outstanding (on a fully diluted basis), assuming that no
  more than \$10 million is raised in the Private Placement
- the risk that there is no assurance that all conditions to the parties' obligations to complete the Spin-Off and/or Merger will be satisfied or waived, and as a result, it is possible that the Spin-Off and/or Merger could be delayed or might not be completed;
- the risks and costs to us if the Transactions do not close, including the diversion of management and employee attention, potential employee attrition and the potential effect on business and customer relationships; and

 the risk of disruption to our business and customer reaction as a result of the public announcement of the Spin-Off and Merger.

The foregoing discussion of the factors considered by the board of directors of Alliqua is not intended to be exhaustive, but does set forth the principal factors considered by the board of directors. The board of directors collectively reached the conclusion to approve the Merger Agreement, the Spin-Off and the Merger in light of the various factors described above, as well as other factors that the board of directors of Alliqua felt were appropriate. In view of the wide variety of factors considered by the board of directors of Alliqua felt were appropriate. In view of the Spin-Off and the merger and the complexity of these matters, the board of directors did not consider it practical, and did not attempt, to quantify, rank or otherwise assign relative weights to the specific factors it considered in reaching its decision. Rather, the board of directors of Alliqua made its recommendation based on the totality of the information presented to, and the investigation conducted by, the board of directors. In considering the factors discussed above, individual directors may have given different weights to different factors.

#### The Companies

# AquaMed

We were incorporated in Delaware on January 13, 2009. We manufacture high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. We specialize in custom gels by capitalizing on proprietary manufacturing technologies. We have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products. Our products are manufactured using proprietary and non-proprietary mixing, coating and cross-linking technologies. Together, these technologies enable us to produce gels that can satisfy rigid tolerance specifications with respect to a wide range of physical characteristics (e.g., thickness, water content, adherence, absorption, moisture vapor transmission rate (a measure of the passage of water vapor through a substance) and release rate) while maintaining product integrity. Additionally, we have the manufacturing ability to offer broad choices in the selection of liners onto which the gels are coated. Consequently, our customers are able to determine tolerances in moisture vapor transmission rate and active ingredient release rates while personalizing color and texture.

Our principal executive offices are located at 2150 Cabot Boulevard West, Suite B, Langhorne, PA 19047. Our telephone number is (215)-702-8550. Following the Spin-Off and the Merger, our website address will be www.topharm.com. Information contained on, or connected to, our website or Alliqua's website does not and will not constitute part of this prospectus or the registration statement on Form S-1 of which this prospectus is a part.

# TOP

TOP was organized on October 21, 2015 in Delaware and is an early stage biopharmaceutical company engaged in the business of discovering, developing and commercializing drugs containing cannabinoids, which are based on a proprietary cannabinoid-based product platform, for the treatment of various diseases, disorders and medical conditions. TOP's business is focused on research and development of potential pharmaceutical products based on compounds derived from the proprietary strains of Tikun Olam Ltd., a corporation formed pursuant to the laws of Israel ("TOL"). Through collaboration with TOL and leading medical experts at major Israeli hospitals and research organizations, TOP has initially focused its research and development efforts on Crohn's Disease, ulcerative colitis, agitation in Alzheimer's or other dementia, autism spectrum disorder, Tourette syndrome, acute migraines and dialvsis.

TOP's principal executive offices are located at 77 Water Street, 8<sup>th</sup> Floor, New York, New York 10005. TOP's telephone number is (212) 837-8333.

# **Emerging Growth Company Status of AquaMed**

Following the Spin-off, we will be an "emerging growth company" as defined in Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As such, we will be eligible to take advantage of certain exemptions from various reporting requirements that apply to other public companies that are not emerging

growth companies, including, compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and the requirements to hold a non-binding advisory vote on executive compensation and any golden parachute payments not previously approved. We have not made a decision whether to take advantage of any or all of these exemptions. If we do take advantage of some or all of these exemptions, some investors may find our common stock less attractive. The result may be a less active trading market for our common stock and its stock price may be more volatile.

In addition, Section 107 of the JOBS Act provides that an emerging growth company may take advantage of the extended transition period provided in Section 13(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), for complying with new or revised accounting standards, meaning that we, as an emerging growth company, can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of this extended transition period; however, it is our present intention to adopt any applicable accounting standards timely. If at some time we delay adoption of a new or revised accounting standard, our financial statements may not be comparable to those of companies that comply with such new or revised accounting standards. Section 107 of the JOBS Act provides that our decision not to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We may remain an emerging growth company until the earliest of (a) the last day of the first fiscal year in which our annual gross revenues exceed \$1 billion, (b) the last day of the fiscal year following the fifth anniversary of the date of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), (c) the date we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of its most recently completed second fiscal quarter, and (d) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three-year period.

# Questions and Answers about the Transactions

The following provides only a summary of the terms of the Spin-Off, the Merger and the transactions contemplated thereby. You should read the sections titled "The Transactions," "The Merger Agreement" and "The Asset Contribution and Separation Agreement and Ancillary Agreements" below in this prospectus for a more detailed description of the matters described below.

### Q: What is the Spin-Off?

A: The Spin-Off is the method by which we will separate from Alliqua. As part of the Spin-Off, Alliqua will undertake the Internal Reorganization so that we hold all assets and liabilities of its custom hydrogel and contract manufacturing business. Thereafter, in the Distribution, Alliqua will distribute to its stockholders all the outstanding shares of our common stock. Following the Spin-Off, we will be an independent, publicly-traded company, and Alliqua will not retain any ownership interest in us.

# Q: What is the Merger?

A: Under the terms of the Merger Agreement, after the Distribution, Merger Sub will merge with and into TOP, with TOP surviving the Merger. As a result of the Merger, TOP will become a wholly owned subsidiary of AquaMed. Immediately after the effective time of the Merger and consummation of the Private Placement, before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in such private placement and it is consummately 10% of the common stock of AquaMed outstanding after the effective time of the Merger and consummation of the Private Placement (on a fully diluted basis), assuming that no more than \$10 million is raised in the Private Placement and it is

consummated on the terms currently proposed. Following the consummation of the Merger, AquaMed will issue shares representing approximately 4.99% and 0.08% of shares outstanding to Bezalel Partners, LLC and the Benchmark Company, LLC, respectively, for advisory and consulting services in connection with the Merger. Following such issuances and the consummation of the Merger and the Private Placement on the terms set forth above, the former Alliqua shareholders will hold approximately 9.5% of the total number of shares of AquaMed stock outstanding. Upon the consummation of the Merger, AquaMed is expected to be renamed "TO Pharma Inc."

## Q: What is the Adynxx Merger?

A: Alliqua, Embark and Adynxx have entered into the Adynxx Merger Agreement, which contains the terms and conditions of the proposed business combination of Alliqua and Adynxx. Under the Adynxx Merger Agreement, Embark will merge with and into Adynxx, with Adynxx surviving as a wholly owned subsidiary of Alliqua. Immediately following the effective time of the Adynxx Merger, Adynxx equityholders will own approximately 86% of the combined company and Alliqua equityholders will own approximately 14% of the combined company, subject to certain adjustments. So long as Alliqua exercises commercially reasonable efforts to cause the Spin-Off to occur concurrently with the effective time of the Adynxx Merger, the occurrence of the Spin-Off is not a condition of Adynxx's obligations to the consummate the transactions contemplated by the Adynxx Merger Agreement. The consummation of the Adynxx Merger, however, is a condition to the closing of the Spin-Off. In the event that Alliqua's stockholders do not approve the Adynxx Merger and the Adynxx Merger is not consummated, then Alliqua may, in its discretion, determine not to effect the Spin-Off, in which case, we will remain a wholly-owned subsidiary of Alliqua.

### Q: Will the number of Alliqua shares I own change as a result of the Spin-Off and the Merger?

A: No, the number of shares of Alliqua common stock you own will not change as a result of the Spin-Off and the Merger.

# Q: What are the reasons for the Spin-Off and Merger?

- A: The board of directors of Alliqua considered the following potential benefits in deciding to pursue the Spin-Off and Merger:
  - Stockholder Value. On October 11, 2018, Alliqua signed the Adynxx Merger Agreement with Adynxx and Embark, pursuant to which Alliqua will consummate the Adynxx Merger. AquaMed's custom hydrogels contract manufacturing business is not synergistic with the potential combined operations of Alliqua and Adynxx. In addition, under the terms of the Adynxx Merger Agreement, Alliqua is required to use its commercially reasonable efforts to spin-off AquaMed's custom hydrogels business. We believe the Spin-Off and the Merger will provide greater value to Alliqua stockholders than if the AquaMed business remained a part of Alliqua following the closing of the Adynxx Merger as the combination of AquaMed and TOP will create an independent, publicly traded company dedicated to discovering, developing and commercializing novel therapeutics based on TOP's proprietary cannabinoid product platform and serving customers in the cannabinoid pharmaceutical therapy industry.
  - *Strategic Focus and Flexibility*. Following the Spin-Off and Merger, we will be better able to dedicate financial and human capital resources to pursue appropriate growth opportunities and execute strategic plans best suited to our business than if it remained a part of Alliqua or as an independent company without the business combination with TOP.
  - Strategic Positioning in Industry. The combination of AquaMed and TOP is a strategic move to position
    the combined company as an independent, publicly traded cannabinoid pharmaceutical therapy-based
    company. The combination of AquaMed and TOP is expected to provide opportunities for the combined
    company to leverage its unique ability to create novel therapeutics based on TOP's proprietary
    cannabinoid product platform in a number of FDA-regulated clinical indications, including a hydrogel
    product.

- *Management Incentives.* The Spin-Off will enable AquaMed to create incentives for its management and employees that are more closely tied to its business performance and stockholder expectations. AquaMed's equity-based compensation arrangements will more closely align the interests of AquaMed's management and employees with the interests of its stockholders and should increase AquaMed's ability to attract and retain personnel.
- Capital Structure and Stockholder Flexibility. The segments in which Alliqua and AquaMed expect to
  operate have historically had different growth profiles and cash flow dynamics. The Spin-Off will allow
  Alliqua and AquaMed to separately manage their capital strategies and cost structures and will allow
  investors to make independent investment decisions with respect to Alliqua and AquaMed, including the
  ability for AquaMed to achieve alignment with a more natural stockholder base. Investment in one or the
  other company may appeal to investors with different goals, strategies, interests and concerns.

The board of directors of Alliqua also considered and balanced against the potential benefits of the Spin-Off and Merger a number of potentially adverse factors concerning the Spin-Off and Merger, including the following:

- the fact that, although we will continue to exercise control and supervision over our operations prior to
  closing, the Merger Agreement prohibits us from taking a number of actions relating to the conduct of its
  business prior to the closing without TOP's consent, which may delay or prevent us from undertaking
  business opportunities that may arise during the pendency of the transactions, whether or not the Spin-Off
  and/or Merger is completed;
- the fact that immediately following the Transactions, the current members of TOP and the third- party
  investors that participate in the Private Placement are expected to hold approximately 90% of the total
  number of shares of AquaMed common stock outstanding (on a fully diluted basis), assuming that no
  more than \$10 million is raised in the Private Placement
- the risk that there is no assurance that all conditions to the parties' obligations to complete the Spin-Off and/or Merger will be satisfied or waived, and as a result, it is possible that the Spin-Off and/or Merger could be delayed or might not be completed;
- the risks and costs to us if the Transactions do not close, including the diversion of management and employee attention, potential employee attrition and the potential effect on business and customer relationships; and
- the risk of disruption to our business and customer reaction as a result of the public announcement of the Spin-Off and Merger.

# Q: Why is the separation of AquaMed structured as a Spin-Off?

A: Alliqua believes that a distribution of our shares is the most efficient way to separate our business from Alliqua in a manner that will achieve the benefits described above.

### Q: What will I receive in the Distribution?

A: As a holder of Alliqua common stock, you will receive a dividend of shares of our common stock for every one share of Alliqua common stock you hold on the Record Date (as defined below). The distribution agent will distribute only whole shares of our common stock in the Distribution. No fractional shares of our common stock will be issued pursuant to the dividend. Instead, any fractional shares of AquaMed common stock otherwise issuable to you will be sold on your behalf, and you will receive a cash payment with respect to that fractional share. Your proportionate interest in Alliqua will not change as a result of the Distribution. For a more detailed description, see "The Transactions."

### Q: How will fractional shares be treated in the Spin-Off?

A: Any fractional shares of AquaMed common stock otherwise issuable to you will be sold on your behalf, and you will receive a cash payment with respect to that fractional share. The distribution agent will aggregate all fractional shares into whole shares and sell the whole shares in the open market at

prevailing market prices on behalf of Alliqua stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required withholding for taxes applicable to each holder). For an explanation of how the cash payments for fractional shares will be determined, see "The Transactions — Treatment of Fractional Shares."

# Q: What is being distributed in the Distribution?

A: Alliqua will distribute approximately 1,750,000 shares of our common stock in the Distribution, based on the approximately 5,005,210 shares of Alliqua common stock outstanding as of December 31, 2018. The actual number of shares of our common stock that you will receive will depend on the actual number of shares of Alliqua common stock that you will receive will depend on the actual number of shares or exercises of outstanding options pursuant to Alliqua'a equity plans on or prior to the Record Date. The shares of our common stock that Alliqua distributes will constitute all of the issued and outstanding shares of our common stock immediately prior to the Distribution. For more information on the shares being distributed in the Spin-Off, see "Description of Our Capital Stock — Common Stock."

Alliqua stockholders will not receive any new shares of common stock of AquaMed in the Merger and will continue to hold the AquaMed shares they received in the Distribution. The Merger will result in the current members of TOP and the third-party investors that participate in the Private Placement owning approximately 90% of the common stock of AquaMed outstanding immediately after the effective time of the Merger (on a fully diluted basis), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in such private placement and it is consummated on the terms currently proposed, before giving effect to any fees payable in equity to financial advisors or other intermediaries. Shares issued to Alliqua stockholders in the Distribution will constitute approximately 10% of the common stock of AquaMed outstanding after the effective time of the Merger (on a fully diluted basis), assuming that no more than \$10 million is raised in the Private Placement and it is consummated on the terms currently proposed.

# Q: What is the record date for the Distribution?

A: Alliqua will determine record ownership as of the close of business on , 2019 which we refer to as the "Record Date," in order to determine the stockholders entitled to receive shares of AquaMed common stock in the Distribution.

# Q: When will the Distribution occur?

A: The Distribution will be effective by 11:59 p.m., New York City time, on , 2019, which we refer to as the "Distribution Date." On or shortly after the Distribution Date, shares of our common stock will be credited in book-entry accounts for Alliqua stockholders entitled to receive the shares in the Distribution. See "How will Alliqua distribute shares of our common stock?" for more information on how to access your bookentry account or your bank, brokerage or other account holding the AquaMed common stock you receive in the Distribution on and following the Distribution Date.

# Q: What do I have to do to participate in the Distribution?

A: You are not required to take any action, but we urge you to read this prospectus carefully. Holders of Alliqua common stock will not need to pay any cash or provide any other consideration, including any shares of Alliqua common stock, in order to receive shares of our common stock in the Distribution. In addition, no stockholder approval of the Distribution is required. We are not asking you for a vote and request that you do not send us a proxy. Neither the Distribution nor the Merger will result in any changes in Alliqua stockholders' ownership of Alliqua common stock. No vote of Alliqua stockholders is required or sought in connection with the Distribution or the Merger.

- Q: If I sell my shares of Alliqua common stock on or before the Distribution Date, will I still be entitled to receive shares of AquaMed common stock in the Distribution?
- A: If you hold shares of Alliqua common stock on the Record Date and sell them on or before the Distribution Date in the "regular-way" market, you also will be selling your right to receive shares of AquaMed common stock in connection with the Distribution. If you wish to sell your Alliqua common stock with or without your entitlement to our common stock, you should discuss these alternatives with your bank, broker or other nominee. See "The Transactions — When and How You Will Receive AquaMed Shares" for more information.

# Q: What is "regular-way" and "ex dividend" trading of Alliqua common stock?

A: We anticipate that, on or shortly before the Record Date, there will be two markets in Alliqua common stock: (1) a "regular-way" market on which shares of Alliqua common stock will trade with the entitlement for the purchaser of Alliqua common stock to receive shares of our common stock to be distributed in the Distribution, and (2) an "ex dividend" market on which shares of Alliqua common stock will trade without the entitlement for the purchaser of Alliqua common stock to receive shares of our common stock. If you hold shares of Alliqua common stock on the Record Date and then sell those shares before the Distribution Date, you should make sure your stockbroker, bank or other nominee understands whether you want to sell your shares of Alliqua common stock with or without your entitlement to AquaMed common stock pursuant to the Distribution.

# Q: How will Alliqua distribute shares of our common stock?

A: *Registered stockholders*. If you own your shares of Alliqua common stock directly through Alliqua's transfer agent, Action Stock Transfer Corporation, you are a registered stockholder. In this case, the distribution agent will credit the shares of our common stock you receive in the Distribution by way of direct registration in book-entry form to a new account with our transfer agent. Registration in book-entry form refers to a method of recording share ownership where no physical stock certificates are issued to stockholders, as is the case in the Distribution. You will be able to access information regarding your book-entry account holding the AquaMed shares at or by calling Action Stock Transfer Corporation at

"Street name" or beneficial stockholders. If you own your shares of Alliqua common stock through a bank, broker or other nominee, your bank, broker or other nominee will credit your account with the shares of our common stock that you receive in the Distribution on or shortly after the Distribution Date. We encourage you to contact your bank, broker or other nominee if you have any questions concerning the mechanics of having shares held in "street name."

We will not issue any physical stock certificates to any stockholders, even if requested. See "The Transactions — When and How You Will Receive AquaMed Shares" for a more detailed explanation.

# Q: What are the U.S. federal income tax consequences to me of the Distribution?

A: The receipt by you of shares of AquaMed common stock in the Spin-Off (including any fractional shares sold on your behalf) will generally be a taxable dividend to the extent of your ratable share of Alliqua's current and accumulated earnings and profits, with the excess treated first as a non-taxable return of capital to the extent of your tax basis in shares of Alliqua's common stock and then as capital gain. STOCKHOLDERS ARE ENCOURAGED TO CONSULT THEIR OWN TAX ADVISORS REGARDING THE PARTICULAR TAX CONSEQUENCES OF THE SPIN-OFF TO THEM, INCLUDING THE APPLICABILITY AND EFFECT OF ANY U.S. FEDERAL, STATE AND LOCAL TAX LAWS, AS WELL AS FOREIGN TAX LAWS.

# Q: How will I determine the tax basis I will have in the AquaMed shares I receive in the Spin-Off?

A: Your tax basis in the shares of AquaMed common stock received generally will equal the fair market value of such shares on the distribution date. For a more detailed discussion see "Material U.S. Federal Income Tax Consequences of the Distribution," included elsewhere in this prospectus.

# Q: Does AquaMed intend to pay dividends?

A: We do not currently anticipate paying any dividends following the Spin-Off. The timing, declaration, amount and payment of any future dividends to our stockholders will fall within the discretion of our Board of Directors and will depend on many factors, including our financial condition, results of operations and capital requirements, legal requirements, regulatory constraints, industry practice and other business considerations that our Board of Directors deems relevant from time to time. In addition, the terms of the agreements governing our debt or debt that we may incur in the future may restrict the payments of dividends. See "Dividend Policy" for more information.

# Q: What are the financing plans for AquaMed, and what will be the indebtedness of AquaMed and its subsidiaries following the completion of the Transactions?

A: AquaMed's intended financing in connection with the Spin-Off and Merger includes a minimum equity financing of \$10 million. See "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed — Liquidity and Capital Resources Following the Transactions" for more information. It is not anticipated that AquaMed will have any outstanding indebtedness following the consummation of the Distribution and Merger other than trade payables incurred in the ordinary course of business.

### Q: How will AquaMed common stock trade?

A: Currently, there is no public market for our common stock. We intend to list our common stock on the Nasdaq Capital Market under the symbol "TOPP."

## Q: What will be the relationship between Alliqua and AquaMed following the Distribution?

A: Following the Distribution, Alliqua will not own any of our shares and we will operate independently of Alliqua. Apart from our Chairman, who will remain a director of Alliqua after the Distribution and the Adynxx Merger, we currently do not expect other members of our Board of Directors to be officers or directors of Alliqua. In addition, we do not expect to depend on Alliqua to conduct our business following the Distribution apart from certain limited transitional support services. In order to govern the ongoing relationships between us and Alliqua after the Spin-Off and to facilitate an orderly transition, we and Alliqua intend to enter into agreements providing for various services and rights following the Spin-Off and under which we and Alliqua will agree to indemnify each other against certain liabilities arising from our respective businesses. These agreements will, among other things, provide arrangements for employee and pension-related matters, tax matters, intellectual property matters as well as transitional services and non-U.S. agency services. See "Risk Factors — Risks Relating to the Spin-Off and the Merger," "The Asset Contribution and Separation Agreement and Ancillary Agreements" and "Certain Relationships and Related Party Transactions — Agreements with Alliqua" for details.

# Q: Will the Spin-Off affect the trading price of my Alliqua common stock?

A: Yes. We expect the trading price of shares of Alliqua common stock immediately following the Distribution to be lower than the "regular-way" trading price of such shares immediately prior to the Distribution because the trading price will no longer reflect the value of the AquaMed business. Furthermore, until the market has fully analyzed the value of Alliqua without the AquaMed business, the trading price of shares of Alliqua common stock may fluctuate. There can be no assurance that, following the Distribution, the combined trading prices of Alliqua common stock and our common stock will equal or exceed what the trading price of Alliqua common stock would have been in the absence of the Spin-Off.

It is possible that after the Spin-Off, the combined market value of the equity of Alliqua and AquaMed will be less than Alliqua's equity value before the Spin-Off.

#### Q: Do I have appraisal rights in connection with the Spin-Off?

A: No. Holders of Alliqua's common stock are not entitled to appraisal rights in connection with the Spin-Off.



Q:	Are there risks associated with owning shares of AquaMed's common stock?
A:	Yes. Our business faces both general and specific risks and uncertainties relating to the AquaMed business at the TOP business. Our business also faces risks relating to the Spin-Off and Merger. Following the Spin-Off, we will also face risks associated with being an independent, publicly-traded company. Accordingly, you should read carefully the information set forth in the section titled "Risk Factors" in this prospectus.
Q:	Who is the distribution agent, transfer agent and registrar for AquaMed common stock?
A:	Action Stock Transfer Corporation.
Q:	Where can I get more information?
A:	If you have any questions relating to the mechanics of the Distribution, you should contact Action Stock Transfer Corporation at:
	Action Stock Transfer Corporation 2469 E. Fort Union Blvd., Suite 214 Salt Lake City, Utah 84121 Phone: 801-274-1088
	Before the Spin-Off, if you have any questions relating to the Spin-Off, you should contact Alliqua at:
	Investor Relations Alliqua BioMedical, Inc. 2150 Cabot Boulevard West Suite B Langhorne, PA 19047 Phone: 215-702-8550 https://alliqua.com
	After the Spin-Off, if you have any questions relating to AquaMed, you should contact us at:
	Investor Relations AquaMed Technologies, Inc. 2150 Cabot Boulevard West Suite B Langhorne, PA 19047 Phone: 215-702-8550

Distributing Company       Alliqua BioMedical, Inc., a Delaware corporation that holds all of our common stock issued and outstanding prior to the Distribution. After the Distribution, Alliqua will not own any shares of our common stock.         Distributed Company       AquaMed Technologies, Inc., a Delaware corporation and a wholly owned subsidiary of Alliqua. At the time of the Distribution, we will hold assets and liabilities relating to Alliqua 'scustom hydrogels manufacturing business. After the Spin-Off, we will be an independent publicly-traded company.         Distributed Securities       100% of our common stock issued and outstanding immediately prior to the Distribution. Based on the approximately 5.005.210 shares of Alliqua common stock outstanding on December 31, 2018, and applying the distribution ratio of shares of AquaMed common stock will we firstribution ratio of shares of Alliqua common stock will we firstribute of shares of Alliqua common stock will we firstribute of shares of AuguaMed common stock outstanding on the Record Date, which will reflect any issuance of new shares or exercises of outstanding options pursuant to Alliqua equity plans on or prior to the Record Date         Distribution Date       The Record Date is the close of business on2019.         Distribution Ratio       Each holder of Alliqua common stock will werein and Acneillary Agreements' for a description of the Internal Reorganization share of a dustanding pusiness. See "The Asset Contribution and Segmation Agreement and Ancillary Agreements' for a description of the Internal Reorganization.         Distribution Ratio       Each holder of Alliqua common stock will receive a dividend of shares of our common stock will distribute on the share of our common stock will be side out while hase of our common		Summary of the Spin-Off
<ul> <li>wholly owned subsidiary of Alliqua. At the time of the Distribution, we will hold assets and liabilities relating to Alliqua's custom hydrogels manufacturing business. After the Spin-Off, we will be an independent publicly-traded company.</li> <li>Distributed Securities</li> <li>100% of our common stock issued and outstanding immediately prior to the Distribution. Based on the approximately 5,005,210 shares of Alliqua common stock outstanding on December 31, 2018, and applying the distribution ratio of shares of AquaMed common stock, approximately 1,750,000 shares of AquaMed common stock, approximately 1,750,000 shares of AquaMed common stock will be distributed in the Spin-Off. The actual number of shares of our common stock you will receive in the Spin-Off will depend on the actual number of shares of Alliqua common stock will be distributed in the Spin-Off will depend on the actual number of shares of Alliqua common stock outstanding on the Record Date, which will reflect any issuance of new shares or exercises of outstanding options pursuant to Alliqua equity plans on or prior to the Record Date.</li> <li>Record Date</li> <li>The Record Date is the close of business on , 2019.</li> <li>Internal Reorganization So that we hold all of the assets relating to the custom hydrogel and contract manufacturing business. See "The Asset Contribution and Separation Agreement and Ancillary Agreements" for a description of the Internal Reorganization.</li> <li>Distribution Ratio</li> <li>Each holder of Alliqua common stock will receive a dividend of shares of our common stock in the Spin-Off. No fractional shares of our common stock will exerce a dividend of shares of Auliqua common stock in the Spin-Off. No fractional shares of our common stock in the Spin-Off. No fractional shares of our common stock in the Spin-Off. No fractional shares of our common stock in the Spin-Off. No fractional shares of our common stock in the Spin-Off. No fractional shares and a sell the whole shares</li></ul>	Distributing Company	of our common stock issued and outstanding prior to the Distribution. After the Distribution, Alliqua will not own any
prior to the Distribution. Based on the approximately 5,005,210shares of Alliqua common stock outstanding on December 31, 2018, and applying the distribution ratio of AquaMed common stock for every one share of Alliqua common stock, approximately 1,750,000 shares of AquaMed 	Distributed Company	wholly owned subsidiary of Alliqua. At the time of the Distribution, we will hold assets and liabilities relating to Alliqua's custom hydrogels manufacturing business. After the
Distribution DateThe Distribution Date is, 2019.Internal ReorganizationIn connection with the Spin-Off, Alliqua will undertake the Internal Reorganization so that we hold all of the assets relating to the custom hydrogel and contract manufacturing business. See "The Asset Contribution and Separation Agreement and Ancillary Agreements" for a description of the Internal Reorganization.Distribution RatioEach holder of Alliqua common stock will receive a dividend of shares of our common stock for every one share of 	Distributed Securities	prior to the Distribution. Based on the approximately 5,005,210 shares of Alliqua common stock outstanding on December 31, 2018, and applying the distribution ratio of shares of AquaMed common stock for every one share of Alliqua common stock, approximately 1,750,000 shares of AquaMed common stock will be distributed in the Spin-Off. The actual number of shares of our common stock you will receive in the Spin-Off will depend on the actual number of shares of Alliqua common stock outstanding on the Record Date, which will reflect any issuance of new shares or exercises of outstanding options pursuant to Alliqua equity plans on or prior to the
Internal Reorganization In connection with the Spin-Off, Alliqua will undertake the Internal Reorganization so that we hold all of the assets relating to the custom hydrogel and contract manufacturing business. See "The Asset Contribution and Separation Agreement and Ancillary Agreements" for a description of the Internal Reorganization. Distribution Ratio Each holder of Alliqua common stock will receive a dividend of shares of our common stock for every one share of Alliqua common stock it holds on the Record Date. The distribution agent will distribute only whole shares of our common stock in the Spin-Off. No fractional shares of our common stock will be issued pursuant to this dividend. Any fractional shares of AquaMed common stock otherwise issuable to you will be sold on your behalf, and you will receive a cash payment with respect to that fractional share. The distribution agent will aggregate all fractional shares into whole shares and sell the whole shares. The distribute the distribution agent will aggregate all fractional shares entitled to receive a fractional share. The distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required	Record Date	The Record Date is the close of business on , 2019.
Internal Reorganization so that we hold all of the assets relating to the custom hydrogel and contract manufacturing business. See "The Asset Contribution and Separation Agreement and Ancillary Agreements" for a description of the Internal Reorganization. Distribution Ratio Each holder of Alliqua common stock will receive a dividend of shares of our common stock for every one share of Alliqua common stock it holds on the Record Date. The distribution agent will distribute only whole shares of our common stock in the Spin-Off. No fractional shares of our common stock will be issued pursuant to this dividend. Any fractional shares of AquaMed common stock otherwise issuable to you will be sold on your behalf, and you will receive a cash payment with respect to that fractional shares and sell the whole shares in the open market at prevailing market prices on behalf of Alliqua stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required	Distribution Date	The Distribution Date is , 2019.
of shares of our common stock for every one share of Alliqua common stock it holds on the Record Date. The distribution agent will distribute only whole shares of our common stock in the Spin-Off. No fractional shares of our common stock will be issued pursuant to this dividend. Any fractional shares of AquaMed common stock otherwise issuable to you will be sold on your behalf, and you will receive a cash payment with respect to that fractional share. The distribution agent will aggregate all fractional shares into whole shares and sell the whole shares in the open market at prevailing market prices on behalf of Alliqua stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required	Internal Reorganization	Internal Reorganization so that we hold all of the assets relating to the custom hydrogel and contract manufacturing business. See "The Asset Contribution and Separation Agreement and Ancillary Agreements" for a description of the Internal
	Distribution Ratio	of shares of our common stock for every one share of Alliqua common stock it holds on the Record Date. The distribution agent will distribute only whole shares of our common stock in the Spin-Off. No fractional shares of our common stock will be issued pursuant to this dividend. Any fractional shares of AquaMed common stock otherwise issuable to you will be sold on your behalf, and you will receive a cash payment with respect to that fractional share. The distribution agent will aggregate all fractional shares into whole shares and sell the whole shares in the open market at prevailing market prices on behalf of Alliqua stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required

	For an explanation of how the cash payments for fractional shares will be determined, see "The Transactions — Treatment of Fractional Shares."
	Please note that if you sell your shares of Alliqua common stock on or before the Distribution Date in the "regular-way" market, the buyer of those shares may in some circumstances be entitled to receive the shares of our common stock to be distributed in respect of the Alliqua shares that you sold. See "The Transactions — When and How You Will Receive AquaMed Shares" for more detail.
The Distribution	On the Distribution Date, Alliqua will release the shares of our common stock to the distribution agent to distribute to Alliqua stockholders. Alliqua will distribute our shares in book-entry form and thus we will not issue any physical stock certificates. We expect that it will take the distribution agent up to two weeks to electronically issue shares of our common stock to you or your bank or brokerage firm on your behalf by way of direct registration in book-entry form. The ability to trade our shares will not be affected during that time. You will not be required to make any payment, surrender or exchange your shares of Alliqua common stock or take any other action to receive your shares of our common stock, however, you generally will be treated as if you received a taxable distribution in an amount equal to the fair market value of AquaMed common stock received (including any fractional share deemed to be received by and sold on your behalf). See "Material U.S. Federal Income Tax Consequences of the Distribution" for more information.
	We urge you to consult your tax advisor as to the specific tax consequences of the Distribution to you, including the effect of any U.S. federal, state, local or foreign tax laws and of changes in applicable tax laws.
Concurrent Private Placement	AquaMed's contemplated financing in connection with the Spin- Off and Merger includes an equity financing in the minimum aggregate amount of \$10 million; provided, that the parties may determine to waive the \$10 million minimum. See "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed — Liquidity and Capital Resources Following the Transactions" for more information.
Conditions to the Spin-Off	The Spin-Off is subject to the satisfaction, or the waiver of Alliqua's board of directors, of the following conditions, among other conditions:
	<ul> <li>the board of directors of Alliqua shall have approved the Internal Reorganization and the Distribution and shall have declared the Distribution of AquaMed common stock to Alliqua stockholders;</li> </ul>
	the ancillary agreements contemplated by the Asset     Contribution and Separation Agreement shall have been

	<ul> <li>the Securities and Exchange Commission ("SEC") shall have declared effective our Registration Statement on Form S-1, of which this prospectus is a part, under the Exchange Act, and no stop order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for that purpose shall be pending before or threatened by the SEC;</li> <li>our common stock shall have been accepted for listing on the Nasdaq Capital Market, subject to official notice of issuance;</li> <li>we shall have concurrently consummated the Private Placement;</li> </ul>
	<ul> <li>the Merger Agreement shall be in full force and effect;</li> <li>Alliqua shall have received an independent third-party valuation of our common stock to be distributed in the Distribution;</li> </ul>
	<ul> <li>no order, injunction or decree issued by any governmental authority of competent jurisdiction or other legal restraint or prohibition preventing consummation of the Internal Reorganization shall be in effect;</li> </ul>
	<ul> <li>Alliqua shall be satisfied the Internal Reorganization and the Distribution will not result in any material tax payable by Alliqua;</li> </ul>
	<ul> <li>the Adynxx Merger Agreement between Alliqua, Embark and Adynxx dated October 11, 2018, shall be in full force and effect and the transactions contemplated thereby shall be consummated immediately following the closing of the Spin-Off; and</li> </ul>
	<ul> <li>no proceeding shall be pending or threatened in writing seeking to enjoin, delay, prohibit or restrict the consummation of the Spin-Off or the Merger.</li> </ul>
Regulatory Approvals	We are not aware of any material federal, foreign or state regulatory requirements with which we must comply, other than SEC rules and regulations, or any material approvals that we must obtain, other than the approval for listing of our common stock by the Nasdaq Capital Market and the SEC's declaration of the effectiveness of the Registration Statement, which are conditions to the Distribution and the Merger.
Trading Market and Symbol	We intend to file an application to list our common stock on the Nasdaq Capital Market under the symbol "TOPP." We anticipate that trading of our common stock will begin the first trading day after the Distribution Date.
	We anticipate that, beginning on or shortly before the Record Date, there will be two markets in Alliqua common stock: (1) a "regular-way" market on which shares of Alliqua common stock will trade with the entitlement for

	the purchaser of Alliqua common stock to receive shares of our common stock to be distributed in the Distribution, and (2) an "ex-dividend" market on which shares of Alliqua common stock will trade without the entitlement for the purchaser of Alliqua common stock to receive shares of our common stock. If you hold shares of Alliqua common stock on the Record Date and then decide to sell any shares of Alliqua common stock before the Distribution Date, you should make sure your stockbroker, bank or other nominee understands whether you want to sell your shares of Alliqua common stock pursuant to the Distribution.
Tax Consequences to Alliqua Stockholders	For U.S. federal income tax purposes, the Distribution by Alliqua of the shares of AquaMed common stock will not be eligible for treatment as a tax-free distribution. Accordingly, each holder of Alliqua common stock who receives shares of AquaMed common stock in the Spin-Off generally will be treated as if such stockholder received a taxable distribution in an amount equal to the fair market value of AquaMed common stock received (including any fractional share deemed to be received by and sold on behalf of the stockholder), which will result in: (a) a dividend to the extent of such stockholder's ratable share of Alliqua's current and accumulated earnings and profits; then (b) a reduction in such stockholder's basis in Alliqua's common stock (but not below zero) to the extent the amount received exceeds the amount referenced in clause (a); and then (c) gain from the sale or exchange of Alliqua common stock to the extent the amount received exceeds the sum of the amounts referenced in clauses (a) and (b). Each stockholder's basis in his, her or its AquaMed common stock will be equal to the fair market value of such stock at the time of the Spin-Off. A stockholder's holding period for such shares will begin the day after the Spin-Off date.
	We urge you to consult your tax advisor as to the specific tax consequences of the Distribution to you, including the effect of any U.S. federal, state, local or foreign tax laws and of changes in applicable tax laws.
Relationship with Alliqua after the Spin-Off	Following the Distribution, Alliqua will not own any of our shares and we will operate independently of Alliqua. In addition, we do not expect to depend on Alliqua to conduct our business following the Distribution apart from certain limited transitional support services. In order to govern the ongoing relationships between us and Alliqua after the Spin-Off and to facilitate an orderly transition, we and Alliqua intend to enter into agreements providing for various services and rights following the Spin-Off and

	under which we and Alliqua will agree to indemnify each other against certain liabilities arising from our respective businesses. These agreements include:
	<ul> <li>the Asset Contribution and Separation Agreement that will set forth Alliqua's and our agreements regarding the principal actions that both parties will take in connection with the Spin-Off, including the assignment by Alliqua to us of the assets relating to our hydrogel business which we do not already own, and aspects of our relationship following the Spin-Off;</li> </ul>
	• a Tax Matters Agreement that will govern the respective rights, responsibilities and obligations of Alliqua and us after the Spin-Off with respect to all tax matters;
	<ul> <li>A Bill of Sale and Assignment and Assumption Agreement (the "Assumption Agreement") whereby we will assume Alliqua's liabilities related to the hydrogel business.</li> </ul>
	We describe these arrangements in greater detail under "The Asset Contribution and Separation Agreement and Ancillary Agreements" and "Certain Relationships and Related Party Transactions — Agreements with Alliqua," and describe some of the risks of these arrangements under "Risk Factors — Risks Relating to the Spin-Off and the Merger."
Dividend Policy	We do not anticipate paying cash dividends following the Spin- Off. The timing, declaration, amount and payment of any future dividends to our stockholders will fall within the discretion of our Board of Directors and will depend on many factors, including our financial condition, results of operations and capital requirements, legal requirements, regulatory constraints, industry practice and other business considerations that our Board of Directors deems relevant from time to time. In addition, the terms of agreements governing any debt that we may incur in the future may restrict or limit the payments of dividends. See "Dividend Policy."
Transfer Agent	Action Stock Transfer Corporation
Risk Factors	We face both general and specific risks and uncertainties relating to the AquaMed business and the TOP business. We also face risks relating to the Spin-Off and Merger. Following the Spin-Off, we will also face risks associated with being an independent, publicly-traded company. Accordingly, you should read carefully the information set forth under "Risk Factors."
	17

	Summary of the Merger
Structure of the Merger	Under the Merger Agreement and in accordance with Delaware law, Merger Sub will merge with and into TOP, with TOP surviving the Merger. As a result of the Merger, TOP will become a wholly owned subsidiary of AquaMed. For details of the structure of the transaction, see "The Merger Agreement."
Consideration for the Merger	At the effective time of the Merger, all of the outstanding membership interests of TOP will be automatically converted into the right to receive, in the aggregate, merger consideration consisting of shares of AquaMed common stock. Immediately after the effective time of the Merger and consummation of the Private Placement, before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis) (the "Merger Consideration"), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in such private placement and it is consummation of the Merger, AquaMed will issue shares representing approximately 4.99% and 0.08% of shares outstanding to Bezalel Partners, LLC and the Benchmark Company, LLC, respectively, for advisory and consulting services in connection with the Merger. Following such issuances and the consummation of the Merger and the Private Placement on the terms set forth above, the former Alliqua shareholders will hold approximately 9.5% of the total number of shares of AquaMed stock outstanding.
	Following the effective time of the Merger, all of the TOP membership interests will be automatically cancelled and cease to exist.
Approval of the Merger	No vote by Alliqua stockholders is required or is being sought in connection with the Merger. Alliqua, as the sole stockholder of AquaMed, has already approved the Merger. The board of managers of TOP has approved the Merger Agreement, the Merger and all other actions necessary to consummate the Merger. A majority of the members of TOP have also approved the Merger Agreement, the Merger and all other actions necessary to consummate the Merger.
Regulatory Approvals	We are not aware of any material federal, foreign or state regulatory requirements with which we must comply, other than SEC rules and regulations, or any material approvals that we must obtain, other than the approval for listing of

	our common stock and the SEC's declaration of the effectiveness of the Registration Statement, which are conditions to the Distribution and the Merger.
Conditions to the Merger	The obligations of each party to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of closing conditions that are contained in the Merger Agreement, including:
	<ul> <li>the Spin-Off having occurred pursuant to the Asset Contribution and Separation Agreement;</li> </ul>
	<ul> <li>the effectiveness of the registration statement of which this prospectus forms a part in connection with the Distribution, and the approval for listing on the Nasdaq Capital Market of the shares of AquaMed common stock to be issued in the Distribution and the Merger, subject to official notice of issuance;</li> </ul>
	• the absence of any order issued by any governmental authority of competent jurisdiction or other legal impediment preventing or making illegal the consummation of the Merger; and
	• we shall have received binding commitments from investors to consummate the Private Placement.
	In addition, our, and Merger Sub's obligations to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of the following conditions, among others:
	<ul> <li>certain fundamental representations and warranties of TOP being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger;</li> </ul>
	<ul> <li>the representations and warranties of TOP, disregarding all materiality or material adverse effect qualifications, being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger (except to the extent such representations and warranties address matters as of a particular date, in which case as of such date) (other than the certain fundamental representations and warranties which must be true and correct in all respects);</li> </ul>
	<ul> <li>the covenants and agreements being performed by TOP in all material respects at or prior to the effective time of the Merger;</li> </ul>
	• TOP shall have obtained the consent of the holders of a majority of its membership interests, and such consent shall not have been invalidated or revoked and shall remain in full force and effect;

• the absence of a TOP Material Adverse Effect since the date of the Merger Agreement;
• TOP shall have completed an audit of its financial statements for the years ended December 31, 2016 and December 31, 2017 by an independent registered auditor; and
• we shall have received an independent third-party valuation of our common stock to be distributed in the Distribution.
Furthermore, the obligations of TOP to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of the following conditions, among others:
<ul> <li>certain fundamental representations and warranties of AquaMed and Merger Sub being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger;</li> </ul>
• the representations and warranties of AquaMed and Merger Sub, disregarding all materiality or material adverse effect qualifications, being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger (except to the extent such representations and warranties address matters as of a particular date, in which case as of such date) (other than the certain fundamental representations and warranties which must be true and correct in all respects);
<ul> <li>the covenants and agreements being performed by AquaMed and Merger Sub in all material respects at or prior to the effective time of the Merger;</li> </ul>
• the absence of any AquaMed Material Adverse Effect since the date of the Merger Agreement;
• AquaMed shall have completed an audit of its financial statements for the years ended December 31, 2016 and December 31, 2017 by an independent registered auditor; and
<ul> <li>we shall have delivered to TOP (a) resignation letters of any of our officers and directors, to be effective as of the time when the Merger shall become effective (the "Effective Time"), who will not be continuing officers or directors of us, and (b) certified resolutions of our Board of Directors (i) causing our whole Board of Directors to consist of five directors as of the Effective Time, (ii) appointing to the Board of Directors such individuals as necessary to cause the Board of Directors as of the Effective Time to conform with the requirements set forth on Schedule 1.4 to the Merger Agreement, and</li> </ul>

	<ul> <li>(iii) appointing as officers of Parent such individuals as necessary to cause our officers as of the Effective Time to conform with the requirements set forth on Schedule 1.4 to the Merger Agreement. We shall also deliver resolutions, in our capacity as the sole member of the surviving company as of the Effective Time, appointing persons to the Board of Managers of the surviving company, and resolutions of such Board of Managers appointing persons to serve as officers of the surviving company.</li> <li>To the extent permitted by applicable law, each party to the Merger Agreement may waive, at its sole discretion, any of the conditions to its respective obligations to complete the Merger.</li> </ul>
Termination of the Merger Agreement	The Merger Agreement may be terminated at any time before the effective time of the Merger by the mutual written consent of AquaMed and TOP. It may also be terminated by either us or TOP if:
	• the effective time of the Merger has not occurred on or before April 11, 2019 unless the failure to effect the Merger by that date is due to the failure of the party seeking to terminate the Merger Agreement to perform its obligations set forth in the Merger Agreement;
	<ul> <li>if a court of competent jurisdiction or other governmental authority shall have issued a final and non-appealable order, or shall have taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Merger.</li> </ul>
	The Merger Agreement may also be terminated by:
	• TOP at any time before the effective time of the Merger if any of AquaMed's representations and warranties shall be inaccurate such that the closing condition set forth above shall not be satisfied or any of AquaMed's covenants or obligations shall have been materially breached, and such breach or inaccuracy has not been cured within 30 business days following notice of such inaccuracy or breach.
	• AquaMed at any time before the effective time of the Merger if any of TOP's representations and warranties shall be inaccurate such that the closing condition set forth above shall not be satisfied or any of TOP's covenants or obligations shall have been materially breached, and such breach or inaccuracy has not been cured within 30 business days following notice of such inaccuracy or breach.
Accounting Treatment of the Merger	The combined financial information presented in the prospectus was prepared using the purchase method of accounting, with TOP treated as the "acquirer" of AquaMed and its respective subsidiaries for accounting purposes.
	21

# SUMMARY HISTORICAL FINANCIAL DATA OF AQUAMED

The following tables summarize the historical financial and other data of AquaMed for the periods and as of the dates indicated.

This summary historical financial data for the years ended December 31, 2018 and 2017, and as of December 31, 2018 and 2017, were derived from AquaMed's audited financial statements and notes thereto included elsewhere in this prospectus.

Historical results are not necessarily indicative of future operating results. Because the data in this table is only a summary and does not provide all of the data contained in our combined financial statements, the information should be read in conjunction with "Selected Historical Financial Data of AquaMed," "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed" and its combined financial statements and the related notes thereto included elsewhere in this prospectus.

As of or for the years ended		
December 31, 2018	December 31, 2017	
Historical		
\$ 2,213	\$ 1,992	
(1,888)	(969)	
(1,888)	(953)	
\$ 739	\$ 894	
407	210	
51	59	
458	269	
\$ (1,544)	\$ (777)	
_	(7)	
1,544	784	
1,544	784	
	December 31, 2018 Histo \$ 2,213 (1,888) (1,888) \$ 739 407 51 458 \$ (1,544) — 1,544	

# SUMMARY HISTORICAL CONSOLIDATED FINANCIAL DATA OF TOP

The following tables summarize the historical consolidated financial and other data of TOP for the periods and as of the dates indicated.

This summary historical consolidated financial data for the years ended December 31, 2018 and 2017, and as of December 31, 2018 and 2017, were derived from TOP's audited consolidated financial statements and notes thereto included elsewhere in this prospectus.

Historical results are not necessarily indicative of future operating results. Because the data in this table is only a summary and does not provide all of the data contained in TOP's consolidated financial statements, the information should be read in conjunction with "Selected Historical Consolidated Financial Data for TOP," "Management's Discussion and Analysis of Financial Condition and Plan of Operation of TOP" and its consolidated financial statements and the related notes thereto included elsewhere in this prospectus.

	As of or for the	As of or for the years ended		
	December 31, 2018	December 31, 2017		
	Histo	Historical		
Consolidated Statement of Operations data:				
Operating Expenses	\$ 1,171,494	\$ 737,670		
Net loss	(1,171,494)	(737,670)		
Consolidated Balance Sheet Data:				
Total assets	\$ 909,252	\$ 471,500		
Total current liabilities	2,842,455	2,269,465		
Total liabilities	2,842,455	2,269,465		
Members' deficit	\$(1,933,203)	\$(1,797,965		
Consolidated Statements of Cash Flows data:				
Cash flows (used in) operating activities	\$ (621,899)	\$ (625,393)		
Cash flows provided by financing activities	981,088	625,393		
Advances from TOG	481,088	625,393		

# SUMMARY PRO FORMA CONDENSED COMBINED FINANCIAL DATA OF THE SURVIVING COMPANY

The following tables summarize the pro forma condensed combined financial data of the surviving company for the periods and as of the dates indicated.

We have derived the summary pro forma condensed combined financial and other data for the periods and as of the dates indicated from the audited financial statements and the notes thereto included elsewhere in this Prospectus.

The pro forma condensed combined financial data are not necessarily indicative of the results that would have been realized had the Spin-Off and the Merger been consummated on those dates, or of future operating results, and the results for any interim period are not necessarily indicative of the results that may be expected for a full fiscal year. Because the data in this table is only a summary and does not provide all of the data contained in our pro forma condensed combined financial statements, the information should be read in conjunction with the audited financial statements and the related notes thereto included elsewhere in this Prospectus.

The following unaudited summary pro forma condensed combined financial information present the pro forma financial information of the surviving company based upon the historical financial statements of each of TOP and AqauMed, after giving effect to the Spin-off and Merger as further described in the section of this document entitled "The Transactions." The unaudited summary condensed combined pro forma financial information are intended to reflect the impact of the Spin-Off and the Merger on AquaMed's historical financial statements as if the relevant transactions occurred on December 31, 2018 for purposes of the unaudited pro forma condensed combined balance sheet and January 1, 2018 for purposes of the unaudited pro forma condensed combined statements of operations data. The unaudited pro forma condensed combined financial information and other data of the surviving company have been prepared using, and should be read in conjunction with (i) TOP's audited historical consolidated financial statements and related notes for the year ended December 31, 2018, and (ii) AquaMed's audited historical financial statements and related notes for the year ended December 31, 2018. The unaudited pro forma condensed combined financial information is presented for informational purposes only and is not intended to represent or to be indicative of the actual results of operations or financial position that the combined company would have reported had the Spin-Off and Merger been completed as of the dates set forth in the pro forma condensed combined financial statements, and should not be taken as being indicative of the combined company's future consolidated results of operations or financial position. The actual results may differ significantly from those reflected in the pro forma condensed combined financial statements for a number of reasons, including differences between the assumptions used to prepare the pro forma condensed combined financial statements and actual amounts. This information is only a summary and has been derived from and should be read in conjunction with the more detailed unaudited pro forma condensed combined financial statements and the notes thereto, included elsewhere in this prospectus, which have been prepared in accordance with Article 11 of Regulation S-X.

(in thousands)	Historical TOP for the Year Ended December 31, 2018	Historical AquaMed for the Year Ended December 31, 2018	Transaction Adjustments	Pro Forma Combined
Revenue	\$ —	\$ 2,213	\$ —	\$ 2,213
Loss before income taxes	(1,171)	(1,888)	(138)	(2,921)
Income tax provision			—	—
Net loss	\$ (1,171)	\$ (1,888)	\$ (138)	\$ (2,921)
Total assets	\$ 909	\$ 739	\$ 10,000	\$ 11,648
Total liabilities	\$ 2,842	\$ 458	\$ (500)	\$ 2,800

#### **RISK FACTORS**

You should carefully consider all of the information in this prospectus and each of the risks described below, which we believe are the principal risks that we face. Some of the risks relate to the businesses of AquaMed and TOP, others to the Spin-Off, and others to the Merger. Some risks relate principally to the securities markets and ownership of our common stock.

Any of the following risks could materially and adversely affect our business, financial condition, results of operations and prospects and the actual outcome of matters as to which forward-looking statements are made in this prospectus. In such case, the trading price of our common stock could decline, and you could lose all or part of your investment. While we believe we have identified and discussed below the material risks affecting our business, there may be additional risks and uncertainties that we do not presently know or that we do not currently believe to be material that may adversely affect our business, financial condition, results of operations and prospects in the future.

Past performance may not be a reliable indicator of future financial performance. Future performance and historical trends may be adversely affected by the following factors, as well as other variables, and should not be relied upon to project future period results.

#### **Risks Relating to AquaMed's Business**

# The report of our independent registered public accounting firm contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses, negative cash flows from operating activities, and no cash on hand, the report of our independent registered public accounting firm, with respect to our financial statements at December 31, 2018, and for the year ended December 31, 2018, contains an explanatory paragraph as to our potential inability to continue as a going concern. This opinion indicates that substantial doubt exists regarding our ability to remain in business. Such an opinion may adversely affect our ability to obtain new financing on reasonable terms or at all.

#### Our future success depends upon market acceptance of our existing and future products.

We believe that our success will depend in part upon the acceptance of its existing and future products by the medical community, hospitals and physicians and other health care providers, third-party payers, and end-users. Such acceptance may depend upon the extent to which the medical community and end-users perceive our products as safer, more effective or cost-competitive than other similar products. Ultimately, for our products to gain general market acceptance, it may also be necessary for us to develop marketing partners for the distribution of our products. There can be no assurance that our products will achieve significant market acceptance on a timely basis, or at all. Failure of some or all of our future products to achieve significant market acceptance could have a material adverse effect on our business, financial condition, and results of operations.

#### We are dependent on significant customers.

Our hydrogel manufacturing business is currently our sole source of revenue, and much of this revenue is generated from a limited number of clients, who account for a substantial percentage of our total revenues. For the year ended December 31, 2018, two major customers accounted for approximately 77% of our revenue, with each customer individually accounting for 63%, and 14%, respectively. The loss of any of our significant customers would have a significantly negative effect on our overall operations.

# We have no contracts in place with our customers. The absence of such contracts could result in periods during which we must continue to pay costs without revenues.

Our sales are made on a purchase order basis and we do not have contracts with our customers. Accordingly, our customers are not required to purchase a minimum amount of our products, and we therefore could have periods during which we have no or limited orders for our products, which will make it

difficult for us to operate as we will have to continue paying our expenses. We cannot provide assurance that we will be able to timely locate new customers, if at all, when our existing customers are not placing orders. The periods in which we have no or limited purchase orders for our products would have a material adverse effect on our business and financial condition.

# We operate in a highly competitive industry.

Competition from other hydrogel manufacturers is intense. There can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

Our competitors enjoy several competitive advantages over us, including some or all of the following:

- large and established distribution networks in the U.S. and/or in international markets;
- greater financial, managerial and other resources for products research and development, sales and marketing efforts and protecting and enforcing intellectual property rights;
- significantly greater name recognition;
- · more expansive portfolios of intellectual property rights; and
- greater experience in obtaining and maintaining regulatory approvals and/or clearances from the FDA and other regulatory agencies.

Our competitors' products will compete directly with our products. In addition, our competitors, as well as new market entrants, may develop or acquire new products that will compete directly or indirectly with our products. The presence of this competition in our market may lead to pricing pressure which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

### We are subject to governmental regulations.

As a manufacturer of medical products, we are generally subject to regulation by the FDA and the Federal Trade Commission, among other state and federal governmental authorities in the U.S., with respect to the manufacturing, marketing, labeling, record keeping, claims and advertising of our products. Our hydrogel manufacturing facility is also subject to various state regulations.

Failure to comply with applicable regulatory requirements can result in, among other things, suspensions or withdrawals of approvals or clearances, seizures or recalls of products, injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals. Meeting regulatory requirements and evolving government standards may delay marketing of our products for a considerable period of time, impose costly procedures upon our activities and result in a competitive advantage to larger companies that compete against us.

# We have limited sales, marketing and distribution capabilities.

We currently have limited sales, marketing and distribution capabilities. We must either develop our own sales, marketing and distribution capabilities, which will be expensive and time consuming, or make arrangements with third parties to perform these services for us. If we enter into third party arrangements, the third parties may not be capable of successfully selling any of our products. If we decide to market any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, our business and financial condition will be adversely affected.

# Our products risk exposure to product liability claims.

We are exposed to potential product liability risks, which are inherent in the testing, manufacturing and marketing of our products. We may incur significant expense investigating and defending any product liability claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

#### We are reliant upon two manufacturers for key ingredients of the manufacture of our hydrogels.

The Dow Chemical Company and the BASF Corporation are the principal manufacturers of the two polymers, polyethylene oxide and polyvinylpyrrolidone, respectively, that we primarily use in the manufacture of hydrogels. Although we have not experienced significant production delays attributable to supply changes, we believe that developing alternative sources of supply for the polymers used to make our current hydrogels would be difficult over a short period of time. Because we have no direct control over its third-party suppliers, interruptions or delays in the products and services provided by these third parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary raw materials or products, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers. In such events, we could experience interruptions, delays, increased costs or quality control problems, which would have a material and adverse effect on our business, results of operations and financial condition.

# There can be no assurance that our internal controls over financial reporting will be able to detect fraud or other issues.

We will be required under the Sarbanes-Oxley Act of 2002 to include a report of management on our internal controls that contains an assessment by management of the effectiveness of our internal control over financial reporting. Because and so long as we are an emerging growth company, our public accounting firm auditing our financial statements will not be required to report on the effectiveness of internal control over financial reporting, and our stockholders will not have the benefit thereof. Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. However, a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. There can be no assurance that all control issues or fraud will be detected. In connection with the Merger, and as we continue to grow our business, our internal controls continue to become more complex and require more resources.

# Our ability to provide customers with competitive services is dependent on our ability to attract and retain qualified personnel, including our senior management team.

Our ability to grow and provide our customers with competitive services is partially dependent on our ability to attract and retain highly motivated people with the skills necessary to serve our customers. Personnel with the requisite skills, qualifications, or security clearance may be in short supply or generally unavailable. The loss of personnel could impair our ability to perform under certain contracts, which could have a material adverse effect on our consolidated financial position, results of operations, prospects and cash flows.

In addition, due to the Merger, uncertainty around future employment opportunities, facility locations, organizational and reporting structures, and other related concerns may impair our ability to attract and retain qualified personnel. If employee attrition is higher than expected due to difficulties encountered in the integration process it may adversely impact our ability to realize the anticipated benefits of the Merger.

### We may need to raise additional capital, and we cannot be sure that additional financing will be available.

Subsequent to the Spin-Off, we will need to fund our ongoing working capital, capital expenditure and operating requirements through cash flows from operations and new sources of capital, including additional financing. Our ability to obtain future financing will depend on, among other things, our financial condition, results of operations and prospects, as well as on the condition of the capital markets or other credit markets at the time we seek financing. Increased volatility and disruptions in the financial markets could make it more difficult and more expensive for us to obtain financing. In addition, the adoption of

new statutes and regulations, the implementation of recently enacted laws or new interpretations or the enforcement of older laws and regulations applicable to the financial markets or the financial services industry could result in a reduction in the amount of available credit or an increase in the cost of credit. Historically, we have relied on Alliqua and its credit facilities and its access to capital for our financing needs but, after the Spin-Off, we will not have access to Alliqua's financial resources. There can be no assurance that, as a new independent public company, we will have sufficient access to the capital markets on terms that we will we find acceptable.

# Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial results or financial condition.

GAAP and related accounting pronouncements, implementation guidelines and interpretations with regard to a wide range of matters that are relevant to our business, including but not limited to revenue recognition, business combinations, impairment of goodwill, indefinite-lived intangible assets and long-lived assets, inventory and equity-based compensation, are highly complex and involve many subjective assumptions, estimates and judgments. Changes in these rules or their interpretation or changes in underlying assumptions, estimates or judgments could significantly change our reported or expected financial performance or financial condition.

# Our ability to pursue strategic acquisitions and partnerships may impact our ability to compete in the markets we serve.

Besides pursuing organic growth, we may explore potential strategic acquisitions that could allow us to expand our operations. However, we may be unable to identify attractive candidates or complete acquisitions on terms favorable to us. In addition, our ability to successfully integrate the operations we acquire and leverage these operations to generate revenue and earnings growth may significantly impact future revenue and earnings as well as investor returns. Integrating acquired operations is a significant challenge and there is no assurance that we will be able to manage such integrations successfully. Failure to successfully integrate acquired operations may adversely affect our cost structure, thereby reducing our margins and return on investment.

We have also entered into, and expect to seek to enter into, additional strategic partnerships with other industry participants as part of an effort to expand our business. However, we may be unable to identify attractive strategic partnership candidates or complete such partnerships on terms favorable to us. In addition, if we are unable to successfully implement our partnership strategies or our strategic partners do not fulfill their obligations or otherwise do not prove advantageous to our business, our investments in such partnerships and our anticipated business expansion could be adversely affected.

Achieving our growth objectives may prove unsuccessful. We may be unable to identify future attractive acquisitions and strategic partnerships, which may adversely affect our growth. In addition, our ability to consummate or integrate acquisitions or to consummate or implement our strategic partnerships may be materially and adversely affected.

### **Risks Relating to TOP's Business**

## There is substantial uncertainty about TOP's ability to continue as a going concern.

For the fiscal year ended December 31, 2018, TOP recorded a net loss from operations of (\$1,171,494) and used cash in operating activities of \$621,899. TOP has incurred losses since inception, resulting in a members' equity deficit of \$1,933,203 as of December 31, 2018. In light of, among other things, TOP's working capital deficit, lack of available cash and cash equivalents and history of operating losses, it is unclear whether TOP will be successful in accomplishing its objectives and there is substantial uncertainty about TOP's ability to continue as a going concern.

# The report of TOP's independent registered public accounting firm contains an explanatory paragraph as to its ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because TOP has recurring losses, negative cash flows from operating activities, and minimal cash on hand, the report of TOP's independent registered public accounting firm, with respect to its financial

statements at December 31, 2018, and for the year ended December 31, 2018, contains an explanatory paragraph as to TOP's potential inability to continue as a going concern. This opinion indicates that substantial doubt exists regarding TOP's ability to remain in business. Such an opinion may adversely affect our ability to obtain new financing on reasonable terms or at all.

# TOP may not be able to successfully develop its pharmaceutical business.

TOP's ability to successfully develop its pharmaceutical business depends on its ability to collaborate with leading medical experts in drug development and clinical research, to identify, develop and commercialize new therapeutic approaches for the treatment of certain medical conditions and diseases as well as the symptoms of disease, to create unique therapeutics capable of patent or other intellectual property protection, and to compete with major pharmaceutical companies and other already established cannabis drug companies. TOP's inability to successfully implement the above could have a detrimental impact on its pharmaceutical business.

# TOP's success will largely depend on the success of its drug candidates, the development of which will require significant capital resources and years of clinical development effort.

While TOP is in the process of conducting certain pre-clinical and clinical trials in Israel, TOP currently has no drug products on the market. TOP's business depends almost entirely on the successful clinical development, regulatory approval and commercialization of its drug candidates. Investors need to be aware that substantial additional investments, including further clinical development and regulatory approval efforts, will be required before TOP is permitted to market and commercialize any drug candidates, and such commercialization may never occur. Clinical trials are subject to extensive and rigorous review and regulation by numerous government authorities in the United States, the European Union, Israel and other jurisdictions where TOP intends, if approved, to conduct research and development efforts and market its drug candidates. Before obtaining regulatory approvals for any of drug candidates, TOP must demonstrate through pre-clinical testing and clinical trials that the drug candidate is safe and effective for its specific application. This process generally is lengthy and may include postmarketing studies and surveillance, and is expected to require the expenditure of substantial resources. Of the large number of drugs in development for approval in the United States and the European Union, only a small percentage will successfully complete the FDA regulatory approval process or be granted authorization to be marketed in the European Commission or the other competent authorities in the European Union ("EU") Member States. Accordingly, even if TOP obtains sufficient financing to fund its current and any additional planned research, development and clinical programs, TOP cannot provide any assurances that any of its drug candidates will be successfully developed or commercialized.

TOP may be unable to formulate or scale-up any or all of its drug candidates. There is no guarantee that any of these drug candidates will be able to be produced in a manner sufficient to meet the applicable criteria for product stability, content uniformity and all other criteria necessary for product approval in the United States and other markets. Any of TOP's drug candidates may fail to achieve their specified endpoints in clinical trials. Furthermore, drug candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with TOP's trial design and interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for TOP's clinical trials. The FDA may also approve a drug for fewer or more limited indications than TOP requests, or may grant approval contingent on the performance of costly post-approval clinical trials (i.e., Phase IV trials). In addition, the FDA may approve the labeling claims that TOP believes are necessary or desirable for the successful commercialization of its drug candidates. TOP faces similar challenges in jurisdictions outside the U.S.

If TOP is unable to expand its pipeline and/or obtain regulatory approval for its drug candidates on the timelines it anticipates, TOP will not be able to execute its business strategy effectively and its ability to substantially grow its revenues will be limited, which could have a material adverse effect on the business, results of operations, financial condition and prospects of TOP.

## TOP's drug candidates may contain controlled substances the use of which may generate public controversy.

Since TOP's drug candidates may contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in

approval of, and increased expenses for, TOP's drug candidates. These pressures could also limit or restrict the introduction and marketing of its drug candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid-derived drugs may adversely affect the commercial success or market penetration achievable by its drug candidates. The nature of its business will likely attract a high-level of public and media interest, and in the event of any resultant adverse publicity, TOP's reputation may be harmed.

TOP's drug candidates are derived from cannabinoid strains which are marketed and sold by unaffiliated third parties in certain states within the U.S., Canada, Australia and elsewhere under licenses from TOL or sublicenses from TOG. TOP cannot control the products sold or claims asserted by such third parties, and no assurance can be given that any such claims might not adversely affect TOP's ability to obtain regulatory approval of its drug candidate products.

#### TOP's products or prospective products may become subject to U.S. controlled substance laws and regulations.

TOP's products and prospective products are likely to contain controlled substances as defined in the U.S. federal Controlled Substances Act of 1970, or CSA. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is also restricted. For example, they may not be refilled without a new prescription.

While cannabis is a Schedule I controlled substance, products approved for medical use in the U.S. that contain cannabis or cannabis extracts should be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. If and when any of TOP's prospective products receive FDA approval, the DEA will make a scheduling determination and place it in a schedule other than Schedule I for it to be prescribed for patients in the United States. If approved by the FDA, TOP expects the finished dosage forms of any of its drug candidates to be listed by the DEA as a Schedule II or III controlled substance. Consequently, their manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use will be subject to a significant degree of regulation by the DEA. The scheduling process may take one or more years beyond FDA approval, thereby significantly delaying the launch of TOP's drugs. However, the DEA must issue a temporary order scheduling necessing and the Deat receives a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services. Furthermore, if the FDA, DEA or any foreign regulatory authority determines that any of TOP's drugs may have potential for abuse, it may require us to generate more clinical data than that which is currently anticipated, which could increase the cost and/or delay the launch of TOP's drugs.

# Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit TOP's ability to sell its proposed cannabis-based products and/or their use in medical treatments.

Most countries are parties to the Single Convention on Narcotic Drugs 1961 and its successor treaties, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in ways that create a legal obstacle to obtaining approval for TOP's products and the prospective use of these products in various medical treatments. These countries and any country with similar obstacles may not be willing or able to amend or otherwise modify their laws and regulations to allow TOP's products or prospective products to be marketed and treatments to be administered, which would adversely affect TOP's business, operations, financial condition and prospects.

# Changes in consumer preferences and acceptance of cannabinoid-based medical products and treatments and any negative trends could adversely affect TOP's business.

TOP is substantially dependent on initial and continued market acceptance and proliferation of cannabinoidbased drugs and treatments. TOP believes that as cannabinoid-derived drugs become more widely accepted by the medical and scientific communities and the public at large, the stigma associated with cannabinoid-derived drugs and treatments will moderate and, as a result, consumer demand will likely continue to grow; however, TOP cannot predict the future growth rate and size of the market, or that the regulatory framework will be favorable, of which there can be no assurance. Any negative trend in outlook on cannabinoid-based medical products would adversely affect TOP's business prospects. Further, TOP cannot provide any assurance that any of its drug candidates will achieve the expected market acceptance and revenue, if and when it obtains the necessary regulatory approvals.

In addition, the market acceptance of any drug depends on a number of factors, including the indication statement and warnings approved by regulatory authorities for the drug label, continued demonstration of efficacy and safety in commercial use, physicians' willingness to prescribe the drug, reimbursement from third-party payers such as government health care systems and insurance companies, the price of the drug, the nature of any post-approval risk management plans mandated by regulatory authorities, competition, and marketing and distribution support. Any factors preventing or limiting the market acceptance of TOP's drugs could have a material adverse effect on the business, results of operations, financial condition and prospects of TOP.

# The pharmaceutical industry is well-funded with a strong and experienced lobbying presence at both the federal and state levels, as well as internationally, that surpasses financial resources of the current group of medical cannabinoid research and development companies.

Some believe that large, well-funded pharmaceutical and other related businesses and industries may have material economic reasons to be in strong opposition to cannabinoid-based drugs, and anecdotal reports indicate that the pharmaceutical industry has provided funding to oppose cannabis legal reform efforts. Continued or increased effort by the pharmaceutical lobby opposing cannabinoid products could or might impede or delay the development of cannabinoid-based drugs and could have a detrimental impact on the business, results of operations, financial condition and prospects of TOP.

# Clinical trials of cannabinoid-based drug candidates and treatments are risky, in part because they are novel, with very limited or non-existing clinical trial history.

While TOP is encouraged by the limited preliminary results of its pre-clinical studies and clinical trials and the clinical trials of others, TOP cannot provide any assurance regarding any conclusions from or proof that its assumptions for any trials are scientifically compelling, or that any clinical trial will result in commercially viable drugs or treatments. Furthermore, no officer or manager of TOP other than Seth Yakatan, TOP's CEO, and Dr. Mitchell Glass, TOP's Chief Medical Officer, has a direct record of accomplishing or conducting such scientific studies, and TOP does not have an internal infrastructure capable of conducting clinical trials. As a result, TOP faces a significant risk that requires it to use outsourced researchers for studies or trials, which is and may continue to be highly costly.

Clinical trials are expensive, time consuming and difficult to design and implement. TOP, as well as the applicable regulatory authorities, may suspend, delay or terminate TOP's clinical trials at any time, may require TOP, for various reasons, to conduct additional clinical trials, or may require a particular clinical trial to continue for a longer duration than originally planned, including, among others:

- · lack of effectiveness of any formulation or delivery system during clinical trials;
- discovery of serious or unexpected toxicities or drug-related side effects experienced by trial participants or other safety issues;
- · slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;

- delays, capacity constraints or other inability to manufacture or otherwise obtain sufficient quantities of materials for use in clinical trials due to regulatory, manufacturing or other limitations;
- delays in obtaining regulatory authorization to commence a trial, including DEA, FDA or Institutional Review Board ("IRB") approvals, licenses or waivers required for obtaining and using cannabis or cannabinoid derived substances for research, either before or after a trial is commenced;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- · patients or investigators failing to comply with study protocols;
- patients failing to return for post-treatment follow-up at the expected rate;
- sites participating in an ongoing clinical study withdrawing, requiring us to engage new sites;
- third-party clinical investigators declining to participate in TOP's clinical studies, not performing the clinical studies on the anticipated schedule, or acting in ways inconsistent with the established investigator agreement, clinical study protocol, good clinical practices, or other IRB requirements;
- · third-party entities not performing data collection and analysis in a timely or accurate manner or at all; or
- regulatory inspections of TOP's clinical studies that require it to undertake corrective action or suspend or terminate its clinical studies, including DEA or comparable foreign regulatory authority-related recordkeeping, reporting or security violations at a clinical trial site.

Any of the foregoing could have a material adverse effect on the business, results of operations, financial condition and prospects of TOP.

## Results of preclinical studies and earlier clinical trials are not necessarily predictive indicators of future results.

Any positive results from pre-clinical testing of TOP's drug candidates and clinical trials may not necessarily be predictive of the results from Phase 1, Phase 2 or Phase 3 clinical trials. In addition, TOP's interpretation of results derived from clinical data or its conclusions based on its pre-clinical data may prove inaccurate. Frequently, pharmaceutical and biotechnology companies have suffered significant setbacks in clinical trials after achieving positive results in pre-clinical testing and early clinical trials, and TOP cannot be certain that it will not face similar setbacks. These setbacks may be caused by pre-clinical and clinical data being susceptible to varying interpretations and analyses. Furthermore, certain drug candidates may perform satisfactorily in pre-clinical studies and clinical trials, but nonetheless fail to obtain FDA approval, a marketing authorization granted by the European Commission, or appropriate approvals by government authorities in other countries. If TOP fails to produce positive results in its clinical trials for its drug candidates, the development timeline and regulatory approval and commercialization prospects for them, as well as the results of TOP's business, results of operations, financial condition and prospects, would be materially adversely affected.

# The regulatory approval processes with the FDA, the European Medicines Agency (the "EMA") and other comparable foreign regulatory authorities are lengthy and inherently unpredictable.

TOP is not permitted to market its drug candidates in the United States or the European Union until it receives approval of a New Drug Application ("NDA") from the FDA or a Marketing Authorization Application ("MAA") from the European Commission, respectively, or in any foreign countries until it receives the approval from the regulatory authorities of such countries. Prior to submitting an NDA to the FDA or an MAA to the EMA for approval of its drug candidates, TOP will need to have completed its pre-clinical studies and clinical trials. Successfully completing any clinical program and obtaining approval of an NDA or MAA is a complex, lengthy, expensive and uncertain process, and the FDA or EMA may delay, limit or deny approval of drug candidates for many reasons, including, among others:

 an inability to demonstrate that TOP's drug candidates are safe and effective in treating patients to the satisfaction of the FDA or EMA;



- results of clinical trials that may not meet the level of statistical or clinical significance required by the FDA or EMA;
- disagreements with the FDA or EMA with respect to the number, design, size, conduct or implementation
  of clinical trials;
- requirements by the FDA and EMA to conduct additional clinical trials;
- disapproval by the FDA or EMA or other applicable foreign regulatory authorities of certain formulations, labeling or specifications of drug candidates;
- findings by the FDA or EMA that the data from preclinical studies and clinical trials is insufficient;
- the FDA or EMA may disagree with the interpretation of data from preclinical studies and clinical trials; and
- the FDA, European Commission or other applicable foreign regulatory agencies may change their approval policies or adopt new regulations.

Any of these factors, many of which are beyond TOP's control, could increase development costs or jeopardize TOP's ability to obtain regulatory approval for its drug candidates.

# TOP may apply for orphan drug status granted by the FDA for some of its drug candidates for the treatment of rare diseases, and orphan drug status does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals annually in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union. Additionally, such designation is granted for drugs intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug.

In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. In addition, if a drug receives the first FDA approval for the drug and indication for which it has orphan drug designation, the drug is entitled to seven years of market exclusivity, which means the FDA may not approve any other application for the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan drug exclusivity.

Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. In the European Union, orphan drug designation also entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the drug is sufficiently profitable so that market exclusivity is no longer justified.

# TOP expects to face intense competition, often from companies with greater resources and experience than TOP has.

Demand for cannabinoid-derived drugs will likely be dependent on a number of social, political and economic factors that are beyond TOP's control. While TOP believes that there will be a demand for such drugs, and that the demand will grow, there is no assurance that such demand will happen, that TOP will benefit from any demand or that its business, in fact, will ever generate revenues from its drug development activities or become profitable.

The emerging market for cannabinoid-derived drugs and medical research and development is and will likely remain competitive. The development and commercialization of drugs is highly competitive. TOP competes with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as products and processes being developed by universities and other research institutions. Many of TOP's competitors have developed, are developing, or will develop drugs and processes competitive with its drug candidates. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments that may enter the market. For some of TOP's drug development candidates, other treatment options are currently available, under development, and may become commercially available in the future. If any of TOP's drug candidates is approved for the diseases and conditions it is currently pursuing, they may compete with a range of therapeutic treatments that are either in development or currently marketed.

TOP is aware of many companies that are engaged in cannabinoid-derived drug development activities. In addition, other U.S.-based and foreign-based companies are in early stage discovery and preclinical development utilizing the cannabinoids CBD and/or THC, as well as other cannabinoids.

Established companies may have a competitive advantage over TOP due to their size and experience, financial resources, and institutional networks. Many of TOP's competitors may have significantly greater financial, technical and human resources than TOP. Due to these factors, TOP's competitors may have an advantage in marketing their approved drugs and may obtain regulatory approval of their drug candidates before TOP is able to, which may limit its ability to develop or commercialize its drug candidates. TOP's competitors may also develop drugs that are safer, more effective, more widely used and less expensive. These advantages could materially impact TOP's ability to develop and, if approved, commercialize its drug candidates successfully. Furthermore, some of these competitors may make acquisitions or establish collaborative relationships among themselves or with third parties to increase their ability to rapidly gain market share.

TOP's drug candidates may compete with other plant-derived or synthetic cannabinoid drugs, in addition to competing with state-licensed medical and adult-use cannabis, in markets where the medical and/or adult use of cannabis is legal. There is continuing support in the United States for further state legalization of cannabis. In markets where medical and/or adult-use cannabis is not legal, TOP's drug candidates, once approved by regulators, may compete with cannabis or cannabis-based products purchased in the illegal drug market.

As generic versions of drug products enter the market, the price for such drugs may be expected to decline rapidly and substantially. Even if TOP is the first to obtain FDA approval of one of its drug candidates, the future potential approval of generics could adversely affect the price it is able to charge and the profitability of its product would likely decline.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in more resources being concentrated among a smaller number of TOP's competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies may compete with TOP in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to TOP's research projects.

### Product shipment delays could have a material adverse effect on TOP's business, results of operations, financial condition and prospects.

The shipment, import and export of any products which TOP develops require import and export licenses. In the U.S., the FDA, U.S. Customs and Border Protection and the DEA, and in the United Kingdom, the Home Office, and in other countries, similar regulatory authorities regulate the import and export of pharmaceutical products that contain controlled substances. TOP may not be granted, or if granted, maintain, such licenses from the authorities in certain countries. Even if TOP obtains the relevant licenses, shipments of any products which TOP develops may be held up in transit, which could cause significant delays and may lead to product batches being stored outside required temperature ranges. Inappropriate storage may damage product shipments, resulting in a partial or total

loss of revenue from one or more shipment of any products which TOP develops. A partial or total loss of revenue from one or more shipments could have a material adverse effect on TOP's business, results of operations, financial condition and prospects.

### Failure to obtain regulatory approval in jurisdictions outside the United States, Israel and the European Union would prevent TOP's drug candidates from being marketed in those jurisdictions.

To market and sell TOP's future drugs in jurisdictions other than the United States, Israel and the European Union, TOP must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The regulatory approval process outside the United States, Israel and the European Union generally includes all of the risks associated with obtaining FDA approval or approval from the Israeli Ministry of Health or the European Commission but may involve additional testing.

TOP may need to partner with third parties to obtain approvals outside the United States, Israel and the European Union. In addition, in many countries worldwide, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. TOP may not obtain approvals from regulatory authorities outside the United States, Israel and the European Union on a timely basis, if at all. Even if TOP were to receive approval in the United States, Israel or the European Union, such approval does not ensure approval by regulatory authorities in other countries or jurisdictions. Similarly, approval by one regulatory authorities in other countries or by the FDA, Israeli Ministry of Health or the European Commission. If TOP is unable to obtain approval of its drug candidates may be significantly reduced, and this could have a material adverse effect on TOP's business, results of operations, financial condition or prospects.

### Laws and regulations affecting therapeutic uses of cannabinoids are constantly evolving and the legalization and use of medical and recreational cannabis in the U.S. and elsewhere may impact TOP's business.

There is a substantial amount of change occurring in the U.S. regarding the use of medical and adult-use cannabis products. While cannabis products not approved by FDA are Schedule I substances as defined under federal law, and their possession and use is not permitted according to federal law, 34 states in the United States, plus the District of Columbia, Puerto Rico and Guam, have legalized the use of medical cannabis. Ten states, plus the District of Columbia, that have legalized the use of adult-use cannabis. Sixteen states have legalized high-CBD, low-THC oils for a limited class of patients and 13 states, plus the U.S. Virgin Islands, have decriminalized cannabis, which generally means that there is no arrest, prison time, or criminal record for the first-time possession of a small amount of cannabis for personal consumption. The 2018 U.S. Farm Bill, de-scheduled CBD extracts and other material derived from certain hemp plants with extremely low THC content, although the marketing of such products for medical or other purposes would still be subject to regulatory premarketing approval requirements and other applicable laws and regulations, including by the FDA. Although TOP's business is quite distinct from that of non-FDA approved cannabis products could affect its business, results of operations, financial condition or prospects.

The potential ongoing evolution of laws and regulations affecting the research and development of cannabinoid-based medical drugs and treatments could detrimentally affect TOP's business. Laws and regulations related to the therapeutic uses of cannabinoid-based drugs may be subject to changing interpretations. These changes may require TOP to incur substantial costs associated with legal and compliance fees and may ultimately require TOP to alter its business plan. Furthermore, violations or alleged violation of these laws could disrupt TOP's business and result in a material adverse effect on its business, results of operations and financial condition. In addition, TOP cannot predict the nature of any future laws, regulations, interpretations or applications of laws and regulations may be enacted in the future that will be directly applicable to its business.

TOP has not commenced active development of or any preclinical studies or clinical trials with respect to any pharmaceutical products in the United States. To date, TOP has conducted all research and all development activities concerning any cannabinoids in Israel. TOP intends to continue its drug

development activities in jurisdictions, including Israel, with more favorable laws and regulations regarding research using plant-derived cannabinoids. Therefore, TOP does not believe that any of its current operations are subject to federal or state laws regarding the possession or use of cannabis products.

### TOP's failure to comply with existing and potential future laws and regulations relating to drug development could harm its business.

TOP's business is, and will be, subject to wide-ranging existing federal and state laws and regulations and other governmental bodies in each of the countries it may develop and/or market its drug candidates. TOP must comply with all regulatory requirements if it expects to be successful.

If any of TOP's cannabinoid-derived drug candidates are approved in the United States, they will be subject to ongoing regulatory requirements, including federal and state requirements. As a result, TOP and its collaborators and/or joint venture partners must continue to expend time, money and effort in all areas of regulatory compliance, including, if applicable, manufacturing, production, quality control and assurance and clinical trials. TOP will also be required to report certain adverse reactions and production problems, if any and applicable, to the FDA, and to comply with advertising and promotion requirements for its cannabinoid-derived drug candidates.

Any failure to comply with ongoing regulatory requirements may significantly and adversely affect its ability to conduct clinical trials which are prerequisites to its ability to commercialize TOP's cannabinoid-based drugs and related treatments. If regulatory sanctions are applied or if regulatory approval, once obtained, is for any reason withdrawn, TOP's business, results of operations, financial condition or prospects could be materially adversely affected.

## Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for TOP to obtain marketing approval of and commercialize its product candidates.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of TOP's product candidates, restrict or regulate post-approval activities or affect its ability to profitably sell any product candidates for which it obtains marketing approval.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact TOP's business, results of operations, financial condition or prospects. The Affordable Care Act is likely to continue the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program, and may also increase TOP's regulatory burdens and operating costs.

TOP expects that the Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that it receives for any approved product, and could seriously harm its future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may compromise its ability to generate revenue, attain profitability or commercialize TOP's products. In addition, other legislative changes have been proposed and adopted since passage of the Affordable Care Act. If TOP ever obtains regulatory approval and commercializes its products, new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on TOP's customers and accordingly, its business, results of operations, financial condition or prospects.



### *Even if TOP is able to commercialize its products, the products may not receive coverage and adequate reimbursement from third-party payors, which could harm its business.*

The availability of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive drug treatments. Sales of TOP's products, if approved, will depend substantially on the extent to which the costs of these products will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, TOP may not be able to successfully commercialize its products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow TOP to establish or maintain pricing sufficient to realize a sufficient return on TOP's investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including cannabinoid-based products. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or "CMS", an agency within the U.S. Department of Health and Human Services, or "HHS", as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Furthermore, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors. In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or "Medicare Modernization Act", established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could decrease the coverage and reimbursement rate that TOP receives for any of its approved products.

The intended use of a drug product by a physician can also affect pricing. For example, CMS could initiate a National Coverage Determination administrative procedure, by which the agency determines which uses of a therapeutic product would and would not be reimbursable under Medicare. This determination process can be lengthy, thereby creating a long period during which the future reimbursement for a particular product may be uncertain.

Outside the United States, including in member states of the European Union, the pricing of prescription drugs often is subject to governmental control. In these countries, pricing negotiations or the successful completion of health technology assessment procedures with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Certain countries allow companies to fix their own prices for medicines but monitor and control company profits. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, TOP or its collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of its product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, TOP's business, financial condition, results of operations or prospects could be adversely affected.

### TOP is an early stage company with limited operating history or experience.

TOP is an early stage company with no operating revenue to date. As such, it is extremely difficult to make accurate predictions and forecasts of its finances and prospective investors do not have a significant operating history upon which to evaluate TOP's ability to achieve its current business plan and future objectives. This is compounded by operating in the pharmaceutical industry, which is rapidly transforming.

There can no assurance that TOP's products or services will be or remain attractive to potential and current. Furthermore, TOP's management may have limited insight into trends that might emerge and could materially affect TOP's business, results of operations, financial condition or prospects.

### TOP has experienced substantial cash flow and financing constraints.

TOP's business has generated net losses and negative cash flows from operating activities since its inception. In the near term, TOP expects that its net losses and cash used in operating activities will increase as compared to prior periods as it increases its development activities. TOP expects to incur additional losses as it continues to research and develop drug candidates and conduct clinical trials, and in any event, until its revenues exceed its expenses. Even if TOP succeeds in obtaining regulatory approval to market its products, it may still incur losses for the foreseeable future.

### Managers of TOP may pursue other ventures.

The obligations to TOP of its managers and executive officers are not exclusive, and TOP's managers and executive officers may be involved in other business activities. Liabilities incurred and commitments undertaken by officers, members, managers or general partners with respect to projects other than TOP's business could adversely affect their ability to manage TOP. Such activities could compete with TOP and/or result in a conflict of interest. Conflicts of interest may expose TOP to the risks, among others, that such persons' allocation of time to TOP, or that decisions made on behalf of TOP, or transactions entered into between TOP and such persons may not reflect the best interests of TOP or its members from their perspective.

### The directors and officers and a small number of stockholders will own a large percentage of AquaMed's equity and such directors and officers will have the ability to control matters affecting AquaMed's stockholders.

The directors and officers of AquaMed beneficially own approximately 29.1% of AquaMed's outstanding shares of common stock, and together with four additional stockholders would beneficially own a majority of AquaMed's outstanding shares of common stock. The AquaMed shareholders elect TOP's Board of Directors and have the ability to control the acquisition or disposition of TOP's assets, and the future issuance of its capital stock. Accordingly, other shareholders will find it impossible to replace TOP's directors if they disagree with the way TOP's business is being operated. Because the influence by these insiders could result in management making decisions that are in the best interest of those insiders and not in the best interest of the shareholders, shareholders may lose some or all of the value of their investment in AquaMed.

### If TOP is unable to meet its future capital needs, TOP may be required to reduce or curtail operations or shut down completely.

TOP's future capital requirements will depend on many factors, including:

- its ability to successfully implement its business objectives and strategic growth plans;
- its ability to obtain and maintain relationships with third-parties conducting pre-clinical studies and clinical trials and such persons fulfilling their obligations;
- development of novel pharmaceutical products;
- market acceptance of its drug candidates, once approved for sale;
- generating cash flow from operations;
- · locating and retaining talent; and
- · market and regulatory developments.

Based on TOP's current financial situation, it may have difficulty continuing its operations at its current level, or at all, if it does not raise additional financing in the near future. Although TOP currently has no specific arrangements for additional financing, TOP intends to raise funds through private placements, public offerings or other financings. Sources of debt financing may result in high interest



expense or be difficult to procure and would increase the liabilities and future cash commitments of TOP. Any financing, if available, may be on unfavorable terms, and TOP may be forced to relinquish rights to its proprietary compounds, technology or other intellectual property or marketing rights, which could result in the receipt of only a portion of any revenue that may be generated from a partnered product or business. If adequate funds are not obtained, TOP may be required to reduce, curtail, or discontinue operations. There is no assurance that TOP's cash flow will be adequate to satisfy its existing operating expenses and capital requirements. In addition, if TOP issues equity or convertible debt securities to raise additional funds, its existing shareholders may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of existing shareholders.

### There is no assurance that TOP will generate significant revenues, earn profits or pay distributions.

There is no assurance as to whether TOP will generate significant revenues, be profitable, or pay dividends or distributions to its members. TOP anticipates that it will continue to incur substantial expenses relating to the development and operation of its business for the foreseeable future. TOP currently intends to retain any future earnings for reinvestment in TOP's business until TOP generates sufficient excess cash flow to pay dividends or distributions.

The payment and amount of any future distributions will be made at the discretion of the Board of Directors of AquaMed, and will depend upon, among other things, the results of TOP's operations, cash flows and financial condition, operating and capital requirements, and other factors as the Board considers relevant. There is no assurance that future dividends or distributions will be paid, and, if dividends or distributions are paid, there is no assurance with respect to the amount of any such dividends or distributions.

### TOP may not be able to effectively manage its growth and operations, which could materially and adversely affect its business, results of operations, financial condition and prospects.

TOP may in the future experience rapid growth and development in a relatively short period of time. The management of this growth will require, among other things, continued development of TOP's financial and management controls and management information systems, stringent control of costs, the ability to attract and retain qualified management personnel and the training of new personnel. TOP intends to utilize outsourced resources, and hire additional personnel, in order to manage its expected growth and expansion. Failure to successfully manage its possible growth and development could have a material adverse effect on the business, results of operations, financial condition and prospects of TOP.

### TOP may be unable to adequately protect its proprietary and intellectual property rights.

TOP's ability to compete may depend on the superiority, uniqueness and value of its intellectual property and technology, including both internally developed intellectual property and technology and intellectual property licensed from third parties such as TOL. To the extent TOP is able to do so, in order to protect the proprietary rights of TOP and/or TOL, TOP intends to rely on a combination of patent, trademark, copyright and trade secret laws, confidentiality agreements with its employees and third parties, and protective contractual provisions. Despite these efforts, any of the following occurrences may reduce the value of TOP's intellectual property:

- U.S. federal trademark and patent protection may not be available for the intellectual property of TOP due to the current classification of cannabis and CBD as a Schedule I controlled substance;
- The market for TOP's products and services may depend to a significant extent upon the goodwill
  associated with its patents, trademarks and trade names, and its ability to register its intellectual property
  under U.S. federal and state law may be impaired by the illegality of cannabis and related drug
  paraphernalia under U.S. federal law;
- Patents containing cannabinoid-derived compositions and/or methods industry involve complex legal and scientific questions and patent protection may not be available for some products, strains or brands;



- Certain products based on previously known cannabinoids found in nature may not be subject to effective patent protection;
- TOP's pending patent applications, provisional patent applications and applications for trademarks and copyrights relating to its business may not be granted and, if granted, may be challenged or invalidated;
- Issued patents, trademarks and registered copyrights may not provide TOP with any competitive advantages;
- TOP's efforts to protect its intellectual property rights may not be effective in preventing misappropriation of any of its technology, products or intellectual property;
- TOP's efforts may not prevent the research, development and design by others of products or technologies similar to or competitive with, or superior to those TOP develops;
- Another party may obtain a blocking patent and TOP would need to either obtain a license or design
  around the patent in order to continue to offer the contested feature or service in its products; or
- Much of the intellectual property which TOP utilizes, including certain cannabis strains, is owned by TOL, and is licensed by TOP pursuant to the licenses therefrom. In the event that such license was terminated, TOP would no longer be permitted to use such intellectual property. In such event, the resources where TOP had invested therein would have been wasted.

In addition, TOP does not know whether any of the pending patent applications or provisional patents for any of its drug candidates will result in the issuance of patents. The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have often been the subject of litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any of TOP's potential future patents are highly uncertain. The steps TOP will take to protect its proprietary rights may not be adequate to preclude misappropriation of its proprietary information or infringement of its intellectual property rights, both inside and outside the United States. Patent examination processes may require TOP to narrow the claims for its pending patent applications, which may limit the scope of patent protection that may be obtained if the patents are granted. The rights to be granted under future patents issued to OTOP may not provide TOP with the proprietary protection or competitive advantages it seeks. If TOP is unable to obtain and maintain patent protection for its technology and drugs, or if the scope of the patent protection obtained is not sufficient, TOP's competitors could develop and commercialize technology and drugs similar or superior to TOP's, and its ability to successfully commercialize its technology and drugs may be adversely affected.

The issuance of a patent may not always be conclusive as to its inventorship, scope, validity or enforceability. TOP's issued patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit TOP's ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection for TOP's technology and drugs.

### Federal trademark and patent protection may not be available for the intellectual property of TOP due to the current classification of cannabis and CBD as a Schedule I controlled substance.

As long as cannabis remains illegal under U.S. federal law as a Schedule I controlled substance pursuant to the CSA, the benefit of certain federal laws and protections which may be available to most businesses, such as federal trademark and patent protection regarding the intellectual property of a business, may not be available to TOP in the United States. As a result, TOP's intellectual property may never be adequately or sufficiently protected against the use or misappropriation by third-parties in the United States. In addition, since the regulatory framework of the cannabis industry is in a constant state of flux, TOP can provide no assurance that it will ever obtain any protection of its intellectual property, whether on a federal, state or local level in the United States.

### Costly litigation may be necessary to protect TOP's intellectual property rights and TOP may be subject to claims alleging the violation of the intellectual property rights of others.

TOP may face significant expense and liability due to litigation or other proceedings relating to patents and other intellectual property rights of others. If another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by TOP in pending applications, TOP may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and costs for TOP, even if the eventual outcome were favorable to TOP. TOP or TOL also could be required to participate in an interference proceeding sinvolving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require TOP to cease using the technology or to license rights from prevailing third parties.

The cost to TOP of any patent application or patent litigation, even if resolved in TOP's favor, could be substantial. TOP's ability to enforce its patent protection could be limited by its financial resources, and may be subject to lengthy delays.

A third party may claim that TOP uses inventions claimed by their patents and may go to court to stop TOP from engaging in research, development and/or the sale of any of TOP's future drugs. Such lawsuits are expensive and would consume time and other resources. There is a risk that the court will decide that TOP is infringing on the third party's patents and will order TOP to stop the activities claimed by the patents. In addition, there is a risk that a court will order TOP to pay the other party damages for having infringed their patents.

Moreover, there is no assurance that any prevailing patent owner would offer TOP a license so that it could continue to engage in activities claimed by the patent, or that such a license, if made available to TOP, could be acquired on commercially acceptable terms. In addition, third parties may in the future, assert other intellectual property infringement claims against TOP with respect to its drug candidates, technologies or other matters.

### TOP relies on confidentiality agreements that could be breached and may be difficult to enforce which could result in third parties using its intellectual property to compete against them.

TOP has taken and will continue to take reasonable steps to protect TOP's intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to TOP of the rights to the ideas, developments, discoveries and inventions of its employees and consultants while it employs them. These agreements may be difficult and costly to enforce. Although TOP has obtained and plans to continue to obtain these types of agreements from these third parties, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of TOP's projects, disputes may arise as to the intellectual property rights associated with its drug candidates. If a dispute arises, a court may determine that the right belongs to a third party. Enforcement of TOP's rights can be costly and unpredictable. Despite the protective measures TOP employs, TOP will still face the risk that:

- these agreements may be breached;
- · these agreements may not provide adequate remedies for the applicable type of breach;
- TOP's trade secrets or proprietary know-how will otherwise become known; or
- TOP's competitors will independently develop similar technology or proprietary information.

### Intellectual property rights may not necessarily address all potential threats to TOP's competitive advantage.

The degree of future protection afforded by TOP's intellectual property rights may be uncertain because intellectual property rights have limitations, and may not adequately protect TOP to enable it to maintain any competitive advantage. The following factors may weaken its protection:

 compounds or formulations may be made by others that are the same or similar to TOP's drug candidates, but are not covered by TOP's patent claims;

- inventions covered by TOP's patents or pending patents may have been discovered by others previously;
- independently developed similar or alternative technologies may duplicate any of TOP's proprietary
  assets without infringing TOP's intellectual property rights;
- pending patents may not lead to issued patents;
- any patents issued in the future may not provide TOP with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- TOP's competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where TOP does not have patent rights; and
- · the patents of others may have an adverse effect on TOP's business.

#### TOP may become subject to litigation or regulatory action.

TOP may be named as a defendant in a lawsuit or regulatory action. TOP may also incur uninsured losses for liabilities which arise in the ordinary course of business, or which are unforeseen, including, but not limited to, employment liability and business loss claims. There is no assurance that shareholders will not lose their entire investment in TOP as a result of unforeseen litigation or regulatory action.

### If TOP is unable to attract and retain key personnel, it may not be able to compete effectively in the cannabis market.

As of March 25, 2019, TOP has one full-time employee and three consultants. TOP's success will depend, in part, on its ability to attract and retain key scientific, management and other personnel. There is intense competition for qualified personnel in TOP's area of activities, and TOP may not be able to attract and retain the qualified personnel necessary for the development of its business. In addition, TOP may have difficulty recruiting necessary personnel as a result of its limited operating history.

TOP will attempt to enhance its management, scientific and technical expertise by continuing to recruit qualified individuals who possess desired skills and experience in certain targeted areas and has entered into agreements with TOL to obtain the services of certain experienced scientific/technical personnel. TOP's inability to retain employees and attract and retain sufficient additional employees or other scientific, engineering and technical support resources, could have a material adverse effect on TOP's business, results of operations, financial condition and prospects.

### TOP may suffer uninsured losses.

TOP does not currently have insurance coverage such as general liability, fire or other similar policies that may be customarily obtained for businesses similar to TOP, and any such event could cause significant losses for which no recovery would be available, and which could result in a material adverse impact on TOP's business, results of operations, financial condition and prospects. Certain types of losses of a catastrophic nature, such as losses resulting from floods, tornadoes, thunderstorms, and earthquakes, are uninsurable or not economically insurable to the full extent of potential loss. Acts of God, work stoppages, regulatory actions or other causes, could adversely affect TOP's business, operations, financial condition and prospects.

### TOP may face adverse tax consequences.

The Internal Revenue Service and/or similar state and foreign government bodies may not accept the tax structure or tax positions taken by TOP. If TOP's tax structure and/or tax positions are challenged or invalidated, any tax advantages contemplated by TOP with respect to TOP's anticipated future profits or otherwise, may not be available, and this may result in adverse tax consequences to TOP and the holders of its securities.

### **Risks Related to Collaboration with Third Parties**

### Collaboration agreements that TOP has entered into and may enter into in the future may not be successful, which could adversely affect its ability to develop and commercialize cannabis-based products.

TOP has entered into and may enter into additional collaboration agreements with pharmaceutical companies or university, hospital, healthcare or biotechnology institutes or organizations in connection with the research, development or commercialization of its prospective cannabinoid-based products and treatments. TOP expects to face significant competition in seeking additional appropriate collaborators and in negotiating agreements on acceptable terms, and may not be successful in its efforts to enter into, implement and maintain collaboration agreements. Disagreements stemming from such collaboration agreements concerning development, intellectual property, regulatory or commercialization matters can lead to delays and, in some cases, termination of such collaboration agreements, or otherwise result in the potentially significant costs and fees in seeking to enforce or protect TOP's rights, if any.

#### TOP will depend on third parties to conduct its research activities.

TOP has entered into agreements with third parties, such as medical institutions and clinical investigators, to design, conduct, supervise and monitor TOP's pre-clinical studies and clinical trials (the "Third Parties"). TOP and the Third Parties are required to comply with various regulations and guidelines from regulatory authorities to ensure that the health, safety and rights of patients are protected in clinical development and clinical trials, and that trial data integrity is assured. Relying on Third Parties does not relieve TOP of certain responsibilities and requirements. If TOP or any of the Third Parties fail to comply with applicable requirements, the clinical data generated in such clinical trials may be deemed unreliable and the FDA, the EMA or other comparable foreign regulatory authorities may require TOP to perform additional clinical trials before approving its marketing applications. There is no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of TOP's clinical trials comply with such requirements. Failure to comply with these regulations may require TOP to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

The Third Parties will not be employees of TOP. TOP therefore cannot control whether they devote sufficient time and resources to TOP's ongoing pre-clinical and clinical programs. If the Third Parties do not successfully carry out their contractual duties or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to clinical protocols and/or regulatory requirements, TOP's clinical trials may be extended, delayed or terminated and TOP may not be able to obtain regulatory approval for, or successfully commercialize its drug candidates. As a result, TOP's commercial prospects for its drug candidates would be harmed, its costs could increase and its ability to generate revenue could be delayed or reduced.

TOP has relied and intends to continue to rely upon Third Parties to formulate and produce its drug candidates in accordance with TOP's clinical protocols and all applicable regulatory requirements, including, to the extent required, the FDA's good clinical practice regulations and current good manufacturing practices and DEA and state regulations governing the handling, storage, security and recordkeeping for controlled substances, and corresponding regulations in other countries such as Israel. TOP also relies and intends to continue to rely on Third Parties to conduct and oversee its pre-clinical studies and clinical trials. These Third Parties have played and will continue to play a significant role in the formulation process and the development of TOP's drug candidates. TOP intends to likely rely on these Third Parties for the formulation and development of the products to be utilized in its pre-clinical studies and clinical trials, and TOP will likely control minimally certain aspects of their activities. If these Third Parties do not meet TOP's deadlines or otherwise conduct the trials as required, TOP may not be able to obtain regulatory approval for or commercialize its drug candidates when expected or at all.

If any of TOP's clinical trial sites terminate their involvement in one of its clinical trials for any reason, TOP may experience the loss of follow-up information on patients enrolled in its ongoing clinical trials unless TOP is able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for TOP's clinical trials may serve as scientific advisors or consultants to TOP from time to time and receive cash or equity compensation in connection with their 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 questioned by the FDA.



### TOP conducts clinical trials for its drug candidates outside the United States and the FDA may not accept data from such trials.

TOP has conducted and continues to conduct clinical trials outside the United States, especially in Israel. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom TOP intends to label the product in the United States. In addition, such studies would be subject to the applicable local laws, and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA, the EMA or any comparable foreign agency will accept data from trials conducted outside of the United States, as much of the criteria is evaluated in the discretion of the FDA. Further, there is no assurance that the EMA or any comparable foreign agency will accept such data or otherwise satisfy or comply with the applicable requirements for preclinical studies and clinical trials in such jurisdictions. If the FDA, EMA or applicable foreign agency does not accept any such data or deems the data generated from any such preclinical studies or clinical trials as unreliable or insufficient, then it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of TOP's business plan.

Since TOP relies on Third Parties, TOP's internal capacity to perform these functions will be limited. Outsourcing these functions involves risk that third parties may not perform to TOP's standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of Third Parties requires TOP to disclose its proprietary information to these parties, which could increase the risk that this information will be misappropriated. Though TOP carefully manages its relationships with these Third Parties, there can be no assurance that challenges or delays in the future will not have a material adverse impact on the business, results of operations, financial condition and prospects of TOP.

### **Risks Relating to the Spin-Off and Merger**

### The proposed Spin-Off and Merger are contingent upon the satisfaction of a number of conditions, and the Spin-Off and Merger may not be consummated on the terms or timeline currently contemplated.

On November 5, 2018, our and Alliqua's board of directors unanimously approved a plan to combine Alliqua's custom hydrogels business with TOP's business to form a separate, independent publicly traded company. For further discussion regarding aspects of the Spin-Off and Merger see "Summary — Questions and Answers about the Transaction".

The consummation of the Merger is subject to certain conditions, including (i) the effectiveness of the registration statement to be filed with the SEC and the approval for listing on the Nasdaq Capital Market of the shares of AquaMed common stock to be issued in the Distribution, (ii) the accuracy of the parties' representations and warranties and the performance of their respective covenants contained in the Merger Agreement, and (iii) consummation of the Private Placement. The consummation of the Spin-Off is subject to the foregoing conditions, plus certain additional conditions, including (i) the Adynxx Merger Agreement being in full force and effect and the Adynxx Merger being consummated immediately following with the Spin-Off and (ii) Alliqua being satisfied that the Spin-Off will not result in any material tax payable by Alliqua.

For these and other reasons, the Spin-Off and Merger may not be completed on the terms or timeline contemplated, if at all.

### The proposed Spin-Off and Merger may result in disruptions to relationships with customers and other business partners or may not achieve the intended results.

If we complete the Spin-Off and Merger, there can be no assurance that we will be able to realize the intended benefits of the transactions or that the combined company will perform as anticipated. Specifically, the proposed transactions could cause disruptions in our business and the TOP business.



Further, it is possible that current or prospective employees of AquaMed or TOP could experience uncertainty about their future roles with the combined company, which could harm the ability of the combined company to attract and retain key personnel. Any of the foregoing could adversely affect our financial condition and results of operations and prospects.

### The actions required to implement the Spin-Off and Merger will take significant management time and attention and may require us to incur significant costs.

The Spin-Off and Merger will require significant amounts of management's time and resources, which will be in addition to and may divert management's time and attention from the operation of our business and the execution of our other strategic initiatives. Additionally, we may incur significant costs in connection with the Spin-Off and Merger. The Merger Agreement contains certain termination rights for us and TOP.

### The Spin-Off is a taxable transaction and Alliqua and its stockholders may be subject to a tax liability in connection with the Distribution.

For U.S. federal income tax purposes, the distribution by Alliqua of the shares of AquaMed common stock will not be eligible for treatment as a tax-free distribution. Accordingly, each holder of Alliqua common stock who receives shares of AquaMed common stock in the Spin-Off generally will be treated as if such stockholder received a taxable distribution in an amount equal to the fair market value of AquaMed common stock received (including any fractional share deemed to be received by and sold on behalf of the stockholder), which will result in: (a) a dividend to the extent of such stockholder's ratable share of Alliqua's current and accumulated earnings and profits; then (b) a reduction in such stockholder's basis in Alliqua's common stock (but not below zero) to the extent the amount received exceeds the amount referenced in clause (a); and then (c) gain from the sale or exchange of Alliqua common stock to the extent the amount received exceeds the sum of the amounts referenced in clauses (a) and (b). Accordingly, the amount of taxable income realized by each Alliqua stockholder in the Spin-Off may depend upon its basis in its Alliqua stock, but such tax liability may be significant.

In addition, a corporate level U.S. federal income tax will be payable by the consolidated group of which Alliqua is the common parent if gain realized in the Spin-Off exceeds any net operating losses that may be available to offset such gain. The tax would be based upon the gain, if any, computed as the difference between the fair market value of the AquaMed common stock and Alliqua's adjusted basis in such stock. Alliqua expects that it will have sufficient losses available to fully offset any gain realized as a result of the Spin-Off.

### After the Spin-Off, one of our directors and officers may have actual or potential conflicts of interest because of his previous or continuing positions at Alliqua.

Because of his current or former positions with Alliqua, our expected chairman of the board will own Alliqua common stock and equity awards. Following the Spin-Off, even though our Board of Directors will consist of a majority of directors who are independent, our chairman of the board will continue to have a financial interest in Alliqua common stock and equity awards. Continuing ownership of Alliqua common stock and equity awards, or service as a director at both companies could create, or appear to create, potential conflicts of interest if we have disagreements with Alliqua about the contracts between us that continue or face decisions that could have different implications for us and Alliqua.

#### We may be unable to achieve some or all of the benefits that we expect to achieve from the Spin-Off.

We believe that, as an independent publicly-traded company, we will be able to, among other things, better focus our financial and operational resources on our specific business, implement and maintain a capital structure designed to meet our specific needs, design and implement corporate strategies and policies that are targeted to our business, more effectively respond to industry dynamics and create effective incentives for our management and employees that are more closely tied to our business performance. However, by separating from Alliqua, we may be more susceptible to market fluctuations and other adverse events. In addition, we may be unable to achieve some or all of the benefits that we expect to achieve as an

independent company in the time we expect, if at all. If we fail to achieve some or all of the benefits that we expect to achieve as an independent company, or do not achieve them in the time we expect, our business, financial condition, results of operations and prospects could be adversely affected.

### We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent publicly-traded company, and we may experience increased costs after the Spin-Off.

We have historically operated as part of Alliqua's corporate organization, and Alliqua has provided us with various corporate functions. Following the Spin-Off, Alliqua will have no obligation to provide us with assistance other than limited transition services pursuant to the Asset Contribution and Separation Agreement between us and Alliqua. These services do not include every service that we have received from Alliqua in the past. Accordingly, following the Spin-Off, we will need to provide internally or obtain from unaffiliated third parties the services we currently receive from Alliqua. These services include IT, tax administration, treasury activities, technical accounting, benefits administration, procurement, legal and ethics and compliance program administration, the effective and appropriate performance of which are critical to our operations. We may be unable to replace these services in a timely manner or on terms and conditions as favorable as those we receive from Alliqua.

## We have no recent operating history as an independent publicly-traded company, and our historical financial information is not necessarily representative of the results we would have achieved as an independent publicly traded company and may not be a reliable indicator of our future results.

We derived our historical financial information included in this prospectus from Alliqua's combined and consolidated financial statements, and this information does not necessarily reflect the results of operations and financial positions we would have achieved as an independent publicly-traded company during the periods presented, or those that we will achieve in the future. This is primarily because of the following factors:

- Prior to the Spin-Off, we operated as part of Alliqua's broader corporate organization and Alliqua
  performed various corporate functions for us, including IT, tax administration, treasury activities,
  technical accounting, benefits administration, procurement, legal and ethics and compliance program
  administration. Our historical financial information reflects allocations of corporate expenses from
  Alliqua for these and similar functions. These allocations may not reflect the costs we will incur for
  similar services in the future as an independent publicly-traded company.
- Our historical financial information does not reflect changes that we expect to experience in the future as a
  result of our separation from Alliqua, including changes in our cost structure, personnel needs, tax profile,
  financing and business operations. As part of Alliqua, we enjoyed certain benefits from Alliqua's
  operating diversity, size, purchasing power, borrowing leverage and available capital for investments, and
  we will lose these benefits after the Spin-Off. As an independent entity, we may be unable to purchase
  goods, services and technologies, such as insurance and health care benefits and computer software
  licenses, or access capital markets on terms as favorable to us as those we obtained as part of Alliqua prior
  to the Spin-Off.
- The Merger will result in our consolidated operations and the results therefrom being substantially
  different than Alliqua's operations and the results therefrom and as a result, our historical information will
  not necessarily reflect our results of operations going forward.

Following the Spin-Off, we will also be responsible for the additional costs associated with being an independent publicly-traded company, including costs related to corporate governance, investor and public relations and public reporting. Therefore, our financial statements may not be indicative of our future performance as an independent publicly-traded company. For additional information about our past financial performance and the basis of presentation of our financial statements, see "Selected Historical Financial Data for AquaMed," "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed" and our historical financial statements and the notes thereto included elsewhere in this prospectus.

## Our and TOP's historical and pro forma financial data are not necessarily representative of the results the combined company would have achieved and may not be a reliable indicator of the combined company's future results.

Our and TOP's historical and pro forma financial data included in this prospectus may not reflect what our or TOP's results of operations and financial position would have been had we been a combined company, and publicly traded, during the periods presented, or what the combined company's results of operations, financial condition and cash flows will be in the future. In addition, the pro forma financial data we have included in this prospectus are based in part upon a number of estimates and assumptions. These estimates and assumptions may prove not to be accurate, and accordingly, our pro forma financial data should not be assumed to be indicative of what our financial condition or results of operations actually would have been as a combined company and may not be a reliable indicator of what our financial condition or results of operations actually may be in the future.

## Some of the contracts to be transferred or assigned to us contain provisions requiring the consent of third parties in connection with the transactions contemplated by the Internal Reorganization and Distribution. If these consents are not obtained, we may be unable to enjoy the benefit of these contracts in the future.

Some of the contracts to be transferred or assigned to us in connection with the Internal Reorganization and Distribution contain provisions that require the consent of third parties to the Internal Reorganization, the Distribution or both. Failure to obtain such consents on commercially reasonable and satisfactory terms may impair our entitlement to the benefit of these contracts in the future.

### Our potential indemnification liabilities pursuant to the Asset Contribution and Separation Agreement could materially and adversely affect us.

The Asset Contribution and Separation Agreement between us and Alliqua will provide for, among other things, the principal corporate transactions required to effectuate the Spin-Off, certain conditions to the Spin-Off and provisions governing the relationship between us and Alliqua after the Spin-Off. For a description of the Asset Contribution and Separation Agreement, see "The Asset Contribution and Separation Agreement and Ancillary Agreements — Separation Agreement." Among other things, the Asset Contribution and Separation Agreement will provide for indemnification obligations designed to make us financially responsible for substantially all liabilities that may exist relating to or arising out of our business. If we are required to indemnify Alliqua under the circumstances set forth in the Asset Contribution and Separation Agreement, we may be subject to substantial liabilities.

## In connection with the Spin-Off, Alliqua will indemnify us for certain liabilities. However, there can be no assurance that these indemnities will be sufficient to insure us against the full amount of such liabilities, or that Alliqua's ability to satisfy its indemnification obligation will not be impaired in the future.

Pursuant to the Asset Contribution and Separation Agreement and other agreements we will enter into in connection with the Spin-Off, Alliqua will agree to indemnify us for certain liabilities. However, third parties could seek to hold us responsible for any of the liabilities that Alliqua will agree to retain pursuant to these agreements, and there can be no assurance that Alliqua will be able to fully satisfy its indemnification obligations under these agreements. Moreover, even if we ultimately succeed in recovering from Alliqua any amounts for which we are held liable, we may be temporarily required to bear these losses while seeking recovery from Alliqua.

### The Distribution may not be completed on the terms or timeline currently contemplated, if at all.

We are actively engaged in planning for the Distribution. We expect to incur expenses in connection with the Distribution and any delays in the anticipated completion of the distribution may increase these expenses. Unanticipated developments could delay or negatively impact the distribution, including those related to the filing and effectiveness of appropriate filings with the SEC, the listing of our common stock on the Nasdaq Capital Market, and receiving any required regulatory approvals. Until the consummation of the Distribution, Alliqua's Board of Directors will have the sole and absolute discretion to determine and change the terms of the Distribution, including the establishment of the record date and distribution date.

### **Risks Relating to our Common Stock and Capital Structure**

### No market for our common stock currently exists and an active trading market may not develop or be sustained after the Spin-Off. Following the Spin-Off our stock price may fluctuate significantly.

There is currently no public market for our common stock. We intend to apply to list our common stock on the Nasdaq Capital Market. However, an active trading market for our common stock may not develop as a result of the Spin-Off or may not be sustained in the future. The lack of an active market may make it more difficult for stockholders to sell our shares and could lead to our share price being depressed or volatile.

We cannot predict the prices at which our common stock may trade after the Spin-Off. The market price of our common stock may fluctuate widely, depending on many factors, some of which may be beyond our control, including:

- · actual or anticipated fluctuations in our operating results due to factors related to our business;
- success or failure of our business strategies;
- our quarterly or annual earnings, or those of other companies in our industry;
- our ability to obtain financing as needed;
- · announcements by us or our competitors of significant acquisitions or dispositions;
- · changes in accounting standards, policies, guidance, interpretations or principles;
- · the failure of securities analysts to cover our common stock after the Spin-Off;
- changes in earnings estimates by securities analysts or our ability to meet those estimates;
- the operating and stock price performance of other comparable companies;
- overall market fluctuations;
- results from any material litigation or government investigation;
- · changes in laws and regulations (including tax laws and regulations) affecting our business;
- · changes in capital gains taxes and taxes on dividends affecting stockholders; and
- general economic conditions and other external factors.

Furthermore, our business profile and market capitalization may not fit the investment objectives of some Alliqua stockholders and, as a result, these Alliqua stockholders may sell their shares of our common stock after the Distribution. Substantial sales of our common stock may occur in connection with the Spin-Off, which could cause our stock price to decline. Low trading volume for our stock, which may occur if an active trading market does not develop, among other reasons, would amplify the effect of the above factors on our stock price volatility.

### Substantial sales of our common stock may occur in connection with the Spin-Off, which could cause our stock price to decline.

Although we have no actual knowledge of any plan or intention of any significant Alliqua and TOP stockholder to sell our common stock following the Spin-Off, it is likely that some such stockholders, possibly including some larger stockholders, will sell their shares of our common stock received in the Distribution or the Merger if, for reasons such as our business profile or market capitalization as an independent company, we do not fit their investment objectives or, in the case of index funds, we are not a participant in the index in which they are investing. Following the Merger, approximately 38% of our outstanding shares of common stock will be beneficially owned by our five largest stockholders, including Berel Farkas (who is also a director), who would be expected to exercise substantial influence on any matters subject to a stockholder vote. These shares will also be eligible for resale in the public market



without registration subject to volume, manner of sale and holding period limitations under Rule 144 under the Securities Act commencing 90 days after the date of this prospectus. The sales of significant amounts of our common stock or the perception in the market that this will occur may decrease the market price of our common stock.

### The combined post-Spin-Off value of Alliqua common stock and our common stock may not equal or exceed the pre-Spin-Off value of Alliqua common stock.

We cannot assure you that the combined trading prices of Alliqua common stock and our common stock after the Spin-Off will be equal to or greater than the trading price of Alliqua common stock prior to the Spin-Off. Until the market has fully evaluated the business of Alliqua without our business, the price at which Alliqua common stock trades may fluctuate more significantly than might otherwise be typical. Similarly, until the market has fully evaluated the stand-alone business of our company, the price at which shares of our common stock trades may fluctuate more significantly than might otherwise be typical, including volatility caused by general market conditions.

### We cannot assure you that we will pay dividends on our common stock, and our indebtedness may limit our ability to pay dividends on our common stock.

Following the Spin-Off, the timing, declaration, amount and payment of future dividends to stockholders will fall within the discretion of our Board of Directors. Our Board of Directors' decisions regarding the payment of future dividends will depend on many factors, including our financial condition, earnings, capital requirements of our business and covenants associated with debt obligations, as well as legal requirements, regulatory constraints, industry practice and other factors that our Board of Directors deems relevant. For more information, see "Dividend Policy." There can be no assurance that we will pay a dividend in the future or continue to pay any dividend if we do commence paying dividends, and there can be no assurance that, in the future, the combined annual dividends paid on Alliqua common stock, if any, and our common stock, if any, after the Spin-Off will equal the annual dividends on Alliqua common stock prior to the Spin-Off.

#### Your percentage ownership in us may be diluted in the future.

Your percentage ownership in us may be diluted in the future because of equity awards that we expect to grant to our directors, officers and other employees. Prior to completion of the Spin-Off, we expect to approve an incentive plan that will provide for the grant of common share-based equity awards to our directors, officers and other employees. In addition, we may issue equity as all or part of the consideration paid for acquisitions and strategic investments that we may make in the future or as necessary to finance our ongoing operations.

# We are an "emerging growth company" and a "smaller reporting company" and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, and are subject to lesser public company reporting requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more; (ii) the fifth anniversary of the Distribution; (iii) the date on which we have eased more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act. We anddition, we are a "smaller reporting company" and accordingly are required to provide less public disclosure than larger public companies. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.



### We will incur costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public reporting company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act and rules subsequently implemented by the SEC, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will entail significant legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept low policy limits and coverage.

## Provisions in our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws and of Delaware law may prevent or delay an acquisition of our company, which could decrease the trading price of our common stock.

Several provisions of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware law may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable. These include provisions that:

- permit us to issue blank check preferred stock as more fully described under "Description of Our Capital Stock Anti-Takeover Effects of Various Provisions of Delaware Law and Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws";
- require stockholders to follow certain advance notice and disclosure requirements in order to propose business or nominate directors at an annual or special meeting; and
- limit our ability to enter into business combination transactions with certain stockholders.

These and other provisions of our Amended and Restated Certificate of Incorporation, Amended and Restated Bylaws and Delaware law may discourage, delay or prevent certain types of transactions involving an actual or a threatened acquisition or change in control of us, including unsolicited takeover attempts, even though the transaction may offer our stockholders the opportunity to sell their shares of our common stock at a price above the prevailing market price. See "Description of Our Capital Stock Anti-Takeover Effects of Various Provisions of Delaware Law and Our Amended and Restated Articles of Incorporation and Amended and Restated Bylaws" for more information.

### Our Amended and Restated Bylaws include a forum selection clause, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our Amended and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any internal corporate claims within the meaning of the Delaware General Corporation Law ("DGCL"), (ii) any derivative action or proceeding brought on our behalf, (iii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or employees to us or to our stockholders, or (iv) any action asserting a claim arising pursuant to any provision of the DGCL, will be a state or federal court located within the State of Delaware, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock is deemed to have notice of and consented to the foregoing provisions. This forum selection provision in our bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. It is also possible that, notwithstanding the forum selection clause included in our bylaws, a court could rule that such a provision is inapplicable or unenforceable.



### CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

All statements and assumptions contained in this prospectus that do not directly and exclusively relate to historical facts constitute "forward-looking statements." Forward-looking statements often include words such as "anticipates," "believes," "estimates," "expects," "forecast," "goal," "intends," "objective," "plans," "projects," "strategy," "target," and "will" and words and terms of similar substance in discussions of future operating or financial performance. These statements represent current expectations and beliefs, and no assurance can be given that the results described in such statements will be achieved

Forward-looking statements include, among other things, statements with respect to our financial condition, results of operations, cash flows, business strategies, prospects, operating efficiencies or synergies, competitive position, growth opportunities, plans and objectives of management and other matters. Such statements are subject to numerous assumptions, risks, uncertainties and other factors that could cause actual results to differ materially from those described in such statements, many of which are outside of our control. Important factors that could cause actual results to differ materially from those described in forward-looking statements include, but are not limited to:

- the inability or failure to perform under the various transaction agreements effecting the Spin-Off or the Merger;
- the ability to realize the benefits expected to result from the Merger within the anticipated time frame or in the anticipated amounts;
- other risks related to the Spin-Off and the Merger, including anticipated tax treatment, unforeseen liabilities, and future capital expenditures;
- the occurrence of any event, change or other circumstances that could give rise to the termination of the Adynxx Merger Agreement;
- · risks arising from the diversion of management's attention from our ongoing business operations;
- inadequate or an inability to raise sufficient capital to execute our business plan;
- any inability to successfully develop drug candidates, obtain regulatory approval and achieve market acceptance thereof;
- failure to design and achieve successful results in pre-clinical and clinical trials for our prospective drug candidates;
- our ability to comply with current good manufacturing practices;
- loss or retirement of key executives;
- adverse economic conditions and/or intense competition;
- loss of a key customer or supplier;
- entry of new competitors;
- adverse federal, state and local government regulation;
- · technological obsolescence of our manufacturing process and equipment;
- technical problems with our research and products;
- price increases for supplies and components; and
- · the inability to carry out our business plans

There may be other factors that may cause our actual results to differ materially from the forward-looking statements, including factors disclosed under the sections titled "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed" and "Management's Discussion and Analysis of Financial Condition and Plan of Operations of TOP" in this prospectus. You should evaluate all forward-looking statements made in this prospectus in the context of these risks and uncertainties.



No assurance can be given that any goal or plan set forth in any forward-looking statement can or will be achieved, and readers are cautioned not to place undue reliance on such statements which speak only as of the date they are made. We do not undertake any obligation to update or release any revisions to any forward-looking statement or to report any events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events, except as required by law.

#### THE TRANSACTIONS

#### Background

On November 28, 2018, Alliqua announced plans for the complete legal and structural separation of its custom hydrogels contract manufacturing business and the subsequent combination of AquaMed and TOP to create a new public bio-pharmaceutical company focused on discovering, developing and commercializing novel therapeutics based on TOP's proprietary cannabinoid product platform in a number of FDA-regulated clinical indications.

See also "Reasons for the Spin-Off and Merger - Spin-Off".

To effectuate the separation, Alliqua is undertaking the Internal Reorganization described under "The Asset Contribution and Separation Agreement and Ancillary Agreements."

Following the Internal Reorganization, Alliqua will distribute all of its equity interest in us, consisting of all of the outstanding shares of our common stock, to the record holders of Alliqua common stock on a pro rata basis.

Following the Spin-Off, Alliqua will not own any equity interest in us, and we will operate independently from Alliqua. No approval of Alliqua's stockholders is required in connection with the Spin-Off, and Alliqua's stockholders will not have any appraisal rights in connection with the Spin-Off.

Completion of the Spin-Off is subject to the satisfaction, or the waiver of the board of directors of Alliqua, of a number of conditions. For a more detailed description, see "Conditions to the Spin-Off."

Following the Spin-Off, under the Merger Agreement and in accordance with Delaware law, Merger Sub will merge with and into TOP, with TOP continuing as the surviving company. As a result of the Merger, TOP will become a wholly-owned subsidiary of us. As a result of the Merger, immediately after the effective time of the Merger and consummation of the Private Placement, before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in the Private Placement and it is consummated on the terms currently proposed. Following the consummation of the Merger, AquaMed will issue shares representing approximately 4.99% and 0.08% of shares outstanding to Bezalel Partners, LLC and the Benchmark Company, LLC, respectively, for advisory and consulting services in connection with the Merger. Following such issuances and the consummation of the Merger and the Private Placement on the terms set forth above, the former Alliqua shareholders will hold approximately 9.5% of the total number of shares of AquaMed stock outstanding. For details of the structure of the transaction, see "The Merger Agreement."

#### **Reasons for the Spin-Off and Merger**

The board of directors of Alliqua regularly conducts strategic reviews of its businesses. In reaching the decision to pursue the Spin-Off and Merger, the board of directors of Alliqua considered a range of potential strategic alternatives for Alliqua, including the continuation of Alliqua's current operating strategy in light of the Adynxx Merger as well as potential acquisition and divestiture transactions. In evaluating these alternatives, the board of directors of Alliqua considered a number of factors, including (a) the relative values to Alliqua's stockholders of (i) AquaMed operating as an independent business versus (ii) continuing with the combined Alliqua/Adynxx business, (b) the strategic focus and flexibility for Alliqua and AquaMed after the Spin-Off and Merger, (c) the ability of Alliqua and AquaMed to operate efficiently and effectively (including AquaMed's ability to retain and attract management talent) after the Spin-Off and Merger, (d) the financial profile of Alliqua, AquaMed and TOP, (e) the potential reaction of customers, employees and investors and (f) the probability of successful execution of the various strategic alternatives and the risks associated with those alternatives.

During this process, the board of directors of Alliqua considered the possibility of continuing AquaMed with the combined Alliqua/Adynxx business. Among other things, the board of directors of Alliqua considered AquaMed's expected future earnings and expenses, the potential disadvantages of

AquaMed's relatively small scale as compared to other hydrogels manufacturers, the proposed change in direction (away from the custom hydrogels business) that the combined Alliqua/Adynxx organization would be expected to take following the Adynxx Merger, and the fact that under the Adynxx Merger Agreement, Alliqua was required to use commercially reasonable efforts to spin-off AquaMed's custom hydrogels business.

The board of directors of Alliqua also considered the possible liquidation and dissolution of AquaMed and the distribution of its assets to Alliqua stockholders. When comparing the possible liquidation and dissolution of AquaMed to other strategic alternatives, the board of directors of Alliqua considered the costs of continuing to operate AquaMed based on its current asset size and expenses, and the timing and approvals associated with a liquidation and dissolution of AquaMed. The board of directors of Alliqua also considered potentially negative factors in its deliberations concerning the possible liquidation and dissolution of AquaMed, including that there could be no assurance that Alliqua will be successful in disposing of the AquaMed assets for values equal to or exceeding Alliqua's expectations or that such dispositions would occur in the time frame expected, the anticipated expenses and potential for unforeseen expenses that may be incurred in connection with the sale of AquaMed's assets and the continued operation of AquaMed through its dissolution.

As a result of this evaluation, the board of directors of Alliqua determined that proceeding with the Spin-Off and the Merger would be in the best interests of Alliqua and its stockholders as the Spin-Off and the Merger would likely maximize stockholder value within a reasonable period of time and with greater certainty than if Alliqua were to pursue the other strategic alternatives that were considered. The board of directors of Alliqua considered the following potential benefits of this approach:

- Stockholder Value. On October 11, 2018, Alliqua signed the Adynxx Merger Agreement with Adynxx
  and Embark, pursuant to which Alliqua will consummate the Adynxx Merger. AquaMed's custom
  hydrogels contract manufacturing business is not synergistic with the potential combined operations of
  Alliqua and Adynxx. In addition, under the terms of the Adynxx Merger Agreement, Alliqua is required to
  use its commercially reasonable efforts to spin-off AquaMed's custom hydrogels business. We believe the
  Spin-Off and the Merger will provide greater value to Alliqua stockholders than if the AquaMed business
  remained a part of Alliqua following the closing of the Adynxx Merger as the combination of AquaMed
  and TOP will create an independent, publicly traded company dedicated to discovering, developing and
  commercializing novel therapeutics based on TOP's proprietary cannabinoid product platform and serving
  customers in the cannabinoid pharmaceutical therapy industry.
- *Strategic Focus and Flexibility*. Following the Spin-Off and Merger, we will be better able to dedicate financial and human capital resources to pursue appropriate growth opportunities and execute strategic plans best suited to our business than if it remained a part of Alliqua or as an independent company without the business combination with TOP.
- Strategic Positioning in Industry. The combination of AquaMed and TOP is a strategic move to position
  the combined company as an independent, publicly traded cannabinoid pharmaceutical therapy-based
  company. The combination of AquaMed and TOP is expected to provide opportunities for the combined
  company to leverage its unique ability to create novel therapeutics based on TOP's proprietary
  cannabinoid-based product platform in a number of FDA-regulated clinical indications, including a
  hydrogel product.
- Management Incentives. The Spin-Off will enable AquaMed to create incentives for its management and employees that are more closely tied to its business performance and stockholder expectations. AquaMed's equity-based compensation arrangements will more closely align the interests of AquaMed's management and employees with the interests of its stockholders and should increase AquaMed's ability to attract and retain personnel.
- Capital Structure and Stockholder Flexibility. The segments in which Alliqua and AquaMed expect to
  operate have historically had different growth profiles and cash flow dynamics. The Spin-Off will allow
  Alliqua and AquaMed to separately manage their capital strategies and cost

structures and will allow investors to make independent investment decisions with respect to Alliqua and AquaMed, including the ability for AquaMed to achieve alignment with a more natural stockholder base. Investment in one or the other company may appeal to investors with different goals, strategies, interests and concerns.

The board of directors of Alliqua also considered and balanced against the potential benefits of the Spin-Off and Merger a number of potentially adverse factors concerning the Spin-Off and Merger, including the following:

- the fact that, although we will continue to exercise control and supervision over our operations prior to
  closing, the Merger Agreement prohibits us from taking a number of actions relating to the conduct of its
  business prior to the closing without TOP's consent, which may delay or prevent us from undertaking
  business opportunities that may arise during the pendency of the Transactions, whether or not the SpinOff and/or Merger is completed;
- the fact that immediately following the Transactions, the current members of TOP and the third-party
  investors that participate in the Private Placement are expected to hold approximately 90% of the total
  number of shares of AquaMed common stock outstanding (on a fully diluted basis), assuming that no
  more than \$10 million is raised in the Private Placement;
- the risk that there is no assurance that all conditions to the parties' obligations to complete the Spin-Off and/or Merger will be satisfied or waived, and as a result, it is possible that the Spin-Off and/or Merger could be delayed or might not be completed;
- the risks and costs to us if the transactions do not close, including the diversion of management and employee attention, potential employee attrition and the potential effect on business and customer relationships; and
- the risk of disruption to our business and customer reaction as a result of the public announcement of the Spin-Off and Merger.

In determining whether to effect the Spin-Off, the board of directors of Alliqua considered the costs and risks associated with the Spin-Off, including the costs associated with preparing AquaMed to become an independent, publicly-traded company, the risk of volatility in our stock price immediately following the Spin-Off due to sales by Alliqua's stockholders whose investment objectives may not be met by our common stock, the time it may take for us to attract our optimal stockholder base, the possibility of disruptions in our business as a result of the Spin-Off, the risk that the combined trading prices of our common stock and Alliqua's common stock after the Spin-Off may drop below the trading price of Alliqua's common stock before the Spin-Off and the loss of synergies and scale from operating as one company. Notwithstanding these costs and risks, taking into account the factors discussed above, the board of directors of Alliqua determined that the Spin-Off, in conjunction with the Merger, was the best alternative to achieve the above benefits and enhance stockholder value.

In assessing and approving the Merger, the board of directors of Alliqua considered that the expected value to Alliqua and its stockholders from pursuing the Merger was greater than the value to Alliqua and its stockholders of the stand-alone Spin-Off. In the context of the Merger, the board of directors of Alliqua considered that as a result of the Merger, AquaMed will gain access to TOP's exclusive, worldwide license covering the TOL pharmaceutical products and exclusive access to TOL's cannabis strains and database of Israeli medical cannabis patients which contains important patient and treatment data. Even though TOP has not yet developed any pharmaceutical products that have been approved by a regulatory authority, the post-Merger company's operation as an independent, publicly traded cannabinoid pharmaceutical therapy-based company is expected to provide opportunities for the combined company to leverage its unique ability to create novel therapeutics based on TOP's proprietary cannabinoid-based product platform, including via a hydrogel product, with the ultimate objective of obtaining approval by the FDA, the European Medicines Agency ("EMA") and from regulatory authorities in other countries and regions. In addition, the board of directors of Alliqua reviewed with the management of Alliqua TOP's current plans for development of its product candidates to confirm the likelihood that the combined organization would possess sufficient financial resources to allow the management team to focus on the continued development of its product candidates.



Alliqua's board of directors also considered that, prior to entering into negotiations with TOP regarding the Merger, Alliqua had sought other potential acquirers for the hydrogel business. While no formal offers were ever received, discussions with potential acquirers indicated that a disposition of the hydrogel business as a standalone business was unlikely to result in meaningful value to Alliqua's shareholders. Alliqua's board of directors also took into account that AquaMed has significant operating costs and that AquaMed does not generate sufficient free cash flow or net income to fund its ongoing operations, and therefore operating AquaMed as a stand-alone business would require immediate financing which Alliqua's board does not believe would be available on acceptable terms or at all. With no alternative other than the liquidation of AquaMed, which the board of directors of Alliqua, as discussed above, did not believe would provide the same level of stockholder value as the Spin-Off and Merger, in negotiating the Merger with TOP, Alliqua's board sought a meaningful stake for Alliqua's shareholders in the post-Merger combined company. Upon entering negotiations with TOP, TOP proposed that Alliqua's shareholders own approximately 5% of the post-Merger company. Alliqua senior management proposed a counter-offer of 12% and TOP ultimately proposed that Alliqua's shareholders receive 10% of the post-Merger Company. Although Alliqua's board of directors could not determine a precise value of the post-Merger company, Alliqua's board of directors determined to accept 10% of the post-Merger company because it believed that it represented a meaningful stake in a combined enterprise that would exceed the value of AquaMed as a standalone company and with the potential for future growth given the current perceived investor interest in companies developing cannabinoid-based therapies.

The board of directors of Alliqua also considered the potential risks and countervailing factors associated with the Merger, including that the anticipated benefits of the Merger might not be realized.

After consideration of the above factors and based on review of due diligence materials furnished by TOP to Alliqua, including TOP's worldwide licenses with TOL and other material agreements and the research materials and data from TOP's pre-clinical and clinical trials in Israel and the terms of the Merger Agreement and related agreements as finally negotiated by Alliqua, the board of directors of Alliqua concluded that the expected value to Alliqua and its stockholders from pursuing the Transactions was greater than the value to Alliqua and its stockholders of the stand-alone Spin-Off.

The foregoing discussion of the factors considered by the board of directors of Alliqua is not intended to be exhaustive, but does set forth the principal factors considered by the board of directors. The board of directors collectively reached the conclusion to approve the Merger Agreement, the Spin-Off and the Merger in light of the various factors described above, as well as other factors that the board of directors of Alliqua felt were appropriate. In view of the wide variety of factors considered by the board of directors of Alliqua in connection with its evaluation of the Spin-Off and the Merger and the complexity of these matters, the board of directors did not consider it practical, and did not attempt, to quantify, rank or otherwise assign relative weights to the specific factors it considered in reaching its decision. Rather, the board of directors of Alliqua made its recommendation based on the totality of the information presented to, and the investigation conducted by, the board of directors. In considering the factors discussed above, individual directors may have given different weights to different factors.

#### When and How You Will Receive AquaMed Shares

Alliqua will distribute to its stockholders, as a pro rata dividend, shares of our common stock for every one share of Alliqua common stock outstanding as of , the Record Date of the Distribution.

Prior to the Spin-Off, Alliqua will deliver all of the issued and outstanding shares of our common stock to the distribution agent. Action Stock Transfer Corporation will serve as distribution agent in connection with the Distribution and as transfer agent and registrar for our common stock.

If you own Alliqua common stock as of the close of business on , 2019, the shares of our common stock that you are entitled to receive in the Distribution will be issued to your account as follows:

Registered stockholders. If you own your shares of Alliqua common stock directly through Alliqua's transfer agent, Action Stock Transfer Corporation, you are a registered stockholder. In this case, the distribution agent will credit the shares of our common stock you receive in the Distribution by way of direct registration in book-entry form to a new account with our transfer agent. Registration in book-entry form refers to a method of recording share ownership where no

physical stock certificates are issued to stockholders, as is the case in the Distribution. You will be able to access information regarding your book-entry account holding the AquaMed shares at or by calling Action Stock Transfer Corporation at .

- Commencing on or shortly after the Distribution Date, the distribution agent will mail to you an account statement that indicates the number of shares of our common stock that have been registered in bookentry form in your name. We expect it will take the distribution agent up to two weeks after the Distribution Date to complete the distribution of the shares of our common stock and mail statements of holding to all registered stockholders. Trading of our common stock will not be affected by this delay in issuance by the distribution agent.
- "Street name" or beneficial stockholders. Most Alliqua stockholders own their shares of Alliqua common stock beneficially through a bank, broker or other nominee. In these cases, the bank, broker or other nominee holds the shares in "street name" and records your ownership on its books. If you own your shares of Alliqua common stock through a bank, broker or other nominee, your bank, broker or other nominee will credit your account with the shares of our common stock that you receive in the Distribution on or shortly after the Distribution Date. We encourage you to contact your bank, broker or other nominee if you have any questions concerning the mechanics of having shares held in "street name."

If you sell any of your shares of Alliqua common stock on or before the Distribution Date, the buyer of those shares may in some circumstances be entitled to receive the shares of our common stock to be distributed in respect of the Alliqua shares you sold. We anticipate that, on or shortly before the Record Date and continuing up to and including the Distribution Date, there will be two markets in Alliqua common stock: a "regular-way" market and an "ex-dividend" market. Shares of Alliqua common stock that trade on the "regular-way market" will trade with the entitlement to receive shares of our common stock in the Distribution. Shares that trade on the ex-dividend market will trade without the entitlement to receive shares of our common stock in the Distribution. Therefore, if you sell shares of Alliqua common stock in the "regular-way" market up to and including the Distribution Date, you will be selling your right to receive shares of our common stock in the Distribution. If you hold shares of Alliqua common stock on the Record Date and then decide to sell any shares of Alliqua common stock before the Distribution Date, you should make sure your stockbroker, bank or other nominee understands whether you want to sell your shares of Alliqua common stock with or without your entitlement to our common stock pursuant to the Distribution.

We are not asking Alliqua stockholders to take any action in connection with the Spin-Off. No stockholder approval of the Spin-Off is required. We are not asking you for a proxy and request that you do not send us a proxy.

We are also not asking you to make any payment or surrender or exchange any of your shares of Alliqua common stock for shares of our common stock. The number of outstanding shares of Alliqua common stock will not change as a result of the Spin-Off.

### Number of Shares You Will Receive

On the Distribution Date, we will distribute shares of our common stock for every one share of Alliqua common stock.

#### **Treatment of Fractional Shares**

The distribution agent will not distribute any fractional shares of our common stock in connection with the Distribution. Instead, the distribution agent will aggregate all fractional shares into whole shares and sell the whole shares in the open market at prevailing market prices on behalf of Alliqua stockholders entitled to receive a fractional share. The distribution agent will then distribute the aggregate cash proceeds of the sales, net of brokerage fees and other costs, pro rata to these holders (net of any required withholding for taxes applicable to each holder). The distribution agent will, in its sole discretion, without any influence by Alliqua or us, determine when, how, through which broker-dealer and at what price to sell the whole shares. The distribution agent is not, and any broker-dealer used by the distribution agent will not be, an affiliate of either Alliqua or us.

The distribution agent will send to each registered holder of Alliqua common stock entitled to a fractional share a check in the cash amount deliverable in lieu of that holder's fractional share as soon as practicable following the Distribution. We expect the distribution agent to take about two weeks after the Distribution to complete the distribution of cash in lieu of fractional shares to Alliqua stockholders. If you hold your shares through a bank, broker or other nominee, your bank, broker or nominee will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales. No interest will be paid on any cash you receive in lieu of a fractional share will generally be taxable to you for U.S. federal income tax purposes. See "Material U.S. Federal Income Tax Consequences of the Distribution" below for more information.

### **Results of the Spin-Off**

After the Spin-Off, we will be an independent publicly-traded company. Immediately following the Spin-Off, we expect to have approximately registered holders of shares of our common stock and approximately shares of our common stock outstanding. The actual number of shares of our common stock you will receive in the Spin-Off will depend on the actual number of shares of Alliqua common stock outstanding on the Record Date, which will reflect any issuance of new shares or exercises of outstanding options pursuant to Alliqua's equity plans, and any repurchase of Alliqua shares by Alliqua under its common stock repurchase program, on or prior to the Record Date. The Spin-Off will not affect the number of outstanding price of shares of Alliqua common stock immediately following the Distribution to be lower than immediately prior to the Distribution because the trading price of Alliqua common stock will no longer reflect the value of the AquaMed business. Furthermore, until the market has fully analyzed the value of Alliqua without the AquaMed business, the trading price of shares of Alliqua common stock may fluctuate.

Before our separation from Alliqua, we intend to enter into an Asset Contribution and Separation Agreement and several other agreements with Alliqua related to the Spin-Off. These agreements will govern the relationship between AquaMed and Alliqua up to and after completion of the Spin-Off and allocate between AquaMed and Alliqua various assets, liabilities, rights and obligations, including employee benefits and tax-related assets and liabilities. We describe these arrangements in greater detail under "The Asset Contribution and Separation Agreement and Ancillary Agreements" and "Certain Relationships and Related Party Transactions — Agreements with Alliqua."

#### Listing and Trading of Our Common Stock

As of the date of this prospectus, we are a wholly owned subsidiary of Alliqua. Accordingly, no public market for our common stock currently exists. We intend to list our shares of common stock on the Nasdaq Capital Market under the symbol "TOPP." Following the Spin-Off, Alliqua common stock will continue to trade on the Nasdaq Capital Market under the symbol "ALQA."

Neither we nor Alliqua can assure you as to the trading price of Alliqua common stock or our common stock after the Spin-Off, or as to whether the combined trading prices of our common stock and Alliqua common stock after the Spin-Off will be less than, equal to or greater than the "regular-way" trading price of Alliqua common stock prior to the Spin-Off. The trading price of our common stock may fluctuate significantly following the Spin-Off. See "Risk Factors — Risks Relating to Our Common Stock and the Securities Market" for more detail.

The shares of our common stock distributed to Alliqua stockholders will be freely transferable, except for shares received by individuals who are our affiliates. Individuals who may be considered our affiliates after the Spin-Off include individuals who control, are controlled by or are under common control with us, as those terms generally are interpreted for federal securities law purposes. These individuals may include some or all of our directors and executive officers. Individuals who are our affiliates will be permitted to sell their shares of our common stock only pursuant to an effective registration statement under the Securities Act of 1933, as amended ("Securities Act") or an exemption from the registration requirements of the Securities Act, such as those afforded by Section 4(a)(1) of the Securities Act or Rule 144 thereunder.

#### Conditions to the Spin-Off

We expect that the separation will be effective on the Distribution Date, provided that the following conditions, in addition to other customary closing conditions, shall have been satisfied or waived by Alliqua:

- the board of directors of Alliqua shall have approved the Internal Reorganization and the Distribution and shall have declared the Distribution of AquaMed common stock to Alliqua stockholders;
- the ancillary agreements contemplated by the Asset Contribution and Separation Agreement shall have been executed by each party to those agreements;
- the SEC shall have declared effective our Registration Statement on Form S-1, of which this prospectus is
  a part, under the Exchange Act, and no stop order suspending the effectiveness of the Registration
  Statement shall be in effect and no proceedings for that purpose shall be pending before or threatened by
  the SEC;
- our common stock shall have been accepted for listing on the Nasdaq Capital Market, subject to official notice of issuance;
- we shall have concurrently consummated the Private Placement;
- the Merger Agreement shall be in full force and effect;
- Alliqua shall have received an independent third-party valuation of our common stock to be distributed in the Distribution;
- no order, injunction or decree issued by any governmental authority of competent jurisdiction or other legal restraint or prohibition preventing consummation of the Internal Reorganization shall be in effect;
- Alliqua shall be satisfied the Internal Reorganization and the Distribution, will not result in any material tax payable by Alliqua;
- the Adynxx Merger Agreement, shall be in full force and effect and the transactions contemplated thereby shall be consummated immediately following the closing of the Spin-Off; and
- no proceeding shall be pending or threatened in writing seeking to enjoin, delay, prohibit or restrict the consummation of the Spin-Off or the Merger.

The fulfillment of the above conditions will not create any obligation on Alliqua's part to effect the Spin-Off. We are not aware of any material federal, foreign or state regulatory requirements with which we must comply, other than SEC rules and regulations, or any material approvals that we must obtain, other than the approval for listing of our common stock and the SEC's declaration of the effectiveness of the Registration Statement, in connection with the Distribution.

### Conditions to Consummation of the Merger

The obligations of each party to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of closing conditions that are contained in the Merger Agreement, including:

- the Spin-Off having occurred pursuant to the Asset Contribution and Separation Agreement;
- the effectiveness of the registration statement of which this prospectus forms a part in connection with the Distribution, and the approval for listing on the Nasdaq Capital Market of the shares of AquaMed common stock to be issued in the Distribution and the Merger, subject to official notice of issuance;
- the absence of any order issued by any governmental authority of competent jurisdiction or other legal impediment preventing or making illegal the consummation of the Merger; and
- · we shall have received binding commitments from investors to consummate the Private Placement.



In addition, our, and Merger Sub's obligations to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of the following conditions:

- certain fundamental representations and warranties of TOP being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger;
- the representations and warranties of TOP, disregarding all materiality or material adverse effect qualifications, being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger (except to the extent such representations and warranties address matters as of a particular date, in which case as of such date) (other than the certain fundamental representations and warranties which must be true and correct in all respects);
- the covenants and agreements being performed by TOP in all material respects at or prior to the effective time of the Merger;
- TOP shall have obtained the consent of a majority of its members, and such consent shall not have been invalidated or revoked and shall remain in full force and effect;
- the absence of a TOP Material Adverse Effect since the date of the Merger Agreement;
- TOP shall have completed an audit of its financial statements for the years ended December 31, 2017 and December 31, 2016 by an independent registered auditor; and
- we shall have received an independent third-party valuation of our common stock to be distributed in the Distribution.

Furthermore, the obligations of TOP to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of the following conditions:

- certain fundamental representations and warranties of AquaMed and Merger Sub being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger;
- the representations and warranties of AquaMed and Merger Sub, disregarding all materiality or material
  adverse effect qualifications, being true and correct in all respects in each case as of the date of the Merger
  Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger (except
  to the extent such representations and warranties address matters as of a particular date, in which case as
  of such date) (other than the certain fundamental representations and warranties which must be true and
  correct in all respects);
- the covenants and agreements being performed by AquaMed and Merger Sub in all material respects at or prior to the effective time of the Merger;
- the absence of any AquaMed Material Adverse Effect since the date of the Merger Agreement;
- AquaMed shall have completed an audit of its financial statements for the years ended December 31, 2017 and December 31, 2016 by an independent registered auditor; and
- we shall have delivered to TOP (a) resignation letters of any of our officers and directors, to be effective as of the Effective Time, who will not be continuing officers or directors of us, and (b) certified resolutions of our Board of Directors (i) causing our whole Board of Directors to consist of five directors as of the Effective Time, (ii) appointing to the Board of Directors such individuals as necessary to cause the Board of Directors as of the Effective Time to conform with the requirements set forth on Schedule 1.4 to the Merger Agreement, and (iii) appointing as officers of Parent such individuals as necessary to cause our officers as of the Effective Time to conform with the requirements set forth on Schedule 1.4 to the Merger Agreement. We shall also deliver resolutions, in our capacity as the sole member of the surviving company as of the Effective Time, appointing persons to the Board of Managers of the surviving company.



To the extent permitted by applicable law, each party to the Merger Agreement may waive, at its sole discretion, any of the conditions to its respective obligations to complete the Merger.

### **Regulatory Approvals**

We must complete the necessary registration under U.S. federal securities laws of the AquaMed common stock to be issued in the Distribution and the Merger. We must also complete the applicable listing requirements of the Nasdaq Capital Market for such shares.

Other than these requirements, we do not believe that any other material governmental or regulatory filings or approvals will be necessary to consummate the Spin-Off or the Merger.

### Accounting Treatment

The combined financial information presented in the prospectus was prepared using the purchase method of accounting, with TOP treated as the "acquirer" of AquaMed and its respective subsidiaries for accounting purposes.

#### THE MERGER AGREEMENT

The following is a summary of material provisions of the Merger Agreement, which we entered into on November 27, 2018. This summary is qualified in its entirety by reference to the full text of the Merger Agreement which is filed as an exhibit to our Registration Statement on Form S-1 of which this prospectus forms a part.

### The Merger

Under the Merger Agreement and in accordance with Delaware law, Merger Sub will merge with and into TOP, with TOP continuing as the surviving company. As a result of the Merger, TOP will become a wholly-owned subsidiary of AquaMed. As a result of the Merger, immediately after the Effective Time and consummation of the Private Placement, before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in such private placement and it is consummated on the terms currently proposed. Following the consummation of the Merger, AquaMed will issue shares representing approximately 4.99% and 0.08% of shares outstanding to Bezalel Partners, LLC and the Benchmark Company, LLC, respectively, for advisory and consulting services in connection with the Merger. Following such issuances and the consummation of the Merger and the Private Placement on the terms set forth above, the former Alliqua shareholders will hold approximately 9.5% of the total number of shares of AquaMed stock outstanding.

### **Closing and Effective Time**

The Merger will occur following the consummation by Alliqua of the Internal Reorganization and Spin-Off pursuant to the Asset Contribution and Separation Agreement between Alliqua and AquaMed and all other Separation Agreements (as defined below) and the consummation of the Adynxx Merger.

Under the terms of the Merger Agreement, the closing of the Merger will take place on a date and at a time to be specified by the parties to the Merger Agreement (the "Closing Date"), which will be no later than the third business day after the satisfaction or, to the extent permitted by applicable law, waiver of the conditions set forth in the Merger Agreement and discussed below in "Conditions to Consummation of the Merger".

On the Closing Date, Merger Sub and TOP will execute and file with the office of the Secretary of State of the State of Delaware the necessary certificate of merger executed in accordance with the Delaware Limited Liability Company Act. The Merger will become effective at the time of filing of the necessary certificate of merger, or at such later time as is agreed upon by the parties and set forth in such certificate of merger.

#### **Merger Consideration**

At the effective time of the Merger, all of the outstanding membership units of TOP will be automatically converted into the right to receive, in the aggregate, merger consideration consisting of shares of AquaMed common stock. Immediately after the effective time of the Merger and consummation of the Private Placement, before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis) (the "Merger Consideration"), of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that not more than \$10 million is raised in the Private Placement and it is consummated on the terms currently proposed.

Following the effective time of the Merger, all membership units of TOP will be automatically cancelled and cease to exist.

#### **Transaction Agreements**

The form of the Asset Contribution and Separation Agreement that will govern the terms of the Spin-Off is attached as an exhibit to the Merger Agreement. We will also enter into a Tax Matters Agreement and an Assumption Agreement (collectively and together with the Asset Contribution and Separation Agreement, the "Separation Agreements") in connection with the Spin-Off. See "The Asset Contribution and Separation Agreements."

#### Conditions to Consummation of the Merger

The obligations of each party to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of closing conditions that are contained in the Merger Agreement, including:

- · the Spin-Off having occurred pursuant to the Asset Contribution and Separation Agreement;
- the effectiveness of the registration statement of which this prospectus forms a part in connection with the Distribution, and the approval for listing on the Nasdaq Capital Market of the shares of AquaMed common stock to be issued in the Distribution and the Merger, subject to official notice of issuance;
- the absence of any order issued by any governmental authority of competent jurisdiction or other legal impediment preventing or making illegal the consummation of the Merger; and
- we shall have received binding commitments from investors to consummate the Private Placement immediately prior to the effective time of the Merger.

In addition, our, and Merger Sub's obligations to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of the following conditions:

- certain fundamental representations and warranties of TOP being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger;
- the representations and warranties of TOP, disregarding all materiality or material adverse effect qualifications, being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger (except to the extent such representations and warranties address matters as of a particular date, in which case as of such date) (other than the certain fundamental representations and warranties which must be true and correct in all respects);
- the covenants and agreements being performed by TOP in all material respects at or prior to the effective time of the Merger;
- TOP shall have obtained the consent of a majority of its members, and such consent shall not have been
  invalidated or revoked and shall remain in full force and effect;
- the absence of a TOP Material Adverse Effect since the date of the Merger Agreement;
- TOP shall have completed an audit of its financial statements for the years ended December 31, 2017 and December 31, 2016 by an independent registered auditor; and
- we shall have received an independent third-party valuation of our common stock to be distributed in the Distribution.

Furthermore, the obligations of TOP to consummate the Merger are subject to the satisfaction or waiver (to the extent permitted by applicable law) of the following conditions:

- certain fundamental representations and warranties of AquaMed and Merger Sub being true and correct in all respects in each case as of the date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger;
- the representations and warranties of AquaMed and Merger Sub, disregarding all materiality or material
  adverse effect qualifications, being true and correct in all respects in each case as of the



date of the Merger Agreement and as of the closing date of the Merger as if made as of the closing date of the Merger (except to the extent such representations and warranties address matters as of a particular date, in which case as of such date) (other than the certain fundamental representations and warranties which must be true and correct in all respects);

- the covenants and agreements being performed by AquaMed and Merger Sub in all material respects at or prior to the effective time of the Merger;
- the absence of any AquaMed Material Adverse Effect since the date of the Merger Agreement;
- AquaMed shall have completed an audit of its financial statements for the years ended December 31, 2017 and December 31, 2016 by an independent registered auditor; and
- we shall have delivered to TOP (a) resignation letters of any of our officers and directors, to be effective as of the Effective Time, who will not be continuing officers or directors of us, and (b) certified resolutions of our Board of Directors (i) causing our whole Board of Directors to consist of five directors as of the Effective Time, (ii) appointing to the Board of Directors such individuals as necessary to cause the Board of Directors as of the Effective Time to conform with the requirements set forth on Schedule 1.4 to the Merger Agreement, and (iii) appointing as officers of Parent such individuals as necessary to cause our officers as of the Effective Time to conform with the requirements set forth on Schedule 1.4 to the Merger Agreement. We shall also deliver resolutions, in our capacity as the sole member of the surviving company as of the Effective Time, appointing persons to the Board of Managers officers of the surviving company.

To the extent permitted by applicable law, each party to the Merger Agreement may waive, at its sole discretion, any of the conditions to its respective obligations to complete the Merger.

### **Representations and Warranties**

The Merger Agreement contains substantially reciprocal customary representations and warranties that AquaMed, Merger Sub and TOP made to each other as of specific dates.

The representations and warranties by each of AquaMed, Merger Sub and TOP in the Merger Agreement relate to, among other things:

- · due organization, good standing, corporate power;
- capitalization;
- authority to enter into the Merger Agreement (and other transaction-related agreements);
- no conflicts with or violations of governance documents, other obligations or laws;
- financial statements;
- absence of undisclosed liabilities;
- absence of certain changes or events;
- litigation and similar actions;
- employee benefit matters;
- compliance with applicable laws and ownership of certain licenses;
- environmental matters;
- tax matters;
- IP matters;
- · ownership of real and personal property;
- · existence and enforceability of material contracts;



- labor and employment matters;
- insurance; and
- payment of fees to brokers or finders in connection with the Merger Agreement.

In addition, TOP made representations and warranties that relate to controlled substances.

Many of the representations and warranties contained in the Merger Agreement are subject to a "material" or "material adverse effect" standard and none survive the closing.

Under the Merger Agreement, an "AquaMed Material Adverse Effect" means any effect, change, claim, event or circumstance (collectively "Effect") that, considered together with all other Effects, is or would reasonably be expected to be or to become materially adverse to, or has or would reasonably be expected to have or result in a material adverse effect on: (1) the business, financial condition or results of operations of AquaMed and its subsidiaries taken as a whole, or (2) the ability of AquaMed to consummate the Merger or the other transactions contemplated by the Merger Agreement. However, any adverse effect, change, claim, event or circumstance, individually or in the aggregate, arising from or relating to the following will not be deemed either to constitute, or be taken into account in determining whether there has occurred an AquaMed Material Adverse Effect:

- conditions generally affecting the industries in which we participate or the U.S. or global economy as a whole, to the extent that such conditions do not have a disproportionate impact on us, taken as a whole, as compared to other industry participants;
- general conditions in the financial markets, and any changes therein (including any changes arising out of
  acts of terrorism, war, weather conditions or other force majeure events), to the extent that such conditions
  do not have a disproportionate impact on us, taken as a whole, as compared to other industry participants;
- · changes in trading price or trading volume of our common stock; or
- changes in GAAP (or any interpretations of GAAP) applicable to us or any of our subsidiaries.

In addition, the term "TOP Material Adverse Effect" means any Effect that, considered together with all other Effects, is or would reasonably be expected to be or to become materially adverse to, or has or would reasonably be expected to have or result in a material adverse effect on: (1) the business, financial condition or results of operations of TOP taken as a whole, or (2) the ability of TOP to consummate the Merger or any of the other transactions contemplated by the Merger Agreement However, any adverse effect, change, claim, event or circumstance, individually or in the aggregate, arising from or relating to the following will not be deemed either to constitute, or be taken into account in determining whether there has occurred a TOP Material Adverse Effect:

- conditions generally affecting the industries in which TOP participates or the U.S. or global economy as a
  whole, to the extent that such conditions do not have a disproportionate impact on TOP, taken as a whole,
  as compared to other industry participants;
- general conditions in the financial markets, and any changes therein (including any changes arising out of
  acts of terrorism, war, weather conditions or other force majeure events), to the extent that such conditions
  do not have a disproportionate impact on TOP, taken as a whole, as compared to other industry
  participants;
- changes in GAAP (or any interpretations of GAAP) applicable to TOP or any of its subsidiaries; or
- the taking of any action expressly required to be taken pursuant to the Merger Agreement or requested by AquaMed to be taken pursuant to the terms of the Merger Agreement to the extent taken in accordance with such request.

### Covenants

In the Merger Agreement, we have made certain covenants relating to our conduct in respect of our business, and TOP has made certain covenants relating to its conduct of its business, with certain

exceptions specified in the Merger Agreement. Some of these covenants are not easily summarized. You are urged to read carefully the sections of the Merger Agreement entitled "Operation of the Business of the Parent Entities." The following summarizes the more significant of these covenants:

#### Conduct of Business

Each of AquaMed, with respect to its business, and TOP, with respect to its existing business, agrees to carry on its respective business in the ordinary course consistent with past practice, pay its respective taxes and debts when due (subject to good faith disputes), pay or perform its respective other obligations when due, and to use reasonable best efforts to preserve intact its respective current business organization, keep available the services of current officers and key employees and preserve relationships with material customers, suppliers, licensors and governmental bodies.

### Required Consent

Without the prior written consent of the other party, subject to certain exceptions and items disclosed in the schedules to the Merger Agreement, and solely with respect to AquaMed, in connection with the Private Placement, the Adynxx Merger, the transactions contemplated by the Asset Contribution and Separation Agreement, or the Distribution as contemplated by the Separation Agreements, none of AquaMed or TOP may take any or all of the following actions or authorize, commit or agree to take any of the following actions:

- declare, accrue, set aside or pay any dividend or make any other distribution in respect of any securities, or repurchase, redeem or otherwise reacquire the company's units or other securities (except for (A) AquaMed's right to repurchase shares of its restricted stock held by an employee of AquaMed upon termination of such employee's employment; or (B) in connection with the withholding of shares of AquaMed common stock to satisfy tax obligations with respect to the exercise, vesting or settlement of equity awards);
- sell, issue, grant or authorize the sale, issuance or grant of: (A) any units of the company or other security;
   (B) any option, call, warrant or right to acquire any units of the company or other security (or whose value is directly related to units of the company); or (C) any instrument convertible into or exchangeable for any units of the company or other security (except for TOP's right to raise up to \$500,000);
- amend, waive any of its rights under any employment agreement or arrangement applicable to the employees of the company;
- amend or permit the adoption of any amendment to its certificate of formation, limited liability company
  agreement or other charter or organizational documents;
- (A) acquire any equity interest or other interest in any other entity; (B) form any subsidiary; or (C) effect
  or become a party to any merger, consolidation, share exchange, business combination, amalgamation,
  recapitalization, reclassification of limited liability company interests, unit split, reverse unit split, division
  or subdivision of units, consolidation of units or similar transaction;
- make any capital expenditure in excess of \$75,000 (except that the applicable company may make any capital expenditure that is provided for in such company's capital expense budget delivered or made available to the other party prior to the date of the Merger Agreement);
- other than in the ordinary course of business and consistent with past practices: (A) enter into or become bound by, or permit any of the assets owned or used by it to become bound by, any material contract; or (B) amend, terminate, or waive any material right or remedy under, any material contract;
- acquire, lease or license any right or other asset from any other person or sell or otherwise dispose of, or lease or license, any right or other asset to any other person (except in each case for assets: (A) acquired, leased, licensed or disposed of by the company in the ordinary course of business and consistent with past practices; or (B) that are immaterial to the business of the company, taken as a whole;

- make any pledge of any of its material assets or permit any of its material assets to become subject to any encumbrances, except for certain permitted encumbrances;
- lend money to any person;
- except as may be required by law with respect to TOP, establish, adopt, enter into or amend any employee
  plan or employment agreement (except as contemplated by the Merger Agreement), pay any bonus or
  make any profit-sharing or similar payment to, or increase the amount of the wages, salary, commissions,
  fringe benefits or other compensation (including equity-based compensation, whether payable in stock,
  cash or other property) or remuneration payable to, or adopt or agree to any retention arrangements with
  or for the benefit of, any of its managers or any of its officers or other employees (except for routine,
  reasonable salary increases to non-officer employees in the ordinary course of business and in accordance
  with past practices in connection with the customary employee review process);
- hire any employee at the level of Vice President or above or with an annual base salary in excess of \$50,000, or promote any employee to the level of Vice President or above;
- other than in the ordinary course of business and consistent with past practices or as required by concurrent changes in GAAP, change any of its methods of accounting or accounting practices in any respect;
- make any material tax election;
- commence any legal proceeding, except with respect to: (A) routine matters in the ordinary course of business and consistent with past practices; (B) in such cases where reasonably determined in good faith that the failure to commence suit would result in a material impairment of a valuable aspect of its business (provided that such party consults with the other party and considers the views and comments of the other party with respect to such legal proceedings prior to commencement thereof); or (C) in connection with a breach of the Merger Agreement or the transactions contemplated by the Merger Agreement;
- settle any legal proceeding or other material claim, other than pursuant to a settlement: (A) that results
  solely in monetary obligation involving payment by of the amount specifically reserved in accordance
  with GAAP with respect to such legal proceedings or claim on such company's latest balance sheet; or
  (B) that results solely in monetary obligation involving only the payment of monies of not more than
  \$20,000 in the aggregate; or
- agree or commit to take any of the foregoing actions.

In addition, AquaMed agreed not to accelerate collection of any accounts receivable without the prior written consent of TOP.

#### Private Placement

We and TOP agreed to use reasonable best efforts to arrange and to consummate the Private Placement on terms and conditions reasonably acceptable to us and TOP. In addition, we and TOP have agreed to use reasonable best efforts, as applicable, to cooperate in all aspects necessary or reasonably requested by us or TOP in connection with the arrangement and consummation of the Private Placement, including, without limitation, (A) participating in a reasonable number of meetings, presentations, and meetings with, and presentations to, prospective investors; (B) assisting with the marketing and due diligence efforts with respect to the Private Placement; (C) furnishing financial and other information regarding us, TOP and our respective subsidiaries, as required by the Private Placement; and (D) to obtain waivers, consents, estoppels and approvals from other parties to material leases, encumbrances and contracts to which we or TOP are a party, in each case to the extent required by the terms of the Private Placement. We also agreed to consult in good faith with TOP and its professional advisers regarding the material aspects of the Private Placement, including the form and manner thereof and to consider in good faith comments provided by TOP and its professional advisers in consummating the Private Placement. We and TOP are obligated to update any



required information in order to ensure that such information does not contain any untrue statement of material fact or omit to state any material fact necessary in order to make the statements contained therein not materially misleading, as and to the extent required by the terms of the Private Placement.

#### Other Covenants and Agreements

The Merger Agreement contains certain other covenants and agreements, including covenants (with certain exceptions specified in the Merger Agreement) relating to:

- delivery of audited financial statements of each of AquaMed and TOP for the fiscal year ended December 31, 2018 on or before March 1, 2019;
- cooperation among the parties relating to the prompt preparation and filing of the registration statement of which this prospectus forms a part in connection with the Distribution;
- cooperation among the parties to obtain all governmental approvals and consents necessary to consummate the Merger and the other transactions;
- resignations of the officers and directors of AquaMed and TOP;
- public disclosure of the Merger and the other transactions contemplated by the Merger Agreement;
- · implementation of internal controls over financial reporting;
- delivery of audited financial statements of each of AquaMed and TOP;
- transaction expenses; and
- obtaining the necessary member and stockholder approvals of each of AquaMed, Merger Sub and TOP.

### Amendment; Extension; Waiver

The Merger Agreement may be amended by the parties at any time. Prior to the effective time of the Merger, the parties may extend the time for the performance of any of the obligations or other acts of the parties or waive any inaccuracies in the representations and warranties or compliance with any of the agreements or conditions contained in the Merger Agreement.

#### **Termination of the Merger Agreement**

The Merger Agreement may be terminated at any time before the effective time of the Merger by the mutual written consent of us and TOP. It may also be terminated by either us or TOP if:

- the effective time of the Merger has not occurred on or before April 11, 2019 unless the failure to effect the Merger by that date is due to the failure of the party seeking to terminate the Merger Agreement to perform its obligations set forth in the Merger Agreement; or
- if a court of competent jurisdiction or other governmental authority shall have issued a final and nonappealable order, or shall have taken any other action, having the effect of permanently restraining, enjoining or otherwise prohibiting the Merger.

The Merger Agreement may also be terminated by:

 TOP at any time before the effective time of the Merger if any of AquaMed's representations and warranties shall be inaccurate such that the closing condition set forth above shall not be satisfied or any of AquaMed's covenants or obligations shall have been materially breached, and such breach or inaccuracy has not been cured within 30 business days following notice of such inaccuracy or breach; or

 AquaMed at any time before the effective time of the Merger if any of TOP's representations and warranties shall be inaccurate such that the closing condition set forth above shall not be satisfied or any of TOP's covenants or obligations shall have been materially breached, and such breach or inaccuracy has not been cured within 30 business days following notice of such inaccuracy or breach.

### Fees and Expenses

All of our transaction expenses (as defined in the Merger Agreement) will be paid by Alliqua prior to the Effective Time, except that the surviving company of the Merger will pay up to \$100,000 of such transaction expenses from the proceeds of the Private Placement and will reimburse \$5,000 to Alliqua from the proceeds of the Private Placement for Alliqua's payment of such amount in connection with our listing on the Nasdaq Capital Market. All of TOP's transaction expenses are required to be satisfied from funds other than the proceeds of the Private Placement, except the surviving company of the Merger shall pay up to \$200,000 of such expenses from the proceeds of the Private Placement.

# THE ASSET CONTRIBUTION AND SEPARATION AGREEMENT AND ANCILLARY AGREEMENTS

The following are summaries of the material provisions of the Asset Contribution and Separation Agreement and ancillary agreements that we intend to enter into before the Distribution. These summaries are qualified in their entirety by reference to the full text of the Asset Contribution and Separation Agreement and ancillary agreements which are filed as exhibits to our Registration Statement on Form S-1, as amended, of which this prospectus forms a part.

## Asset Contribution and Separation Agreement

We intend to enter into an Asset Contribution and Separation Agreement with Alliqua before the Distribution. The Asset Contribution and Separation Agreement will set forth our agreements with Alliqua regarding the principal actions to be taken in connection with the Spin-Off. It will also set forth other agreements that govern aspects of our relationship with Alliqua following the Spin-Off.

Internal Reorganization. The Asset Contribution and Separation Agreement will provide for the transfers of assets and assumptions of liabilities that are necessary in advance of the Distribution so that we hold the assets of, and the liabilities associated with, Alliqua's custom hydrogels business, and certain additional actions related to the Spin-Off that will occur prior to the Distribution.

*Merger Agreement.* The Asset Contribution and Separation Agreement requires us to use reasonable best efforts to consummate the Merger and the other transactions contemplated by the Merger Agreement.

*Representations and Warranties.* In general, Alliqua will make representations or warranties that the material items of equipment and other tangible assets owned by or leased to, and necessary for the operation of, our business that are part of the assets to be contributed by Alliqua to AquaMed are adequate for the uses to which they are being put by Alliqua, are in good and safe working condition and repair (ordinary wear and tear excepted) and are adequate for the conduct of AquaMed business in the manner in which such business is currently being conducted. In addition, Alliqua will represent that all of said tangible assets are being delivered to AquaMed free and clear of any encumbrances, except for certain permitted encumbrances.

*Consents; Assignments Not Effected at Closing.* The parties will use commercially reasonable efforts to obtain any consent required for the transfer and assignment of all contributed contracts, to AquaMed, and to obtain any release, substitution or amendment required to novate any and all contributed contracts or to obtain in writing the unconditional release from such Alliqua Contributed Contracts, and to permit AquaMed to assume the rights and liabilities under such contracts. If any consent required for Alliqua to transfer or assign any of the contributed contracts to AquaMed is not obtained on or before closing, for a two-year period from and after the closing date, Alliqua and AquaMed will use commercially reasonable efforts, and shall cooperate with each other, following the closing, at the sole cost and expense of AquaMed, to obtain such consent. AquaMed has agreed to reimburse Alliqua for any costs or expenses incurred in connection with continued possession or ownership of such contract.

*The Distribution.* The Asset Contribution and Separation Agreement will govern Alliqua's and our respective rights and obligations regarding the proposed Distribution. Prior to the Distribution, Alliqua will deliver all the issued and outstanding shares of our common stock to the Distribution Agent. Following the Distribution, the Distribution Agent will electronically deliver the shares of our common stock to Alliqua stockholders based on the distribution ratio.

*Conditions.* The Asset Contribution and Separation Agreement will also provide that several conditions must be satisfied or waived by Alliqua in its sole and absolute discretion before the Distribution can occur. For further information about these conditions, see "The Transactions — Conditions to the Spin-Off." The board of directors of Alliqua may, in its sole and absolute discretion, determine the Record Date and the Distribution Date.

*Non-solicitation.* The Asset Contribution and Separation Agreement will also provide that Alliqua and we will be restricted from, whether for its own account or for the account of any person, soliciting, endeavoring to entice away from, or otherwise interfering with the relationship with, any person that, during the restricted period, is employed by or otherwise engaged to perform services for the other party (including such party's subsidiaries and other entities the financial statements of which are consolidated with those of the party under GAAP).

*Employee Matters.* We expect certain AquaMed employees will continue with us after the closing. As of the closing, the salary, wages, bonus and/or incentive compensation, and other employee benefit plans, programs, and arrangements with respect to such continuing employees shall be the sole responsibility of AquaMed, on such terms, if any, that AquaMed may determine to provide to such continuing employees. On and after the closing date, Alliqua will be responsible and will agree to assume or retain, pay, perform, fulfill and discharge, in due course in full (i) all liabilities under all of Alliqua's benefit plans, (ii) all liabilities with respect to the employment, service, termination of employment or termination of service of all of the employees and former employees to the extent arising in connection with or as a result of employment with or the performance of services, termination of service of all liabilities with respect to the extent arising in connection with or the performance of services for Alliqua before, on or after the closing date, and (iii) all liabilities with respect to the employment, service, and remination of service of all of the employment, service, termination of service of all alliqua group employees and former employees to the extent arising in connection with or the performance of services for AluaMed before the closing date, and liabilities arising in connection with any claims by any service provider to Alliqua for severance or other rights on account of a change in control in connection with the transactions contemplated by the Asset Contribution and Separation Agreement.

*Indemnification.* We and Alliqua will each agree to indemnify the other and certain affiliates and related persons against certain liabilities incurred in connection with the Spin-Off and our and Alliqua's respective businesses. These indemnities are principally designed to place financial responsibility for the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of our business with us and financial responsibility for the obligations and liabilities of Alliqua's business with Alliqua. Specifically, each party will indemnify, defend and hold harmless the other party, its affiliates and subsidiaries and each of its officers, directors, employees and agents for any loss, damage, liability, judgment, award, fee or expense (including reasonable expenses of investigation and reasonable attorneys', experts', accounting, or advisory fees and expenses in connection with any action, suit or proceeding whether involving a third-party claim or a claim solely between the parties hereto), including any incidental, indirect or consequential damages, losses, liabilities or expenses, but excluding any lost profits or diminution in value (collectively, "Damages") arising out of or due to the breach of any covenant or obligation or representation of such party contained in the Asset Contribution and Separation Agreement.

In addition, Alliqua will indemnify us for Damages that are incurred or suffered based upon, arising out of, with respect to, or by reason of:

• any liabilities retained by Alliqua.

Furthermore, we will indemnify Alliqua for Damages that are incurred or suffered based upon, arising out of, with respect to, or by reason of:

- contracts contributed to us by Alliqua, whether rising prior to, on, or after the closing date;
- · ownership, use or operation after the closing date of the assets contributed to us by Alliqua;
- · conducting our business after the closing date; or
- any liabilities assumed by us.

The amount of each party's indemnification obligations will be subject to reduction by any insurance proceeds received by the party being indemnified.

#### **Tax Matters Agreement**

The Tax Matters Agreement generally sets out the respective rights, responsibilities, and obligations of Alliqua and AquaMed with respect to taxes (including taxes arising in the ordinary course of business and taxes incurred as a result of the Spin-Off), tax attributes, tax returns, tax contests and certain other related tax matters. A copy of the Tax Matters Agreement is included as an exhibit to our Registration Statement on Form S-1, of which this prospectus forms a part, and is incorporated in this prospectus by reference.

The Tax Matters Agreement allocates responsibility for the preparation and filing of certain tax returns (and the payment of taxes reflected thereon), including Alliqua's consolidated federal income tax return, tax returns associated with both the Alliqua business and the AquaMed business, and tax returns associated with either the Alliqua business or the AquaMed business, and provides for certain reimbursements by the parties.

Under the Tax Matters Agreement, Alliqua will generally be liable for its own taxes and taxes of all of its subsidiaries (other than AquaMed, the taxes for which AquaMed shall be liable) for all tax periods (or portion thereof) ending on the date of the separation. AquaMed will be responsible for its taxes, for taxes of Alliqua arising as a result of the Spin-Off and for any transfer taxes incurred in the Spin-Off and for taxes attributable to the AquaMed business.

Each of Alliqua and AquaMed will indemnify each other against any taxes allocated to such party under the Tax Matters Agreement or arising from any breach of its covenants thereunder, and related out-of-pocket costs and expenses.

#### Assumption Agreement

The Assumption Agreement generally sets out the respective rights, responsibilities, and obligations of Alliqua and AquaMed with respect to the assets and liabilities being transferred from Alliqua to AquaMed. Pursuant to the Assumption Agreement, Alliqua will assign to AquaMed all of Alliqua's right, title and interest in the assets owned by Alliqua which primarily relate to our hydrogel business and AquaMed will assume all of the liabilities relating thereto or which primarily relate to our hydrogel business. A copy of the Assumption Agreement is included as an exhibit to our Registration Statement on Form S-1, of which this prospectus forms a part, and is incorporated in this prospectus by reference.

#### MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE DISTRIBUTION

#### General

The following is a summary description of the material U.S. federal income tax aspects of the Spin-Off. This summary is not intended as a complete description of all of the tax consequences of the Spin-Off and does not discuss tax consequences under the laws of state, local or foreign governments or any other jurisdiction. Moreover, the tax treatment of a stockholder may vary, depending upon his, her or its particular situation. In this regard, special rules not discussed in this summary may apply to some of our stockholders. In addition, this summary applies only to shares which are held as capital assets. The following discussion may not be applicable to a stockholder who acquired his, her or its shares by exercising stock options or otherwise as compensation.

The following discussion is based on currently existing provisions of the Code, existing, proposed and temporary treasury regulations promulgated under the Code and current administrative rulings and court decisions. All of the foregoing are subject to change, which may or may not be retroactive, and any of these changes could affect the validity of the following discussion.

Each stockholder is urged to consult his, her or its own tax advisor as to the particular tax consequences to him, her or it of the Spin-Off described herein, including the applicability and effect of any state, local or foreign tax laws, and the possible effects of changes in applicable tax laws.

## Tax Consequences of the Spin-Off

For U.S. federal income tax purposes, the distribution by Alliqua of the shares of AquaMed common stock will not be eligible for treatment as a tax-free distribution. Accordingly, each holder of Alliqua common stock who receives shares of AquaMed common stock in the Spin-Off generally will be treated as if such stockholder received a taxable distribution in an amount equal to the fair market value of AquaMed common stock received (including any fractional share deemed to be received by and sold on behalf of the stockholder), which will result in: (a) a dividend to the extent of such stockholder's ratable share of Alliqua's current and accumulated earnings and profits; then (b) a reduction in such stockholder's basis in Alliqua's common stock (but not below zero) to the extent the amount received exceeds the amount received acceeds the sum of the amounts referenced in clauses (a) and (b). Each stockholder's basis in his, her or its AquaMed common stock will be equal to the fair market value of such stock at the time of the Spin-Off. A stockholder's holding period for such shares will begin the day after the Spin-Off date.

A corporate level U.S. federal income tax will be payable by the consolidated group of which Alliqua is the common parent if gain realized in the Spin-Off exceeds any net operating losses that may be available to offset such gain. The tax would be based upon the gain, if any, computed as the difference between the fair market value of the AquaMed common stock and Alliqua's adjusted basis in such stock. Alliqua expects that it will have sufficient losses available to fully offset any gain realized as a result of the Spin-Off.

Alliqua's earnings and profits generally will be increased by any gain Alliqua recognizes as a result of the contribution of assets to AquaMed and the subsequent Spin-Off. Alliqua will not be able to advise stockholders of the amount of its earnings and profits until after the end of the tax year in which the Spin-Off occurs.

In addition, Alliqua or other applicable withholding agents may be required or permitted to withhold at the applicable rate on all or a portion of the Spin-Off distribution (including cash paid in lieu of fractional shares) payable to non-U.S. stockholders, and any such withholding would be satisfied by Alliqua or the other applicable withholding agent either withholding and selling a portion of our shares of common stock otherwise distributable to non-U.S. stockholders, or withholding such amount from any cash distribution otherwise payable to such non-U.S. stockholders. Any shares or cash so withheld shall be treated as if they were paid to such non-U.S. stockholders. Although Alliqua will be ascribing a value to shares of AquaMed common stock it distributes for tax purposes, this valuation is not binding on the IRS or any other tax authority. These taxing authorities could ascribe a higher valuation to such shares,

particularly if such shares trade at prices significantly above the value ascribed to them by Alliqua in the period following the distribution. Such a higher valuation may cause a larger reduction in the tax basis of a stockholder's shares of Alliqua common stock or may cause a stockholder to recognize additional dividend or capital gain income.

## **Back-up Withholding Requirements**

United States information reporting requirements and backup withholding may apply with respect to dividends paid on, and proceeds from the taxable sale, exchange or other disposition of, AquaMed common stock unless the stockholder: (a) is a corporation or non-U.S. holder or comes within certain other exempt categories, and, when required, demonstrates these facts (including by providing any applicable IRS form); or (b) provides a correct taxpayer identification number, certifies as to no loss of exemption from backup withholding and otherwise complies with applicable requirements of the backup withholding rules. A stockholder who does not supply us with his, her or its correct taxpayer identification number may be subject to penalties imposed by the IRS. Any amount withheld under these rules will be creditable against the stockholder's U.S. federal income tax liability. Stockholders should consult their tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining such an exemption. If information reporting requirements apply to a stockholder, the amount of dividends paid with respect to the stockholder's shares will be reported annually to the IRS and to the stockholder.

# Stockholders should consult their own tax advisors as to the particular tax consequences of the Spin-Off to them.

## **USE OF PROCEEDS**

We will not receive any proceeds from the distribution of our common stock in the Spin-Off.

## DETERMINATION OF OFFERING PRICE

No consideration will be paid for the shares of our common stock in the Spin-Off.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock. For the foreseeable future, we anticipate that all available funds and any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to our shareholders. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our Board of Directors may deem relevant.



## CAPITALIZATION

The following table sets forth our cash and capitalization as of December 31, 2018, on a historical basis and on pro forma basis to give effect to the Spin-Off and the Merger, as if they occurred on December 31, 2018. The historical combined balance sheet data presented in the capitalization table as of December 31, 2018 for AquaMed is derived from AquaMed's audited financial statements and for TOP is derived from TOP's audited consolidated financial statements, included elsewhere in this prospectus. The unaudited pro forma combined financial information was prepared using the purchase method of accounting, with TOP treated as the "acquirer" of AquaMed for accounting purposes. The effect of the Merger presented below includes the impact of preliminary purchase accounting adjustments as well as the assumed conversion of \$500,000 principal amount of convertible promissory notes issued by TOP. The pro forma information presented below is derived from the "Unaudited Pro Forma Combined Financial Statements" included elsewhere in this prospectus. In addition, you should review the following table in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations of AquaMed," "Management's Discussion and Plan of Operations of TOP," "Liquidity and Capital Resources Following The Transactions" and the financial statements and accompanying notes included elsewhere in this prospectus.

(in thousands)	TO Pharmaceuticals as of December 31, 2018		AquaMed Technologies, Inc. as of December 31, 2018	Effect of Mergers	Pro Forma Combined
Cash	\$	359	—	\$10,000	\$ 10,359
Short-term obligations:					
Current maturities of long-term debt	\$	500		\$ (500)	
Current maturities of capitalized lease obligations		—			_
Total short-term debt and current obligations of long- term debt	\$	500	_	\$ (500)	_
Long-term obligations:					
Total long-term debt	\$	—			_
Less: current maturities of long-term debt		_			
Total long-term debt, net of current maturities		_	_	_	_
Stockholders' equity:					
Member's Deficit	\$	(1,933)	\$ —	\$ 1,933	
Parent's Net Investment		_	281	(281)	_
Preferred stock					—
Common stock				17	17
Additional paid in capital				8,831	8,831
Accumulated deficit					—
Accumulated other comprehensive (loss) income					
Total equity		(1,933)	281	10,500	8,848
Total capitalization	\$	(1,433)	\$ 281	10,000	\$ 8,848

# SELECTED HISTORICAL FINANCIAL DATA FOR AQUAMED

The following tables present our selected historical financial data for the periods and as of the dates indicated.

Our historical results are not necessarily indicative of future operating results.

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

## **Statement of Operations Data:**

	Year E Decem	
(in thousands)	2018	2017
REVENUES:		
Revenue, net of returns, allowances and discounts	\$ 2,213	\$ 1,992
Cost of revenues	(1,699)	(1,845)
Gross profit	514	147
OPERATING EXPENSES:		
Selling, general and administrative	(2,402)	(1,116)
Total operating expenses	(2,402)	(1,116)
Loss from operations	(1,888)	(969)
OTHER INCOME:		
Sundry	—	_
Total other income	_	_
LOSS FROM OPERATIONS BEFORE TAX	(1,888)	(969)
INCOME TAX BENEFIT	_	16
NET LOSS	\$(1,888)	\$ (953)

**Balance Sheet Data:** 

(in thousands)	December 31, 2018	December 31, 2017
Consolidated Balance Sheet Data:		
Accounts receivable, net	\$ 34	\$ 99
Inventory, net	101	93
Prepaid expenses and other current assets	226	7
Total assets	739	894
Total liabilities	458	269
Total Parent Net Investment	281	625
Total liabilities and Parent net investment	\$ 739	\$ 894

# SELECTED HISTORICAL CONSOLIDATED FINANCIAL DATA FOR TOP

The following tables present TOP's selected historical consolidated financial and for the periods and as of the dates indicated.

TOP's historical results are not necessarily indicative of future operating results.

You should read this information in conjunction with the section titled "Management's Discussion and Analysis of Financial Condition and Plan of Operations of TOP" and TOP's consolidated financial statements and notes thereto, in each case, included elsewhere in this prospectus.

# **Consolidated Statement of Operations Data:**

		Year Ended December 31,		
	2018	2017		
OPERATING EXPENSES:				
Selling, general and administrative	\$ 740,481	\$ 502,574		
Research and development	431,013	235,096		
Total operating expenses	1,171,494	737,670		
Loss from operations	(1,171,494)	(737,670)		
NET LOSS	\$(1,171,494)	<u>\$(737,670)</u>		

## **Balance Sheet Data:**

	December 31, 2018	December 31, 2017
Consolidated Balance Sheet Data:		
Licenses, net of accumulated amortization	429,250	454,500
Total assets	909,252	471,500
Total liabilities	2,842,455	2,269,465
Members' deficit	\$(1,933,203)	\$(1,797,965)

## UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL INFORMATION

The following TOP and AquaMed unaudited pro forma condensed combined financial statements, which are referred to in this prospectus as the unaudited pro forma financial information, gives effect to the proposed merger in which TOP will become a 100% owned subsidiary of AquaMed. The Unaudited Pro Forma Condensed Combined Balance Sheet is presented as if the Merger had closed on December 31, 2018. The Unaudited Pro Forma Condensed Combined Statement of Operations is presented as if the Merger had closed on January 1, 2018.

The unaudited pro forma combined financial information included herein is derived from the historical financial statements of AquaMed and TOP, included elsewhere herein. The preparation of the unaudited pro forma financial information and related adjustments required management to make certain assumptions and estimates, which it believes to be reasonable, which are described in the section entitled "Notes to Unaudited Pro Forma Combined Financial Information." Management has not performed a complete and thorough valuation analysis necessary to determine the fair market values of all of the AquaMed assets to be acquired and liabilities to be assumed, and accordingly, as described in Note 2(a) below, the unaudited pro forma combined financial information includes a preliminary allocation of the purchase price to reflect the fair value of those assets and liabilities. A final determination of fair values of AquaMed assets and liabilities, along with the fair value of the actual net assets of AquaMed that exist as of the date of completion of the Merger along with the fair value of the common shares to be issued.

Consequently, amounts preliminarily assumed for acquisition consideration and allocated to acquired assets and assumed liabilities could change significantly from those amounts used in the unaudited pro forma condensed combined financial statements presented below.

The unaudited financial information are provided for informational purposes only and does not purport to represent what the combined results of operations actually would have been if the Merger had occurred on January 1, 2018 or what those results will be for any future periods or what the combined balance sheet would have been if the Merger had occurred on December 31, 2018 or what the combined balance sheet will be on any future date. The pro forma adjustments are based on information current as of the time of this filing or as otherwise indicated; and has not been adjusted to reflect any matters not directly attributable to implementing the merger. No adjustment, therefore, has been made for actions which may be taken once the Merger is complete, such as any of TOP integration plans related to AquaMed. In connection with the plan to integrate the operations of TOP and AquaMed following the completion of the merger, TOP anticipates that nonrecurring charges, such as costs associated with systems implementation and other costs related to exit or disposal activities, could be incurred. TOP is not able to determine the timing, nature and amount of these charges as of the date of this prospectus. However, these charges could affect the results of operations of TOP and AquaMed, as well as those of the combined company following the completion of the Merger, in the period in which they are recorded. The unaudited pro forma condensed combined financial statements do not include the effects of the costs associated with any restructuring or integration activities resulting from the merger, as they are nonrecurring in nature and were not factually supportable at the time that the unaudited pro forma condensed combined financial statements were prepared. Additionally, the unaudited pro forma adjustments do not give effect to any nonrecurring or unusual restructuring charges that may be incurred as a result of the integration of the two companies or any anticipated disposition of assets that may result from such integration. As a result, the actual amounts recorded in the future combined financial statements of TOP will differ from the amounts reflected in the unaudited pro forma combined financial information, and the differences may be material.



# UNAUDITED PRO FORMA CONDENSED CONSOLIDATED BALANCE SHEET As of December 31, 2018

	TO Pharmaceuticals <sup>(1)</sup>	AquaMed Technologies, Inc. <sup>(1)</sup>	Transaction Adjustments	Footnote Reference	Pro Forma Consolidation
ASSETS:					
Current Assets:					
Cash and cash equivalents	\$ 359	\$ —	\$ 10,000	3(c)	\$ 10,359
Accounts receivable	—	34	-		34
Inventory, net	—	101	—		101
Prepaid expenses and other current assets	121	226			347
Total current assets	480	361	10,000		10,841
Improvements and equipment, net	—	200	_		200
Intangible assets, net	429	_	—		429
Goodwill	—	—	_		—
Other assets	_	178	_		178
Total assets	\$ 909	\$739	\$ 10,000		\$ 11,648
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current Liabilities:					
Accounts payable	\$ 294	\$157	\$ —		\$ 451
Accrued expenses and other current liabilities	449	250	_		699
Convertible promissory notes payable	500		(500)	3(e)	
Due to parent	1,599				1,599
Total current liabilities	2,842	407	—		3,249
Long-term debt			_		_
Other long-term liabilities		51			51
Total liabilities	2,842	458	(500)		2,800
Commitments and Contingencies					
Stockholders' Equity					
Member Deficit	(1,933)		1,933	3(b)	_
Parent's Net Investment	—	281	(281)	2(a), 3(a)	_
Preferred Stock	_	_	_		_
Common Stock	—	—	17	3(d)	17
Additional paid-in capital	_	_	8,831	3(a), 3(b)	8,331
Accumulated deficit	_	_	_	2(a), 3(c), 3(d)	_
Total stockholders' equity	(1,933)	281	10,500		8,848
Total liabilities and stockholders' equity	\$ 909	\$739	\$ 10,000		\$ 11,648

See Notes to Unaudited Pro Forma Combined Financial Information.

# UNAUDITED PRO FORMA CONDENSED COMBINED STATEMENT OF OPERATIONS For the year ended December 31, 2018

	TO Pharmaceuticals <sup>(1)</sup>	AquaMed Technologies, Inc. <sup>(1)</sup>	Transaction Adjustments	rootnote	Pro Forma Combined
Revenue, net of returns, allowances and discounts	\$	\$ 2,213	\$ —		\$ 2,213
Cost of revenues	_	1,699	_		1,699
Gross profit		514	_		514
Operating expenses					
Selling, general and administrative	740	2,402	(138)	3(f)	3,004
Research and product development	431				431
Total operating expenses	1,171	2,402	(138)		3,435
Loss from operations	(1,171)	(1,888)	138		(2,921)
Other income (expense)					
Total other expense					
Loss before income tax provision	(1,171)	(1,888)			(3,059)
Income tax benefit			138		138
Net loss	\$(1,171)	\$(1,888)	\$ 138		\$ (2,921)
Net loss per common share				3(g)	\$ (0.18)
Weighted average common shares outstanding	_	—	16,278	3(g)	16,278

See Notes to Unaudited Pro Forma Combined Financial Information.

#### Notes to Unaudited Pro Forma Combined Financial Information

## 1. BASIS OF PRESENTATION

The unaudited pro forma combined financial information has been derived from financial statements prepared in accordance with the Generally Accepted Accounting Principles ("GAAP") and reflects the proposed Merger of AquaMed with TOP.

The underlying financial information of TOP has been derived from the audited consolidated financial statements of TOP for the years ended December 31, 2018 and 2017, included elsewhere herein. The underlying financial information of AquaMed has been derived from the audited financial statements of AquaMed for the years ended December 31, 2018 and 2017, included elsewhere herein.

The Merger will be accounted for as a business combination under the scope of the Financial Accounting Standards Board's Accounting Standards Codification 805, Business Combinations, or ASC 805. The unaudited pro forma combined financial information was prepared using the acquisition method of accounting. The acquisition method of accounting, based on ASC 805, uses the fair value concepts defined in ASC 820, "Fair Value Measurement." Pursuant to ASC 805, TOP currently expects that it will be determined to be the accounting acquirer based on the evaluation of the following considerations:

- The former members of TOP are expected to hold a majority of the voting securities of AquaMed upon completion of the Merger.
- The post-Merger composition of the board of directors of AquaMed is expected to be composed of a
  majority of directors appointed by TOP.
- The post-Merger composition of the senior management of AquaMed is expected to be dominated by the former managers of TOP.

As such, the unaudited pro forma combined financial information has been prepared with TOP as the accounting acquirer and AquaMed as the acquiree, assuming that the Merger had been completed on January 1, 2018, for the unaudited pro forma combined statement of operations and on December 31, 2018, for the unaudited pro forma combined statement.

This unaudited pro forma combined financial information is not intended to reflect the financial position and results of operations which would have actually resulted had the Merger been effected on the dates indicated. Further, the unaudited pro forma results of operations and balance sheet are not necessarily indicative of the results of operations that may be achieved in the future or what may be reflected in any future balance sheet. No account has been taken of the impact of transactions that have occurred or might occur subsequent to the dates referred to above. No adjustment, therefore, has been made for actions which may be taken once the merger is complete, such as any integration plans related to AquaMed.

The unaudited pro forma financial information reflects the preliminary assessment of fair values to the assets acquired and liabilities assumed, along with the consideration to be given. Fair value estimates were determined based on preliminary discussions between TOP and AquaMed management, and due diligence efforts. Management believes the carrying value of Aquamed's assets and liabilities along with the consideration to be given is a close proxy for the preliminary fair value.

## 2. ALLOCATION

## (a) Preliminary Allocation of Merger Consideration to Assets Acquired

Receivables and other current assets	260
Property and equipment	200
Inventory	101
Goodwill	0
Other noncurrent assets	178
Other liabilities assumed	(458)
Preliminary valuation of common shares to be issued	\$ 281

#### Notes to Unaudited Pro Forma Combined Financial Information

i. The value prescribed to the shares AquaMed will receive is a preliminary valuation and will be revalued upon the closing of the PIPE transaction.

## 3. PRO FORMA TRANSACTION ADJUSTMENTS

The unaudited pro forma financial information reflects the following adjustments:

## (a) Recapitalization of AquaMed's Parent's Net Investment

An adjustment to recapitalize AquaMed's Parent's Net Investment of \$0.281 million was reflected in the unaudited pro forma combined balance sheet as of December 31, 2018.

## (b) Recapitalization of TOP's Member's Equity

An adjustment to recapitalize TOP's Member's deficit of \$1.933 million was reflected in the unaudited pro forma combined balance sheet as of December 31, 2018.

#### (c) Private Placement

An adjustment to reflect proceeds of approximately \$10 million in the private placement which is expected to be completed contemporaneously with the Merger.

## (d) Recapitalization of the capital structure post merger and private placement.

To reflect the par value of the anticipated 17,189,183 shares of common stock anticipated to be outstanding after the transactions, including the Private Placement, as follows:

Name	Aggregate Number of Shares
Former Alliqua Shareholders	1,750,000
Former TOP Members (excluding conversion of \$500,000 of principal amount of convertible notes)	11,974,112
Shares sold to investors in the Private Placement	2,333,333
Shares issuable upon the assumed conversion of \$500,000 of principal amount of TOP convertible notes	221,889
Shares issued to consultant	758,182
Shares issued to advisor	151,667
Total shares outstanding:	17,189,183

## (e) Convertible Note Payable

Reflects the automatic conversion of the \$500,00 principal amount of convertible notes issued by TOP upon consummation of the merger, at a conversion place equal to the lesser of (a) 80% of the per share price in the Private Placement or (b) \$2.30 per share.

## (f) Direct Merger Cost

To reverse \$138,000 of direct merger costs included in the 2018 historical financial statements.

#### (g) Proforma loss per share

To present proforma loss per share as if the shares were issued on January 1, 2018. The proforma weighted average shares excludes the 892,349 shares to be issued to consultants at the time of the Merger for services performed associated with the Merger.

## Notes to Unaudited Pro Forma Combined Financial Information

## (h) Consultant

In connection with certain consulting services provided in connection with the Merger, the surviving company will issue 758,182 shares of common stock to Bezalel Partners, LLC following the consummation of the Merger.

# (i) Advisor

In connection with certain advisory services in connection with the Merger, including a valuation, the surviving company will issue 151,667 shares of common stock to an investment banking firm.

#### **BUSINESS OF AQUAMED**

#### **Our Company**

We were incorporated in Delaware on January 13, 2009. We manufacture high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. We specialize in custom gels by capitalizing on proprietary manufacturing technologies. We have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products. Our products are manufactured using proprietary and non-proprietary mixing, coating and cross-linking technologies. Together, these technologies enable us to produce gels that can satisfy rigid tolerance specifications with respect to a wide range of physical characteristics (e.g., thickness, water content, adherence, absorption, moisture vapor transmission rate (a measure of the pasage of water vapor through a substance) and release rate) while maintaining product integrity. Additionally, we have the manufacturing ability to offer broad choices in the selection of liners onto which the gels are coated. Consequently, our customers are able to determine tolerances in moisture vapor transmission rate and active ingredient release rates while personalizing color and texture. Once the gels are manufactured according to a customer's specifications, the gels are generally shipped to the customer via a contract carrier (e.g., United Parcel Service, Inc.).

#### Industry and Markets

Hydrogels are currently being marketed in the U.S. and abroad for the following applications:

- Drug Delivery. Delivering medication through hydrogel patches has important advantages over traditional
  methods of drug delivery. Hydrogel patches are less intrusive, painless, allow for pre-planned medication
  time periods, can potentially release medication in a manner consistent with the body's own glandular
  activity (by avoiding dosage spikes and/or digestive alteration), and minimize side effects related to the
  medication via injection or ingestion.
- Other Medical Applications. Hydrogel patches are being used for transdermal applications such as hormone replacement therapy and contraception, treatment of acne, shingles, diabetes, motion sickness, treatment of angina with nitroglycerin and treatment of smoking addiction using nicotine and palliatives (i.e., pain relievers).
- Non-Prescription Therapeutic Applications. Hydrogel patches are also used in the medical community and
  are also directly marketed to consumers for topical application of over the counter ("OTC") drugs such as
  non-prescription acne treatments, pain relievers, diet preparations, cough suppressants, treatment of warts,
  calluses and corns, and pain relief.
- Moist Wound and Burn Dressings. Hydrogel dressings have long been used for treating wounds and burns. Clinical trials have demonstrated the benefits of moist wound healing versus traditional dressings. Some of these benefits include immediate anti-inflammatory effects, allowing for freer cell flow and less scarring, increased absorption of exudate, and accelerated healing.
- Components of Medical Devices. Several medical devices utilize hydrogels as components. These devices
  include active drug delivery systems such as iontophoresis, warming and cooling devices, and medical
  electrodes.
- Cosmetic Applications. Hydrogel patches and applications can deliver cosmetic skin care products to
  consumers and skin care providers for uses that include moisturizers, face masks, cooling masks and
  applicators.

## Sales and Marketing

We continue to focus on sales and marketing efforts in the United States. As of December 31, 2018, we did not have any employees solely dedicated to sales, however, some of our employees perform in a sales capacity in addition to their other duties.



#### Competition

To our knowledge, AquaMed is one of three manufacturers using electron beam technology for high performance hydrogels for the wound care, cosmetic and drug delivery industries.

#### Sources and Availability of Raw Materials; Principal Suppliers

In general, raw materials essential to our business are readily available from multiple sources. For reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. The principal suppliers for our raw materials are Berry Global, Inc., DeWolf Chemical, Inc. and Univar Inc. Our policy is to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Because we have no direct control over these suppliers, interruptions or delays in the products and services provided by these parties may be difficult to remedy in a timely fashion. In addition, if such suppliers are unable or unwilling to deliver the necessary products or raw materials, we may be unable to redesign or adapt our technology to work without such raw materials or products or find alternative suppliers or manufacturers. In such events, we could experience interruptions, delays, increased costs or quality control problems, or be unable to sell the applicable products, all of which could have a significant adverse impact on our revenue.

Other than as discussed above, we believe that, due to the size and scale of production of our suppliers, there should be an adequate supply of raw materials from our other suppliers.

#### Customers

During the year ended December 31, 2018, two major customers accounted for approximately 77% of our revenue, with each customer individually accounting for 63% and 14% respectively. We are uncertain as to these customers' intentions to use our services during the fiscal year ending December 31, 2019. We do not currently have a contract with either customer; our contract manufacturing business, including with respect to these customers, operates on a purchase order basis.

#### Patents, Proprietary Rights and Trademarks

We own or license trademarks covering our company and our products. We currently hold patent rights to one patent in Europe, which covers the use of lignin for inhibiting restenosis and thrombosis formation, and coated medical devices where the coating includes lignin. These patent rights are set to expire in September 2021. In addition, in connection with the Internal Reorganization, we expect to receive an exclusive license with right to sub-license from Specialty Pharmaceutical Products, L.L.C. (which is presently held by Alliqua) to two issued patents, one in the U.S. and one in Europe, which cover technology relating to a transdermal patch containing transcutol. The transdermal patch is effective to deliver lidocaine to a patient. These licensed patent rights are expected to expire in April 2032. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position.

#### **Government Regulation**

*Product Regulation.* Under the Federal Food, Drug and Cosmetic Act, medical devices are classified by the FDA into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. While some applications of hydrogels fall under the jurisdiction of the FDA, hydrogels are generally classified as Class I exempt devices and the majority of the hydrogel products that we manufacture are thereby exempt from the FDA filing of any regulatory submissions and/or pre-market notification requirements. To the extent that any FDA regulatory submissions are required, we will be required to file these submissions and maintain all appropriate documentation. With respect to registering the manufacturing facility with the FDA under the Code of Federal Regulations, 21 CFR 820.1, Scope: Part A, it is stated that the regulation does not apply to manufacturers of component parts of finished devices. Currently, hydrogels are sold as component parts to various medical device/cosmetic manufacturers.

*Quality Assurance Requirements.* The FDA enforces regulations to ensure that the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs and medical devices conform with current good manufacturing practice (CGMP). The CGMP regulations enforced by the FDA are comprehensive and cover all aspects of manufacturing operations, from receipt of raw materials to finished product distribution, insofar as they bear upon whether drugs meet all the identity, strength, quality and purity characteristics required of them. The CGMP regulations for devices, called the Quality System Regulation, are also comprehensive and cover all aspects of device manufacture, from pre-production design validation to installation and servicing, insofar as they bear upon the safe and effective use of the device and whether the device otherwise meets the requirements of the Federal Food, Drug and Cosmetic Act. To assure compliance requires a continuous commitment of time, money and effort in all operational areas.

The FDA also conducts periodic inspections of drug and device registered facilities to assess their current CGMP status. If the FDA were to find serious non-compliant manufacturing or processing practices during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition and cash flows. With respect to domestic establishments, the FDA could initiate product seizures or in some instances require product recalls and seek to enjoin a product's manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with CGMP requirements, sanctions may be imposed that include preventing that company from receiving the necessary licenses to export its products and classifying that company as an "unacceptable supplier", thereby disqualifying that company from selling products to federal agencies.

We conduct audits of our outside manufacturers and believe that we and our suppliers and outside manufacturers are currently in compliance with CGMP requirements. We are currently registered as a device manufacturer and human tissue distributor with the FDA and we intend to register as a drug facility with the FDA when we are required to do so.

*Environmental Regulation.* We are subject to various laws and governmental regulations concerning environmental matters and employee safety and health in the U.S. and other countries. We have made, and continue to make, significant investments to comply with these laws and regulations. We cannot predict the future capital expenditures or operating costs required to comply with environmental laws and regulations. We believe that we are currently compliant with applicable environmental, health and safety requirements in all material respects. However, we cannot assure you that current or future regulatory, governmental, or private action will not have a material adverse effect on our performance, results or financial condition.

In the future, if a loss contingency related to environmental matters, employee safety, health or conditional asset retirement obligations is recognized, we would record a liability for the obligation and it may result in a material impact on net income for the annual or interim period during which the liability is recorded. The investigation and remediation of environmental obligations generally occur over an extended period of time, and therefore we do not know if these events would have a material adverse effect on our financial condition, liquidity, or cash flow, nor can we assure you that such liabilities would not have a material adverse effect on our performance, results or financial condition.

*Federal and State Anti-kickback, Self-referral, False Claims and Similar Laws.* Our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. Certain states have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations. We believe that we are currently compliant with applicable anti-kickback, self-referral, false claims in all material respects.

#### **Research and Development Costs**

For the years ended December 31, 2018 and 2017, we did not incur any research and development costs.

We intend to commit capital resources to research and development only as our cash resources allow. We have incurred all costs associated with the launch of our proprietary products and will only require research and development expenses for product enhancements and modifications and to obtain additional reimbursement coverage, which we do not expect to be significant.

## Employees

As of December 31, 2018, we had six full-time employees. Of these employees, two are involved with finance, sales, marketing, and administration and four are involved with manufacturing and regulatory matters. Our employees are not represented by a labor union or other collective bargaining groups, and we consider relations with our employees to be good. We currently plan to retain and utilize the services of outside consultants for additional research, testing, regulatory, legal compliance and other services on an as needed basis.

## Properties

We maintain a combined corporate office and manufacturing facility in Langhorne, Pennsylvania, where we lease approximately 16,500 square feet of office and manufacturing space. Our lease expires on January 31, 2026. We believe that our facility is well maintained and are suitable and adequate for our current needs.

## Legal Proceedings

From time to time, we may become involved in lawsuits, investigations and claims that arise in the ordinary course of business. As of the date of this prospectus, we are not a party to any litigation whereby the outcome of such litigation, if determined adversely to us, would materially affect our financial position, results of operations or cash flows.

#### **BUSINESS OF TOP**

TOP was incorporated on October 21, 2015 in Delaware and is an early stage biopharmaceutical company engaged in the business of discovering, developing and commercializing drugs containing cannabinoids, which are based on a proprietary cannabinoid product platform, for the treatment of various diseases, disorders and medical conditions, discussed more fully below.

TOP owns an exclusive license covering certain intellectual property of Tikun Olam Ltd. ("TOL"), which is a principal owner of TOP, for worldwide pharmaceutical products. TOL, a privately held Israeli corporation, is a widely recognized leader in medical cannabis research and production. TOL was founded in 2005 by philanthropist Tsachi Cohen and received the first government-issued license to supply medical cannabis in the State of Israel. In building its business, TOP has capitalized and plans to continue to capitalize on the reputation and consistency of TOL's strains. TOP also owns six provisional patent applications with the U.S. Patent Office and three patents pursuant to the Patent Cooperation Treaty. The provisional patent applications cover formulations that include cannabinoids and/or other substances for the purpose of treating various medical conditions and disorders.

TOP's business is focused on research and development of potential pharmaceutical products based on compounds derived from TOL's proprietary strains. Through collaboration with TOL and leading medical experts at major Israeli hospitals and research organizations, TOP has been able to initially focus its efforts on Crohn's Disease, ulcerative colitis, agitation in Alzheimer's or other dementia, autism spectrum disorder, Tourette syndrome and acute migraines.

TOP's former subsidiaries have also exclusively sublicensed certain rights, in each case in connection the production, research, development, promotion, marketing, sale, distribution and commercialization of pharmaceutical products derived from the intellectual property of TOL and TOP to the extent of their rights in and outside the United States, to:

- Tikkun Pharma, Inc., a Delaware corporation ("Tikkun Pharma"), TOP's former ownership interest in
  which has recently been distributed pro rata to its members, as it relates to the prevention, management
  and treatment of autoimmune diseases, disorders or symptoms related thereto (other than certain diseases
  or otherwise as more particularly described in "Sublicenses"), and
- Jay Pharma, Inc., a Canadian corporation ("Jay Pharma"), TOP's former ownership interest in which has
  recently been distributed pro rata to its members, as it relates to the prevention, management and treatment
  of cancer and diseases, disorders or symptoms related thereto.

#### TOP's Objectives and Business Strategy

TOP's corporate strategy is to research and develop pharmaceutical medicine candidates containing cannabinoids based on TOL's proprietary strains for use in the treatment of various diseases, disorders and medical conditions. Cannabinoids may be derived from the cannabis plant or synthesized. Cannabis is a category of plants that include three species and seven sub-species. Although over 160 compounds have been isolated from cannabis plants, most interest has centered on understanding the two major active components: Delta9-Tetrahydrocannibinol ("THC"), which appears to have psychoactive and other effects, and Cannabidiol ("CBD"), which appears to have anti-inflammatory and other effects.

Both plant-derived and synthetic cannabinoids are considered controlled substances subject to United States' Federal Controlled Substances Act of 1970 (the "CSA") and regulations promulgated thereunder, except hemp containing less than .3% THC and cannabinoids derived therefrom to the extent cultivated and produced in accordance with the Agriculture Improvement Act of 2018 (the "2018 Farm Bill") ("Exempt Hemp Products"). See "Government Laws and Regulations" below. At present, TOP intends to focus on research and development of potential pharmaceutical products based on compounds derived from the TOL's proprietary strains. Due to the early stage of TOP's business, its inexperience, and the current status of cannabis as a Schedule I controlled substance in the United States, which under the CSA makes it unlawful to manufacture, distribute, dispense or possess, TOP has not commenced active development of or any clinical trials with respect to any pharmaceutical products in the United States.



Rather, TOP and TOL have conducted all research to date in Israel. In light of the difficulty in proceeding with clinical trials in the United States, TOP intends to continue its drug development activities in jurisdictions, including Israel, with more favorable laws and regulations regarding research utilizing plant-derived cannabinoids.

Although TOP has not yet developed any pharmaceutical products, it has exclusive access to TOL's cannabis strains and database of Israeli medical cannabis patients, which contains important patient and treatment data which it expects will serve as a platform which it can utilize to establish products that TOP believes will be effective to treat specific diseases. TOP intends to continue to collaborate with TOL to further develop new products subject to the required approval of various jurisdictions. In addition, TOP may enter into joint ventures or sublicense the TOL intellectual property or license any intellectual property it may develop, as may be applicable, to more established pharmaceutical companies or other third parties.

TOP plans to invest significant capital and professional efforts in the development of cannabinoid-derived pharmaceuticals with the ultimate objective of obtaining approval by the FDA, the European Medicines Agency ("EMA") and from regulatory authorities in other countries and regions (the "Other Agencies").

TOP's drug development strategy incorporates the following general steps:

- determination of diseases, disorders and medical conditions that could potentially benefit from cannabinoid-based drugs;
- · conducting "freedom to operate" investigations on these conditions;
- preparation of patent applications and securing such applications and/or the licensing of existing patents;
- · identifying the regulatory pathway with the FDA, the EMA and Other Agencies;
- · conducting pre-clinical studies;
- submitting Investigational New Drug ("IND") applications to the FDA and similar required applications to EMA and/or Other Agencies
- proceeding with pre-clinical studies and/or proof of concept trials, and clinical trials under the protocols for submission and obtaining approval for the particular drug development project(s) as required by the FDA, EMA or Other Agencies; and
- Submitting a New Drug Application ("NDA") to the FDA and similar required applications to EMA and/or Other Agencies.

TOP operates in a highly-controlled regulatory environment with strict regulations and established requirements by the FDA, EMA and Other Agencies, relating to analytical, toxicological and clinical standards and protocols with respect to the research and development of pharmaceuticals. Regulations specifically cover research, development, manufacturing and reporting procedures, both pre- and post-approval.

Governmental authorities in many countries require that a new pharmaceutical product be approved or exempted from approval before any such pharmaceutical product can be marketed. The time to obtain approval varies by country and some pharmaceutical drugs may fail in pre-clinical or clinical trials and therefore may never be approved. The approval process is typically a lengthy process that requires conducting pre-clinical studies and clinical trials to seek and then hopefully receive regulatory approval, in compliance with applicable statutes and regulations, and the expenditure of substantial capital resources.

The steps required to obtain approval and the commercialization of a new drug in the United States are lengthy, complex and expensive, and the outcome is far from certain. These steps generally include:

- completion of formulation studies, preclinical studies, and animal studies in compliance with the FDA's good laboratory protocols ("GLP");
- submission to the FDA of an IND to support clinical trials in the United States;

- · approval by an Institutional Review Board ("IRB") before each trial may be initiated;
- performance of controlled clinical trials in accordance with FDA regulations and with current good clinical practice ("GCP") to establish the safety and efficacy of the drug candidate for each target indication;
- if clinical trials show that a therapeutic candidate is safe and effective, submission of NDA to the FDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the drug will be
  produced to assess compliance with current good manufacturing practices ("GMP"), and to assure that the
  facilities, methods and controls are adequate; and
- FDA review and approval of the NDA.

If a drug, such as those contemplated by TOP, contains a controlled substance under the CSA and is categorized in Schedule I, II, or III, it will likely require scheduling by the DEA prior to any potential commercialization, which may never be achieved. This step may be required for drugs containing plant-derived cannabinoids other than Exempt Hemp Products, as well as synthetic cannabinoids.

TOP has established the following two wholly owned subsidiaries:

- TO Pharmaceuticals USA LLC, a Delaware limited liability company ("TOPUSA"), which was formed to
  operate TOP's business in the United States and to hold any United States patents issued in connection
  with TOP's business; and
- Tikun Olam IP Ltd., a Cayman Islands entity ("TOIP"), which was formed to operate TOP's business
  anywhere in the world excluding the United States and to hold all patents issued in any country other than
  the United States.

#### TOP's Relationship with TOL

TOP has developed a strategic relationship with TOL to benefit from the industry experience and expertise of TOL as a foundation for TOP's business. TOP has entered into license agreements with TOL in order to leverage TOL's intellectual property, including its proprietary genetics, trademarks, trademarks and products.

Tikun Olam is Hebrew for "Repairing the World" and is defined by acts of kindness performed to perfect, heal or repair the world. TOP believes that TOL is one of the first large-scale nationally licensed producers and distributors of medical cannabis in the world, has set the global standard for non-pharmaceutical medical cannabis research and is one of the leading medical cannabis companies in the world. Founded in 2005 by philanthropist Tsachi Cohen with products tested by Prof. Rafael Mechoulam at Hebrew University, TOL received the first government-issued license to supply medical cannabis in the State of Israel. TOP believes that TOL is a major participant in the Israeli market, and as of 2017 was reported to be supplying approximately one-third (1/3) of that nation's 32,000 medical cannabis patients.

Over the last ten years, TOL has tracked those patients' progress over time, based on the consistent and documented use of specific strains. TOP believes that this data is beneficial because such extensive data may be shared with scientists, physicians, hospitals, and collaborators for a variety of purposes, which may include prescribing or recommending particular strains of cannabis for patients with certain conditions, further research studies and the development of products.

TOL's most well-known strain is *Avidekel*, a high-CBD and lower-THC variety with little or no psychoactive effects. *Avidekel* is expected to serve as the basis for CBD-based products to be developed by TOP.

By collaborating with TOL, the Company has been able and intends to continue to use TOL's extensive experience in the medical cannabis industry, including its extensive database of medical cannabis patients, which TOP expects will continue to serve as a platform for further research studies and clinical trial products.

## TOP's Research and Development Strategy

Our current focus is on research and development of formulations for the treatment of specific medical conditions, diseases and/or disorders described more fully below.

#### **Product Pipeline**

TOP's business is focused on research and development of potential pharmaceutical products based on compounds derived from TOL's proprietary strains. In connection with its business, TOP endeavors to discover, develop and commercialize new pharmaceutical drugs and treatments, including by exploiting TOL's proprietary cannabinoid derivative product database, subject to approval by the FDA, the EMA and/or Other Agencies. TOP collaborates or intends to collaborate with TOL and leading medical experts at major Israeli and European and/or US hospitals and research organizations in drug development and clinical research. To date, all pre-clinical and clinical trials conducted by or on behalf of TOP have been conducted in Israel in accordance with the requirements of the Israeli Ministry of Health, which is the governmental regulatory body in Israel that regulates medical testing. Accordingly, the data from these studies may be applicable to applicable to approval of drugs in Israel, but may not be applicable to any NDA filed with the FDA. To achieve its goal, TOP has initially focused its research and development efforts on the following diseases and symptoms:

## Crohn's and Colitis

Inflammatory bowel disease ("IBD") is a chronic autoimmune condition where parts of the digestive system become sore and inflamed. The disease can lead to irreversible damage to the gastrointestinal tract and require surgical removal of the intestine and affected areas. Two major forms of the disease are Crohn's disease, which can affect any part of the digestive system, and ulcerative colitis, which often affects the rectum and the colon or the large intestine. IBD is a chronic condition, meaning that it is ongoing and typically lasts throughout life in those that are afflicted. The disease is often unpredictable, and there are periods of remission where there are few or no symptoms, which alternate with periods where symptoms are very active and debilitating. The peak incidence of IBD onset occurs between the ages of 15 and 30 years. Clinicians caring for children and adolescents afflicted with pediatric IBD must treat the underlying disease while also monitoring growth, puberty, and cognitive development, while seeking to minimize hospitalization time.

According to an article published December 6, 2012 in the World Journal of Gastrointestinal Pharmacology and Therapeutics entitled "Antidepressants can treat inflammatory bowel disease through regulation of the nuclear factor-κB/nitric oxide pathway and inhibition of cytokine production: A hypothesis", therapies for IBD include anti-inflammatory therapies, immune system suppressors, antibiotics and surgical interventions. According to a 2018 report by Grand View Research, Inc., anti-inflammatory therapies emerged as the largest therapy type segment for IBD in 2016 due to efficacy and immune system suppressors emerged as the fastest growing segment due to reduction in surgeries and hospitalization rates. According to an article published August 2014 in the Pharmacy and Therapeutics Journal, approximately 1.86 billion patients have been diagnosed with ulcerative colitis globally, with 1.54 billion patients currently receiving treatment. According to a 2018 report by Grand View Research, Inc., increasing awareness of the disease, coupled with rising initiatives by regulatory bodies for development of novel treatment options, is estimated to provide the market with high growth potential. Traditional therapies, including products provided by Janssen Biotech, Pfizer Inc., and AbbVie Inc., have yielded \$4.18 billion in annual sales around the world, which is expected to increase to \$6.85 billion by 2022 with the approval of various pipeline drugs, according to Global Data's Global Drug Forecast and Market Analysis to 2022.

TOP has entered into a clinical trial agreement dated April 28, 2017, (the "MOR Agreement") with Prof. Timna Naftali ("Naftali") and MOR Research Applications Ltd., an Israeli company ("MOR") which is also the technology transfer company of Clalit Health Services ("Clalit") and legal and authorized representative of Clalit and the Meir Hospital (Israel) ("Meir"), with respect to the commercialization of intellectual property that is developed by Clalit's and Meir's employees. The purpose of the MOR Agreement is to examine and use *Avidekel*, a proprietary cannabis plant of TOL to which TOP holds intellectual property rights, with respect to the treatment of patients with IBD, and in particular to conduct a randomized, placebo-controlled study to assess the benefit of *Avidekel* oil in patients with Crohn's disease

and achieve a written study that can be utilized to create an IBD-based treatment or drug approved by the applicable drug administration(s). In this study, approximately 50 patients were administered an oral dosage of oil containing *Avidekel*, while the control group was administered a placebo carrier oil without the active ingredients. Pursuant to the MOR Agreement, (a) TOP is obligated to pay to MOR (i) for the 80 subjects taking part in this study, an amount of US\$120,000 (US\$1,500 per subject), and (ii) an annual amount equal to 8% of TOP's net revenues generated and actually received by TOP from the sale of the IBD drug to the public for the treatment of IDB; and (b) TOP retains all right, title and interest in and to all intellectual property and derivatives, modifications, enhancements and improvements thereto. The administration of this study has been completed and the results are awaiting final analysis. TOP expects Phase 2 trial results from this study to be announced in first quarter of 2019.

The primary endpoint of the study was measurement of reduction in Crohn's Disease Activity Index CDAI Score of at least 100 after 8 weeks of treatment. Secondary efficacy endpoints included:

- (i) disease remission (CDAI drop of 150+)
- (ii) improvement of at least one point in Endoscopic disease activity index
- (iii) improvement of CRP and calprotectine
- (iv) improvement of blood cytokine levels and improved colonoscopy data.

#### Alzheimer's Disease and Dementia

According to the Alzheimer's Association, dementia is not a specific disease. It is an overall term that describes a group of symptoms associated with a decline in memory or other thinking skills severe enough to reduce a person's ability to perform everyday activities. Alzheimer's disease ("AD") is reported to account for 60 to 80 percent of cases. Vascular dementia, which occurs after a stroke, is the second most common dementia type. There are many other conditions that can cause symptoms of dementia, including some that are reversible, such as thyroid problems and vitamin deficiencies. Dementia is caused by damage to brain cells, which damage interferes with the ability of brain cells to communicate with each other. When brain cells cannot communicate normally, thinking, behavior and feelings can be affected. People with dementia typically may have problems with short-term memory, keeping track of a purse or wallet, paying bills, planning and preparing meals, remembering appointments or traveling out of the neighborhood.

According to the Alzheimer's Association, approximately 5.7 million people in the United States are living with AD, approximately half of which are diagnosed. Studies suggest that 40-50 percent of patients diagnosed with AD in the United States exhibit agitation. According to business information and analytics company GlobalData, the global AD market was \$2.9 billion in 2016, and is predicted to reach \$14.8 billion by 2026 across the U.S., Japan, France, Germany, Italy, Spain, and the UK, the seven major markets, reflecting an annual growth rate of 17.5%. Leading pharmaceutical companies in the AD drug market include Allergan plc and Novartis AG, which have expanded their global market presence through acquisitions of emerging brands. Other key players in the global AD drugs market include H. Lundbeck A.S., Eisai Co. Ltd., Daiichi Sankyo Company Limited, Merz Holding GmbH & Co KG., Ono Pharmaceutical Co. Ltd. and Johnson & Johnson.

TOP has entered into a clinical trial agreement dated August 15, 2017, (the "Lanaido Agreement") with Dr. Hermush Vered ("Vered") and Lanaido Hospital, an Israeli company ("Lanaido") which is also the hospital at which Vered practices. Pursuant to the Lanaido Agreement, Lanaido, under the supervision of Vered, is conducting a randomized placebo-controlled study focused on evaluating the safety and efficacy of *Avidekel* oil for the treatment of subjects with agitation related to Alzheimer's and other forms of dementia. Pursuant to the Lanaido Agreement, (a) TOP is obligated to pay to Lanaido \$110,000; (b) TOP retains all right, title and interest in and to all intellectual property subject to the Lanaido Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time. TOP is currently in the process of enrolling approximately 60 patients in this study, who will be administered an oral dosage of oil containing *Avidekel*, while the control group will be administered a placebo carrier oil without the active ingredients. This administration is underway. TOP expects this Phase 2 Trial to be completed in the third quarter of 2019.

The primary efficacy endpoint of the study is the analysis of the proportion of subjects achieving a decrease of four points or more in Cohen-Mansfield Agitation Inventory (CMAI) during the treatment period at week sixteen compared to baseline starting point. Secondary efficacy endpoints include:

- Assessment of the proportion of subjects achieving a CMAI ≥ 4-point decrease during the treatment period at each time point.
- (ii) Time to 4-point reduction in CMAI in treatment as compared to the control group.
- (ii) Mean change in CMAI score.
- (iv) Mean change in Neuropsychiatric Inventory (NPI-NH) agitation/aggression sub-score.

#### Migraine and Headache

According to the American Migraine Foundation, a migraine is an episodic, unpredictable headache disorder that presents with disabling attacks. These migraine attacks may be successfully treated with acute medications. At present, some of these medications are available over the counter and are prescription medications. Acute medications fall into general classes of medicines including analgesics, ergotamines, and triptans.

In the U.S., more than 38 million people suffer from migraines. Some migraine studies estimate that 13% of adults in the U.S. population have migraines, and 2-3 million migraine suffers are chronic. According to a 2018 report by Grand View Research, Inc., the global migraine drug market size is expected to be approximately \$7.8 billion by 2025, reflecting an 18.0% CAGR during the forecast period. TOP believes that this market is driven primarily by a rise in disease prevalence, development of novel therapies, lifestyle changes, and hormonal medications.

The global migraine drugs market has been mainly dominated by usage of generic triptans and other off-label drugs. Many currently prescribed drugs for both acute symptoms and preventative treatment are associated with poor efficacy and unfavorable side-effects. Amgen and Novartis have launched a new CGRP-based drug for migraines, Aimovig and Teva Pharmaceutical Industries Ltd.'s has also introduced its product Ajovy, which may significantly alter the treatment of migraine prevention. TOP anticipates that drug manufacturers such as Eli Lilly, Alder BioPharma, and Biohaven Pharma are likely to enter the market by 2019, and also believes that pricing will be a key differentiating factor as all CGRP-based therapies have a similar efficacy and safety profile.

TOP has entered into a clinical trial agreement dated December 21, 2017 (the "Soroka Agreement") with Prof. Gal Ifergane ("Ifergane") and Clalit through Soroka University Medical Center, an Israeli company ("Soroka"). Pursuant to the Soroka Agreement, Soroka, under the supervision of Ifergane, is conducting a randomized placebo-controlled study in order to assess the safety and efficacy of medical grade cannabis oil derived from the cannabis strain *Erez* in acute migraine patients. Pursuant to the Soroka Agreement, (a) TOP is obligated to pay to Soroka an amount equal to US\$200,000, which is due in installments based upon the achievement of certain thresholds, including a fee per subject of US\$1,927 for up to 88 subjects, (b) TOP retains all right, title and interest in and to all intellectual property subject to the Soroka Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time. TOP is currently enrolling approximately 60 patients in this study, who will be administered an oral dosage of oil containing *Erez*, while the control group will be administered a placebo carrier oil without the active ingredients. This administration is underway.

TOP expects that this Phase 2 trial will be completed in the first half of 2019.

Primary efficacy endpoint of the study is treatment success defined as headache pain relief resulting in improvement of at least two levels in migraine severity from baseline starting point within two hours after treatment initiation. Secondary efficacy endpoints include:

(i) Patient global assessment at 2 hours, 4 hours and 24 hours after investigational product consumption.



- (ii) Overall satisfaction level at 2 hours, 4 hours and 24 hours after investigational product consumption.
- (iii) Pain relief: the percentage of patients with a reduction of headache severity from moderate or severe at baseline to mild or none at 2 hours.
- (iv) Pain free: the percentage of patients with a reduction of headache severity from moderate or severe at baseline to none (i.e. complete abolition of headache) at 2 hours.

#### PEW in Hemodialysis

Hemodialysis-related protein-energy wasting ("PEW") is common in patients with chronic kidney disease ("CKD"). PEW is one of the strongest predictors of mortality in patients with CKD. The International Society of Renal Nutrition and Metabolism (ISRNM) expert panel has defined PEW as a "state of decreased body stores of protein and energy fuels (body protein and fat masses)". The ISRNM panel has also proposed diagnostic criteria of PEW with four categories. Cachexia is a severe form of PEW. The proposed causes of PEW are multi-factorial and include nutritional and non-nutritional mechanisms.

According to statistics by the National Kidney Foundation, as of 2018, there were more than 2 million people across the globe suffering from chronic kidney failure who are currently undergoing dialysis as an alternative treatment provided until renal transplantation is available. Even though the transplant percentages are rising each year, the dialysis rate remains relatively constant, due to the identification of new cases of diabetes and renal disorders such as kidney failure and chronic renal dysfunction. According to Grand View Research, the global hemodialysis and peritoneal dialysis market was \$60.6 billion in 2017 and is expected to grow to \$108.5 billion at a CAGR of 6.0% though 2025.

TOP has entered into a clinical trial agreement dated June 20, 2018 (the "Assaf Harofeh Agreement") with Dr. Ilia Beberashvili ("Beberashvili") and Medical Research and Development Fund for Health Services-Assaf Harofeh Medical Center ("Assaf Harofeh"), an Israeli company ("Assaf Harofeh"). Pursuant to the Assaf Harofeh Agreement, Assaf Harofeh, under the supervision of Beberashvili, is conducting a randomized, double-blind, placebo controlled, parallel-group, pilot study in order to investigate the safety and efficacy of medical grade cannabis oil derived from the strain *Midnight* in maintenance hemodialysis patients with PEW. Pursuant to the Assaf Harofeh Agreement, (a) TOP is obligated to pay to Assaf Harofeh an amount equal to US\$140,000, (b) TOP retains all right, title and interest in and to all intellectual property subject to the Assaf Harofeh Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time. In this study, approximately 40 patients will be enrolled and administered an oral dosage of oil containing *Midnight*, while the control group will be administered a placebo carrier oil without the active ingredients. This study has been approved by Israeli authorities and TOP expects to begin enrolling patients in 2019. TOP expects this Phase 2 trial to be completed in the second half of 2019.

The primary efficacy endpoint of the study is treatment success defined as safety and tolerability after single and multiple oral doses in adult maintenance hemodialysis MHD patients and assessment of the effect on the appetite of adult patients on maintenance hemodialysis. Secondary efficacy endpoints include:

- (i) characterizing the pharmacokinetic profile of the *Midnight* cannabis oil (and its metabolites) after single and multiple oral doses;
- (ii) evaluating the effect nutritional scores (MIS, GNRI, OSND) in the study population;
- (iii) evaluating the effect on health-related quality of life in the study population; and
- (iv) evaluating the effect on muscle strength.

### Additional Research and Development

TOP has entered into a clinical trial agreement dated June 6, 2018 (the "Sheba Agreement") with Prof. Guy Ben Simon ("Simon") and The Sheba Fund for Health Services and Research (R.A.), an Israeli company ("Sheba Fund"). Pursuant to the Sheba Agreement, the Sheba Fund, under the supervision of Simon, is conducting a study in order to assess the use of THC in medical grade cannabis oil derived from

the strain *Erez* in connection with a certain indication. Pursuant to the Sheba Agreement, (a) TOP is obligated to pay to Sheba Fund an amount equal to US\$50,000, which is due on a per subject and per visit basis for up to 20 subjects, (b) TOP retains all right, title and interest in and to all intellectual property subject to the Sheba Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time. TOP expects this Phase 2 trial to be completed in fourth quarter of 2019.

#### Market Opportunities

Many pharmaceutical and biotechnology companies are seeking to capitalize on the anticipated growth in the pharmaceutical market for cannabinoid-based drugs by realizing and leveraging the growing set of data on the therapeutic effects of cannabis and cannabinoids. TOP believes that the potential applications for cannabinoids go beyond the three cannabinoid-based drugs derived from isolated synthetics: *Marinol, Syndros* and *Casamet*, that have been approved by the FDA to date. Cannabinoid-based drug candidates typically use CBD and THC, or a combination thereof, as their active ingredient(s). TOP, with the cooperation of TOL, has been conducting preclinical trials and randomized, placebo-controlled clinical trials on TOP's products, each in Israel, using cannabinoid-based compounds to develop unique, condition-specific formulas, with the goal of ultimately commencing FDA-approved trials in the United States and EMA-approved trials in Europe.

In June 2018, the FDA approved *Epidiolex*, a cannabidiol (CBD) oral solution for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. This is the first FDA-approved drug that contains a purified drug substance derived from cannabis. It is also the first FDA approval of a drug for the treatment of patients with Dravet syndrome. TOP believes that this approval creates a precedent with FDA for similar drug substances derived from cannabis.

TOP believes that it is likely that the pharmaceutical market for cannabinoid-based drugs will eventually be classified as part of the specialty pharmaceutical market. The increasing diagnoses of certain chronic diseases has resulted in an increased need for specialty drugs. According to a 2017 report published by the HDA Research Foundation, "Specialty Pharmaceutical Distribution: Facts, Figures and Trends (2017 Edition)," spending on specialty drugs in 2016 in the U.S. was about \$181 billion and estimated projections suggest that spending on specialty drugs may grow by 2020 to \$300 billion to \$400 billion.

Cannabinoids have a diverse pharmacology which TOP believes could provide significant potential for therapeutic applications across many diseases, disorders and medical conditions in areas that define specialty pharmaceutical drugs.

According to Statista, an online statistic, market research and business intelligence portal that provides access to data from market and opinion research institutions, the U.S. market for cannabinoid-based pharmaceuticals will increase to \$50 billion by 2029. TOP is unable to determine how much of this market would be applicable to TOP's anticipated products. TOP believes these estimates are reasonable given the significant amounts of capital that have been allocated for the development of cannabinoid-derived pharmaceuticals by numerous companies in the U.S. and globally, with the objective of obtaining regulatory approval by the FDA, EMA and other agencies. TOP believes that there will be rising demand for cannabinoid-derived drugs and that future growth is likely to be driven by favorable changes in legislation and demographic factors. Controlled substance laws differ between countries and legislation in certain countries may restrict or limit TOP's ability to distribute or sell its drugs. TOP believes that the U.S. will represent a major market for TOP's cannabinoid-based drug candidates. In the European Community, all medical cannabis products are currently considered pharmaceutical products. Several medical cannabis program regulatory frameworks exist in countries, including the Netherlands, Italy, Germany, Finland and the Czech Republic, and TOP anticipates that there will be policy changes in these and many member countries of the European Union regarding the medical use of cannabinoid-derived drugs, though no assurance can be given in this regard.

Over 160 chemical compounds have been isolated from the cannabis plant. The most common are CBD and THC. CBD and THC are believed to interact with CB1 and CB2 receptors, which are located throughout the human body. CB1 receptors are primarily located in the brain and central nervous system.

CB2 receptors are located throughout the body including on immune processing cells, peripheral nerves and joint tissues and the gastrointestinal and urinary tracts that are responsible for regulating neurotransmission. The CB1 and CB2 receptors help control bodily reactions such as inflammation and pain, which are areas are of significant therapeutic interest with respect to drug development. Identifying cannabinoid receptors and the compounds that interact with them has helped accelerate clinical investigations of cannabinoid-based drugs.

Endogenous cannabinoid receptors are present in the human central nervous system ("CNS") and in peripheral sites. Two main endogenous cannabinoids are Anandamide ("AEA") and 2-Arachydonilglyerol ("2-AG"). Both are synthesized on cell membrane phospholipids and activate neuronal pre-synaptic receptors, CB1 and CB2. AEA and 2-AG, the enzymes that synthesize and degrade them and the CB1 and CB2 receptors, constitute the human endocannabinoid system.

TOP believes cannabinoid-based drugs may provide a superior treatment model for patients suffering from certain diseases, disorders and medical conditions. To date, due to the challenges of researching plant-derived cannabinoids in the United States, including FDA and DEA restrictions, most U.S. research has been conducted utilizing synthetically produced cannabinoids, which as chemical compounds, are chemically identical to plant-derived cannabinoids. At present, there are two synthetic "THC" cannabinoids available, dronabinol and nabilone. Both have been approved in the U.S. for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have not responded adequately to conventional antiemetic treatments. Dronabinol capsules were also approved for treatment of anorexia associated with weight loss in patients with acquired immune deficiency syndrome, or AIDS. They are also often prescribed for pain control, as alternatives to opioids

## Patents, Intellectual Property and Proprietary Rights

TOP has sought and intends to continue to seek patent protection in the U.S. and other countries, as appropriate, related to methods and compositions and proprietary technologies for the use of cannabinoids and cannabis-based compositions and methods for the treatment of certain diseases, disorders and medical conditions.

To date, TOP has filed five provisional patent applications with the USPTO, all related to the use of cannabinoids and/or cannabis-based compositions and methods to treat certain diseases, disorders or medical conditions. Assuming the successful completion of clinical trials, of which there can be no assurance, TOP believes that it will be able to secure patent protections and retain the intellectual property rights relating thereto. The table below sets forth TOP's provisional patent applications:

Application number	Description of Provisional Patent	Filing Date
62/610,589	Use of cannabinoid compositions for the treatment of inflammatory skin disorders*	December 12, 2017
62/632,021	Use of cannabinoid compositions and methods for the treatment of protein energy wasting	February 19, 2018
62/674,235	Use of cannabinoid compositions for the treatment of inflammatory skin disorders	May 21, 2018
62/676,093	Use of cannabis-based compositions for the treatment of autistic spectrum disorders	May 24, 2018
62/776,076	Use of cannabis-based compositions for the treatment of Alzheimer's disease and dementia	December 6, 2018
62/776,084	Use of cannabis-based compositions for the treatment of Migraine and headache	December 6, 2018

\* Sublicensed pursuant to the JP Sublicense Agreements (as defined below).

#### In addition:

- on November 2, 2017, TOP filed a patent application under the Patent Cooperation Treaty, published May 11, 2018 (WO 2018/083697), relating to the methods of using of CBD and glatiramer acetate ("GA" or "copaxone") for treating, preventing, ameliorating or delaying multiple sclerosis, and side effects associated with multiple sclerosis treatment.
- on November 2, 2017, TOP filed a patent application under the Patent Cooperation Treaty, published May 11, 2018 (WO 2018/083695), relating to methods and formulations utilized in the methods which comprise cannabis plant extracts and copaxone.
- on March 28, 2017, TOP filed a patent application under the Patent Cooperation Treaty, published October 5, 2017 (WO 2017/168422), relating to compositions and methods for treating inflammatory condition of the gastrointestinal ("GI") tract, specifically those related to Inflammatory Bowel Disease ("IBD"). Compositions according to this invention, due to their specific content of cannabinoids and methods comprising specific modes of administration thereof, are particularly applicable to the treatment of the two major IBDs, Crohn's disease and colitis.

TOP seeks patent protection for the technology, inventions and improvements that it considers important to the development of its business, but only in those cases where TOP believes that the costs of obtaining patent protection is justified by the commercial potential of the drug candidate and/or proprietary technologies, and typically only in those jurisdictions that it believes present significant commercial opportunities. The commercial success of TOP will depend in part on obtaining and maintaining patent protection and trade secret protection for its drug candidates, and successfully defending these patents against third-party challenges. TOP's ability to protect its drug candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which it has rights under valid and enforceable patents that cover these activities.

#### U.S. and Worldwide Pharmaceutical Licenses with TOL

Pursuant to a 2015 binding memorandum of understanding (the "MOU") between an equityholder of the Company's parent (until July 13, 2018) and TOL, (i) TOP's wholly owned subsidiary TO Pharmaceuticals USA LLC, a Delaware limited liability company ("TOPUSA") entered into a license agreement dated as of April 13, 2017, as amended (the "US Pharma License") with TOL relating to TOP's U.S. pharmaceutical business (the "U.S. Pharmaceutical Business"); and (ii) TOP's wholly owned subsidiary Tikun Olam IP Ltd., a Cayman Islands entity ("TOIP") and TOL entered into a license agreement dated as of April 13, 2017, as amended (the "WW Pharma License") are together with the US Pharma License, the "Pharma Licenses") relating to TOP's non-U.S. pharmaceutical business (the "Worldwide Pharmaceutical Business"; and together with the US. Pharmaceutical Business"; and together with the U.S. Pharmaceutical Business, the "Pharma Licenses, TOL granted an exclusive, perpetual, non-revocable, royalty-free and sublicensable license to use TOL's intellectual property, whenever developed, in connection with TOP's Pharmaceutical Business. TOPUSA is permitted to use such intellectual property solely in the United States.

Each of TOPUSA and TOIP will own all intellectual property and improvements and modifications of TOL's intellectual property relating to the Pharmaceutical Business that is developed or acquired collaboratively with TOL or solely by TOPUSA or TOIP, as applicable (collectively, the "New IP"). Each of TOPUSA and TOIP have the right to use all New IP in connection with the Pharmaceutical Business, including sublicensing such New IP to third-parties. Further, if any clinical trials are conducted solely by TOPUSA or TOIP, as applicable, or in collaboration with TOL, then the results of such clinical trials and all intellectual property in connection with such trials, are owned by TOPUSA or TOIP, as applicable. Each of TOPUSA and TOIP are required to grant to TOL a perpetual, non-revocable, royalty-free, non-exclusive and sublicensable license to New IP, any new strains developed during the term of the Pharma Licenses and the results of such clinical trials, including any improvements and modifications thereof by TOPUSA or TOIP, as applicable, or any other party expect TOL, in each case solely in connection with TOL's cannabis business.

Pursuant to the MOU, TOPUSA, TOIP, or an affiliate, has paid or caused to be paid to TOL an aggregate of two million five hundred thousand U.S. Dollars (\$2,500,000), of which \$500,000 was paid to TOL on behalf of TOPUSA and TOIP. Full payment was made to TOL by or on behalf of each of TOPUSA and TOIP and their affiliates, and no royalties or other payments are required under the Pharma Licenses, except a two percent (2%) royalty payable to TOL with respect to TOIP's sale of over-the-counter pharmaceutical products outside the U.S. which reasonably compete with a non-pharmaceutical medical cannabis product with substantially similar composition of active components sold by TOL or any licensee of TOL (other than TOIP) conducting business in the applicable jurisdiction pursuant to an effective legal license, permit or similar authority.

The Pharma Licenses also provide that TOL (i) is not permitted to operate or license the intellectual property of TOL to any third party with respect to the Pharmaceutical Business anywhere in the world; (ii) TOL is required to continue to conduct research and development efforts, provide training and assistance with research and development, provide design and operations services, and assist in conducting clinical studies or trials; (iii) is required to expend certain additional funds, which it has expended, to enhance the TOL intellectual property; and (iv) is required to pay an amount equal to one-half of the costs and expenses relating to any infringement or threatened infringement action by a third-party which TOPUSA or TOIP, as applicable, takes reasonable action to stop or otherwise enforce its rights, provided, that such amount shall not exceed an aggregate of US\$200,000 (the "Cap"). If the Cap is exceeded, then TOL shall nevertheless participate in and contribute towards, such costs, solely by means of offset against any royalties ("TOLLC Royalties") due to TOL under a license agreement with an affiliate of TOP ("TOLLC") (the "TOLLC License"), in amounts based on percentages of certain TOLLC Royalty thresholds.

With respect to TOL-owned trademarks, trade names and similar intellectual property, whether registered, under application for registration or not, together with the goodwill relating thereto ("TOL Marks"), all rights therein and any goodwill accruing during the term of the Pharma Licenses belongs to TOL. Further, each of TOPUSA and TOIP is not permitted to misuse or misappropriate any TOL Marks or take any other conduct that impairs or might tend to impair the validity or enforceability of any TOL Marks or registrations in connection with such TOL Marks. Each of TOPUSA and TOIP is required to affix all pharmaceutical products subject to the respective Pharma License and any related promotional and packaging materials with such Marks and any notices reasonably requested by TOL. TOL has the right, upon no less than fifteen business days prior written notice to TOPUSA or TOIP, as applicable, to inspect the premises, books and records of TOPUSA or TOIP, in order to verify TOPUSA or TOIP, as applicable, is in compliance with the respective Pharma License and appropriate quality control as it relates to the TOL Marks. Each Pharma License also contains mutual indemnification, confidentiality obligations and non-competition covenants. Such non-competition covenants cover the term of the agreement and a period of twelve months after the termination or cancellation of the respective Pharma License.

#### **Tikkun Pharma Sublicenses**

TOPUSA has entered into an exclusive amended and restated sublicense agreement with Tikkun Pharma, Inc., a Delaware corporation ("Tikkun Pharma"), dated as of September 11, 2017 (the "TP USA Sublicense Agreement"), and TOIP has entered into an exclusive amended and restated sublicense agreement with Tikkun Pharma, dated as of September 11, 2017 (the "TP WW Sublicense Agreement"; and together with the TP USA Sublicense Agreement, the "TP Sublicense Agreements"), pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the TP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and license of their respective intellectual property, in their respective territories, in connection with the production, research, development, promotion, marketing, sale, distribution and commercialization of pharmaceutical products derived from such intellectual property as it relates to the prevention, management and treatment of cancer or autoimmune diseases, disorders or symptoms related thereto, other than (1) Crohn's Disease, coeliac diseases, any type of colitis (including without limitation microscopic and ulcerative colitis), any and all digestive and IBD, together with any diseases, disorders or symptoms related thereto, and (2) all diseases and disorders, and symptoms thereof, using glatiramer acetate (also known as Copaxone), whether alone or in a combination with any product, including not limited to, CBD (the "TP Limited Business").

Pursuant to the TP Sublicense Agreements, TP is obligated to prepare, in consultation with TOP, and provide to the board of directors of Tikkun Pharma, a mutually acceptable commercialization plan covering the development and commercialization of the intellectual property subject thereto, which shall include, among other things, (1) a list of appropriate studies with specific cannabis-related indications and deadlines for initiating one or more such studies, and (2) a list of one or more inventions for which patent rights should be pursued, if appropriate. All improvements and modifications of TOL's and TOP's intellectual property relating solely to the TP Limited Business developed or acquired by Tikkun Pharma will be owned by Tikkun Pharma; provided, that Tikkun Pharma will grant to TOP a perpetual, royalty-free, non-exclusive license to use and exploit such intellectual property. To the extent this is not permissible under any license agreement with TOL, such intellectual property will be assigned to TOP or TOL as required by such license agreement.

With respect to TOL-owned trademarks, trade names, logos service marks, designs, emblems, signs, slogans, other similar designations of source or original and general intangibles of like nature, whether registered, under application for registration or not, together with the goodwill relating thereto ("Sublicensed Marks"), all rights therein and any goodwill accruing during the term of the TP Sublicense Agreements belong to TOL. Further, Tikkun Pharma is not permitted to misuse or misappropriate any Sublicensed Marks or any other conduct that impairs or might tend to impar the validity or enforceability of any Sublicensed Marks or registrations in connection with such Sublicensed Marks. Tikkun Pharma is required to affix all pharmaceutical products subject to the TP Sublicense Agreements and any related promotional and packaging materials with such Sublicensed Marks and any notices reasonably requested by TOP. TOP has the right, upon no less than fifteen business days prior written notice to Tikkun Pharma, to inspect the premises, books and records of Tikkun Pharma in order to verify Tikkun Pharma's compliance with the TP Sublicense Agreement and appropriate quality control as it relates to the Sublicensed Marks.

Each of TOP and Tikkun Pharma have the right to immediately terminate each of the TP Sublicense Agreements upon the occurrence of a material breach of such agreement, subject to a thirty (30) calendar day cure period commencing after written notice by one party to the other, or the filing of a petition in bankruptcy by either TOPUSA or TOIP, respectively, or Tikkun Pharma, whether voluntary or involuntary, or if any petition, application or other pleading is filed or any proceeding is commenced seeking the appointment of a trustee, receiver or liquidator for the other party. The TP Sublicense Agreements also include mutual indemnification and confidentiality obligations. Tikkun Pharma has failed to fulfill certain of its obligations to TOP, with respect to which TOP has not exercised any remedial action.

#### Jay Pharma Sublicenses

TOPUSA has entered into an exclusive sublicense agreement with Jay Pharma, dated as of January 12, 2018 (the "JP USA Sublicense Agreement"), and TOIP has entered into an exclusive sublicense agreement with Jay Pharma, dated as of January 12, 2018 (the "JP WW Sublicense Agreement"; and together with the JP USA Sublicense Agreement, the "JP Sublicense Agreements"), pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the JP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and license of their respective intellectual property, in their respective territories, in connection with the production, research, development, promotion, marketing, sale, distribution and commercialization of pharmaceutical products derived from such intellectual property as it relates to the prevention, management and treatment of cancer and diseases, disorders or symptoms related thereto (the "JP Limited Business").

Pursuant to the JP Sublicense Agreements, Jay Pharma is obligated to prepare, in consultation with TOP, and provide to the board of directors of Jay Pharma, a mutually acceptable commercialization plan covering the development and commercialization of the intellectual property subject thereto, which shall include, among other things, (1) a list of appropriate studies with specific cannabis-related indications and deadlines for initiating one or more such studies, and (2) a list of one or more inventions for which patent rights should be pursued, if appropriate. All improvements and modifications of TOL's and TOP's intellectual property relating solely to the JP Limited Business developed or acquired by Jay Pharma will be owned by Jay Pharma; provided, that Jay Pharma will grant to TOP a perpetual, royalty-free, non-exclusive license to use and exploit such intellectual property. To the extent this is not permissible under any license agreement with TOL, such intellectual property will be assigned to TOP or TOL as required by such license agreement.

With respect to the Sublicensed Marks, all rights therein and any goodwill accruing during the term of the JP US Sublicense Agreements belong to TOL. Further, Jay Pharma is not permitted to misuse or misappropriate any Sublicense Marks or any other conduct that impairs or might tend to impar the validity or enforceability of any Sublicensed Marks or registrations in connection with such Sublicensed Marks. Jay Pharma is required to affix all pharmaceutical products subject to the JP Sublicense Agreements and any related promotional and packaging materials with such Sublicensed Marks and any notices reasonably requested by TOP. TOP has the right, upon no less than fifteen business days prior written notice to Jay Pharma to inspect the premises, books and records of Jay Pharma in order to verify Jay Pharma's compliance with the JP Sublicense Agreements and appropriate quality control as it relates to the Sublicensed Marks.

Each of TOP and Jay Pharma have the right to immediately terminate the JP Sublicense Agreements upon the occurrence of a material breach of such agreement, subject to a thirty (30) calendar day cure period commencing after written notice by one party to the other, or the filing of a petition in bankruptcy by either TOPUSA or TOIP, respectively, or Jay Pharma, whether voluntary or involuntary, or any petition, application or other pleading is filed or any proceeding is commenced seeking the appointment of a trustee, receiver or liquidator for the other party. The JP Sublicense Agreements also include mutual indemnification and confidentiality obligations.

#### Competition

The emerging markets for cannabinoid-based drug research and development is and will likely remain competitive. In general, the biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary drugs.

TOP expects that it will be required to compete with a variety of multinational pharmaceutical companies and specialized biotechnology companies, as well as drugs and processes being developed at universities and other research institutions. TOP's competitors may develop or may already have developed drugs comparable or competitive with TOP's drug candidates. Competitive therapeutic treatments for diseases, disorders and medical conditions that are included in TOP's drug development projects have already been approved and accepted by the medical community and any new treatments that may enter the market would face fierce competition. In addition to major pharmaceutical and biotechnology companies, such as the aforementioned competitors, TOP's competitors also include public and private research institutions and several other U.S.-based companies that are in early stage discovery and preclinical development utilizing synthetic and/or plant-derived CBD and/or THC.

Currently, there are a number of large, well-established companies that are engaged in cannabinoid-based drug development. These include:

- GW Pharmaceuticals, PLC, a United Kingdom company (NASDAQ: GWPH), has developed*Epidiolex*, which is pure plant-derived CBD and has been approved by the FDA for the treatment of Dravet syndrome, a form of childhood epilepsy. With respect to GW Pharmaceutical's *Sativex* (nabiximols), a cannabis plant-derived formulation approved for the treatment of spasticity due to multiple sclerosis in numerous countries outside of the U.S., GW Pharmaceuticals has full commercial rights to this product and plans to meet with the FDA in the second half of 2018 to discuss data from its completed Phase 3 trials in Europe and to determine the optimal regulatory pathway in the U.S.
- Arena Pharmaceuticals, Inc. ("Arena"), which is developing a synthetic selective CB2 receptor agonist for treatment of Crohn's disease pain.
- Insys Therapeutics, Inc. (NASDAQ: INSY), which in July 2016 obtained FDA approval for Syndros, an
  orally administered liquid formulation of dronabinol.
- Nabilone, the first FDA approved synthetic THC drug, was originally developed by Eli Lilly & Company and received FDA approval in 1985. However, Eli Lilly withdrew that approval in 1989 for commercial reasons. Valeant Pharmaceuticals International Inc. (NYSE: VRX) acquired the rights from Eli Lilly in 2004 and the drug was approved again 2006.

- Therapix Biosciences, Ltd., an Israeli corporation (NASDAQ: TRPX) is also exploring the use of THC
  plus palmidrol for Tourette Syndrome.
- Nexien Biopharma, Inc., a Delaware corporation, is a development stage biopharmaceutical company
  researching and developing cannabinoid-based formulations for the treatment of specific medical
  conditions, and/or disorders, which may include research and development as it relates to cannabinoid
  receptor modulators and/or terpenes in acute treatment situations during exposure to organophosphorus
  nerve agents and/or organophosphorus insecticides.

TOP believes that it has been able to and will continue to differentiate itself from its competitors because of, among other things, the following factors:

	DATA		RESEARCH		CLINICAL DEVELOPMENT
•	TOL has amassed one of the largest medical cannabis treatment databases in the world, with over 20,000 patient records.	•	TOP and TOL scientists have been researching cannabinoids for over 40 years. At least ten published peer-	•	Two completed Phase II double-blind trials related to Crohn's disease and colitis in two different treatment platforms.
•	Patients have reported on the strain used, dosage prescribed and outcomes across a wide		reviewed journal articles have been published by the TOP and TOL team.	•	Currently recruiting accruing patients for two additional Phase II trials.
•	variety of diseases. TOP has leveraged TOL's data to selectively apply for 7 patents.	•	TOP and TOL regularly conduct retrospective analyses on its patient dataset to identify optimal strains/disease states for clinical investigation.	•	By early 2019, TOP anticipates that three additional Phase II trials will have commenced.

Established companies may have a competitive advantage due to their size and experiences, positive cash flows and institutional networks. Many of TOP's competitors may have significantly greater financial, technical and human resources than TOP do. Due to these factors, TOP's competitors may have a range of competitive advantages and may obtain regulatory approval of their drug candidates before TOP is able to develop or commercialize any drug candidates. TOP's competitors may also develop drugs that are safer, more effective, more widely used and less expensive than those of TOP. Furthermore, some of these competitors may make acquisitions or establish collaborative relationships among themselves or with third parties to increase their ability to rapidly gain market share and/or increase their drug line. Large pharmaceutical companies may eventually enter or dominate the market for cannabinoid-derived pharmaceutical products. Given the rapid changes affecting the global, national, and regional economies in general and cannabis-related medical research and development in particular, TOP may not be able to create and maintain a competitive advantage in the marketplace. Time-to-market is an important factor and TOP's success will depend on TOP's ability to identify and develop innovative products that will be accepted by patients, regulators and insurance carriers.

TOP's drug candidates may compete with synthetic and/or plant-derived cannabinoid drugs, in addition to competing with medical and recreational cannabis, in states or countries where the recreational and/or medical use of cannabis is legal. There is support in the United States for further legalization of cannabis, and as a result in markets where recreational and/or medical cannabis is not legal, TOP's drug candidates may compete with cannabis purchased in the state-illegal drug market.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of competitors. Smaller and other early-stage companies, such as TOP, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. TOP anticipates competition in the United States with large and small companies in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to its research projects.

#### Government Laws and Regulations

TOP is an early stage company that ultimately intends to have its drug candidates approved in the U.S. If TOP commences this approval process, it would be subject to extensive regulation by regulatory agencies and its research and development, future manufacturing, distribution and sale of its drugs will become subject to the United States' federal Controlled Substances Act of 1970 and regulations promulgated thereunder. While cannabis (other than Exempt Hemp Products) is a Schedule I controlled substance, drugs approved for medical use in the United States that contain cannabis or cannabis extracts must be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. Depending on the schedule onto which TOP's approved drug candidates, if any, are placed, the manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use of TOP's future drugs may be subject to a significant degree of regulation by the DEA. In addition, individual states in the United States have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may ultimately be more restrictive than the CSA.

The U.S. Food, Drug, and Cosmetic Act (the "FDCA") and its implementing regulations set forth, among other things, requirements for the research, testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of drugs. Generally, TOP's activities in other countries are and/or will be subject to regulations that are similar in nature and scope as those in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way through the EMA and the European Commission, but country-specific regulation remains essential in many respects. The process of obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources, and TOP may not be successful.

## **Regulations Related to the Drug Approval Process**

TOP operates in a highly controlled regulatory environment. Strict regulations establish requirements relating to analytical, toxicological and clinical standards and protocols with respect to the testing of pharmaceuticals. Regulations also cover research, development, manufacturing and reporting procedures, sales and marketing, and advertising and promotional efforts, both pre- and post-approval. Failure to comply with regulations can result in stringent sanctions, including product recalls, withdrawal of approvals, seizure of products, civil penalties, and criminal prosecution. Further, many countries have stringent regulations relating to the possession and use of cannabis and/or drugs derived from cannabis.

Before obtaining regulatory approvals for the commercial sale of future drug candidates, TOP must demonstrate through pre-clinical studies and clinical trials that its drug candidates are safe and effective. Historically, the results from pre-clinical studies and early clinical trials often have not accurately predicted results of later clinical trials. In addition, many therapeutic candidates have shown promising results in clinical trials but subsequently failed to establish sufficient safety and efficacy results to obtain necessary regulatory approvals.

TOP has incurred and expects to incur substantial expense for, and continue to devote a significant amount of time to, pre-clinical studies and clinical trials. Many factors can delay the commencement and rate of completion of clinical trials, including the inability to recruit patients at the expected rate, the inability to follow patients adequately after treatment, the failure to manufacture sufficient quantities of materials used for clinical trials, or the emergence of unforeseen safety issues and governmental and regulatory delays. If a drug candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other drug candidates, prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of these products, and hinder TOP's ability to conduct related pre-clinical studies and clinical trials in general. Additionally, if TOP experiences such failures, it may also experience challenges, delays or even the inability to obtain additional financing on acceptable terms and conditions.

Governmental authorities in all major markets require that a new drug be approved or exempted from approval before it is marketed, and have established high-standards for technical appraisal, which can result in an expensive and lengthy approval process. The time to obtain approval varies by country and some drugs are never approved. The lengthy process of conducting clinical trials, seeking approval and the

subsequent compliance with applicable statutes and regulations, if approval is obtained, are very costly and require the expenditure of substantial resources.

## United States

TOP intends to conduct some of its research and development relating to its drug candidates in the United States, at which time, TOP's research and development, future manufacturing, distribution and sale of TOP's drugs will become subject to the United States' federal Controlled Substances Act of 1970 and regulations promulgated thereunder, which, among other things, places controlled substances onto one of five schedules, ranging from most restrictive to least. Cannabis (other than Exempt Hemp Products) is currently classified under Schedule I, which is reserved for those drug products viewed as having a high potential for abuse with no currently accepted medical use in treatment in the United States. No prescriptions may be written for Schedule I substances, and such substances are subject to production quotas imposed by the U.S. Drug Enforcement Administration (DEA). Accordingly, drugs approved for medical use in the United States that contain cannabis or cannabis extracts must be placed in Schedules II-V, since approval by the FDA satisfies the "accepted medical use" requirement. Depending on the schedule onto which TOP's approved drug candidates, if any, are placed, the manufacture, importation, exportation, domestic distribution, storage, sale and legitimate use of TOP's future drugs may be subject to a significant degree of regulation by the DEA. In addition, individual states in the United States have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may ultimately be more restrictive than the CSA.

Pre-clinical tests include in vitro and in vivo evaluation of the drug candidate, its chemistry, formulation and stability, and animal studies to assess potential safety and efficacy. Pre-clinical tests must be conducted in compliance with good laboratory practice regulations. Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. After laboratory analysis and pre-clinical testing, a sponsor files an Investigational New Drug Application, or IND, to begin human testing. Typically, a manufacturer conducts a three-phase human clinical testing program which itself is subject to numerous laws and regulatory requirements, including adequate monitoring, reporting, record keeping and informed consent. In Phase I, small clinical trials are conducted to assess endpoints, such as metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase II clinical trials usually involve a limited patient population and are conducted to assess the effectiveness of the drug for a particular tissue-specific, or possibly genetically specific patient population, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a candidate demonstrates evidence of effectiveness and an acceptable safety profile in Phase II, Phase III clinical trials are conducted to obtain additional information about clinical efficacy and safety in a larger sample of patients, typically at geographically dispersed study sites, to provide the FDA with data to evaluate the overall risk-benefit relationship of the drug and information that may inform required labeling. The time and expense that will be required for TOP to perform this clinical testing can vary and is substantial. TOP cannot be certain that it will successfully complete Phase I, Phase II or Phase III testing for any drug candidate within any specific period, if at all. Furthermore, the FDA, applicable IRB(s), Data Safety Monitoring Board(s), where used or required, or TOP may suspend clinical trials for a given drug candidate at any time on various grounds, including finding that subjects or patients are exposed to unacceptable health risk.

If the clinical data from clinical trials (Phases I, II and III) are deemed to support the safety and effectiveness of any of TOP's drug candidates for its intended use, then TOP may file with the FDA, a New Drug Application, or NDA, seeking approval to market the drug candidate for one or more specified intended uses. The purpose of the NDA is to provide the FDA with sufficient information so that it can assess whether it should approve the drug candidate for marketing for specific intended uses. The NDA normally contains, among other things, sections describing the chemistry, manufacturing, and controls, non-clinical pharmacology and toxicology, human pharmacokinetics and bioavailability, microbiology, the results of the clinical trials, and the proposed labeling which contains, among other things, the intended uses of the candidate drug. TOP has not completed clinical trials for any candidate drug for any intended use

and therefore, cannot ascertain whether the clinical data will support and justify filing an NDA. Nevertheless, if and when TOP is able to ascertain that the clinical data supports and justifies filing an NDA, TOP intends to make such appropriate filing.

TOP cannot take any action to market any new drug in the United States until a marketing application has been approved by the FDA. The FDA has substantial discretion over the approval process and may disagree with TOP's interpretation of the data submitted. The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on a threshold determination that the application is sufficiently complete to permit a substantive review. Once a submission is accepted for filing, the FDA begins an exhaustive review, which currently takes ten-to-twelve months (but which may take a longer or shorter amount of time at the time (if ever) that TOP may be able to submit an NDA). The process may be significantly extended by requests for additional information or clarification regarding information already provided. As part of this review, the FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians. Accordingly, the actual time required may vary substantially based upon the type, complexity and novelty of the drug. Government regulation may delay or prevent marketing of potential drugs for a considerable period and impose costly procedures on TOP's activities. TOP cannot be certain that the FDA or other regulatory agencies will approve any of its proposed drugs in a timely manner, if at all. Success in pre-clinical or early stage clinical trials does not assure success in later-stage clinical trials. Even if a drug receives regulatory approval, the approval may be significantly limited to specific indications or uses and these limitations may adversely affect the commercial viability of the drug. Delays in obtaining, or failure to obtain, regulatory approvals, would have a material adverse effect on the business of TOP.

Even after TOP obtains FDA approval, it will be subject to pervasive and continuing regulation by the FDA and other regulatory agencies. Such post-approval regulatory requirements include, without limitation, recordkeeping requirements; adverse event reporting; providing updated safety and efficacy information via postmarket clinical trials (i.e., Phase IV trials); therapeutic sampling and distribution requirements; and complying with FDA promotion and advertising requirements, which include, among other things, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations not consistent with the product's approved labeling, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet. TOP also would be required to gain separate approval. In addition, side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the drug's use and, potentially, withdrawal of the drug from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against TOP.

Additionally, therapeutic manufacturers, their subcontractors, and other entities involved in the manufacture and distribution of approved therapeutic candidates are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with current Good Manufacturing Practices (cGMPs). The FDA periodically inspects manufacturing facilities to assess compliance with ongoing regulatory requirements, including cGMPs, which impose extensive procedural, substantive, and record-keeping requirements upon TOP and any third-party manufacturers that it may decide to use if its drug products are approved. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require FDA approval before being implemented. FDA regulations would also require investigation and correction of any deviations from cGMPs and impose reporting and documentation requirements upon TOP and the third-party manufacturers, if any. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory actions, including, without limitation, warning letters, product recalls, seizure, injunction, and civil penalties.

## Orphan Drug Designation in the U.S.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States. If the disease or condition affects more than 200,000 individuals in the United States, orphan drug designation may nevertheless be available if there is no reasonable expectation that the cost of developing and making the drug would be recovered from sales in the United States. In the United States, a drug that has received orphan drug designation is eligible for financial incentives, such as opportunities for grant funding towards clinical trial costs, tax credits for certain research and user fee waivers under certain circumstances. The Orphan Drug Act provides that, if a designated drug is approved for the rare disease or condition for which it was designated, the approved drug will be granted seven years of orphan drug exclusivity, which means the FDA generally will not approve any other application for a drug containing the same active moiety for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the drug with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. In the European Union, orphan drug designation also entitles a party to financial incentives such as a reduction of fees or fee waivers and ten years of market exclusivity following drug approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the drug is sufficiently profitable not to justify maintenance of market exclusivity.

Orphan drug designation must be requested before submission of an application for marketing approval. Products that qualify for orphan designation may also qualify for other FDA programs that are intended to expedite the development and approval process and, as a practical matter, clinical trials for orphan products may be smaller, simply because of the smaller patient population. Nonetheless, the same approval standards apply to orphandesignated products as for other drugs. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

#### Priority Review, Fast Track, Breakthrough Therapy, and Accelerated Approval

The FDA has programs to expedite submission and consideration of certain drug drugs that address serious or life-threatening diseases or conditions. An application for a drug will receive priority review designation if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. Priority review means that FDA will seek to complete its first-cycle review and take action on the application within six months rather than the customary ten-month standard review period. An applicant may request priority review at the time it submits its application. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, the fast track program is intended to expedite or facilitate the process for reviewing new drugs that demonstrate the potential to address unmet medical needs involving serious or life-threatening diseases or conditions. If a drug receives fast track designation, the FDA may consider reviewing sections of the NDA on a rolling basis, rather than requiring the entire application to be submitted to begin the review. Products with fast track designation also may be eligible for more frequent meetings and correspondence with the FDA about the drug's development. Other FDA programs intended to expedite development and review include accelerated approval (approval based on a surrogate endpoint that is reasonably likely to predict clinical benefit) and breakthrough therapy designation, which is available for drugs under development for serious or life-threatening conditions and where preliminary clinical evidence shows that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. If a drug receives breakthrough therapy designation, it will be eligible for the benefits of fast track designation as well as for more intensive guidance from the FDA on an efficient drug development program and a commitment from the agency to involve senior FDA managers in such guidance. Even if a drug qualifies for fast track designation or breakthrough therapy designation, the FDA may later decide that the drug no longer meets the conditions for these designations, and/or may determine that the drug does not meet the standards for approval.

In addition to regulating and auditing human clinical trials, the FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of drugs prior to providing approval to market a drug.

#### Pediatrics

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs must contain data to assess the safety and efficacy 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 generally does not apply to a drug for an indication for which orphan designation has been granted; however, beginning in 2020, PREA will apply to NDAs for orphan-designated drugs if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that FDA has determined is substantially relevant to the growth or progression of a pediatric cancer. The Best Pharmaceuticals for Children Act (BPCA) provides NDA 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 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 conferred by such designation.

#### Federal and State Healthcare Fraud and Abuse Laws and Regulations

If TOP obtains regulatory approval for its drug products, it may also be subject to various federal, state and international laws pertaining to health care "fraud and abuse," among others. These laws include, without limitation, anti-kickback, false claims, and drug pricing and transparency laws and regulations.

The federal Anti-Kickback Statute makes it illegal to solicit, offer, receive or pay any remuneration in exchange for, or to induce, the referral of any healthcare item or service payable under federal healthcare programs (e.g., Medicare, Medicaid, etc.), including the purchase or prescription of a specific drug. Many states have similar laws that are not restricted to federal healthcare programs. Federal and state false claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to the federal government (including, but not limited to, Medicare and Medicaid), claims for reimbursement, including claims for the sale of drugs or services, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

The U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, includes a fraud and abuse provision that imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

TOP may also be subject to federal transparency laws, including the federal Physician Payment Sunshine Act, which requires applicable manufacturers of drugs and biologics, among others, to track and disclose payments and other transfers of value they make to physicians and teaching hospitals, as well as physician ownership and investment interests in the manufacturer. This information is subsequently made publicly available in a searchable format online. Failure to disclose required information may result in substantial civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. Some states impose a legal obligation on companies to adhere to voluntary industry codes of behavior (e.g., the PhRMA Code and the AdvaMed Code of Ethics), which apply to pharmaceutical and medical device companies' interactions with healthcare providers; some mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

Most recently, there has been a trend in federal and state legislation aimed at requiring pharmaceutical companies to disclose information about their production and marketing costs, and ultimately lowering



costs for drug products. Several states have passed or introduced bills that would require disclosure of certain pricing information for prescription drugs that have no threshold amount or are above a certain annual wholesale acquisition cost. For example, Vermont passed legislation requiring certain drug companies to disclose information relating to justification of certain price increases. The U.S. Congress has also introduced bills targeting prescription drug price transparency, and two such bills — the Patient Right to Know Drug Prices Act (for private plans) and the Know the Lowest Price Act (for Medicare Parts C and D) — were signed into law on October 10, 2018.

If the government or a private "whistleblower" were to allege that TOP violated these laws, there could be a material adverse effect on TOP and its business, including its stock price. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, which could have a material adverse effect on TOP's business, results of operations and financial condition. A finding of liability under these laws can have significant adverse financial implications for TOP and can result in payment of large penalties and possible exclusion from federal healthcare programs. Given the complexity and broad reach of these laws and regulations, and the increasing attention given by law enforcement authorities, TOP cannot assure you that some of its activities, or the activities of its employees, partners, agents, or other affiliates, will not be challenged or deemed to violate some of these laws.

### The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring such companies to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

#### European and Other International Government Regulation

In addition to regulations in the United States, TOP will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of TOP's drugs. Regardless of whether TOP obtains FDA approval for a drug, TOP must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the drug in those countries.

Approximately 250 substances, including cannabis, are listed in the Schedules annexed to the United Nations Single Convention on Narcotic Drugs (New York, 1961, amended 1972), the Convention on Psychotropic Substances (Vienna, 1971) and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (introducing control on precursors) (Vienna, 1988). The purpose of these listings is to control and limit the use of these drugs according to a classification of their therapeutic value, risk of abuse and health dangers, and to minimize the diversion of precursor chemicals to illegal drug manufacturers. The 1961 UN Single Convention on Narcotic Drugs, as amended in 1972 classifies cannabis as Schedule I ("substances with addictive properties, presenting a serious risk of abuse") and as Schedule IV ("the most dangerous substances, already listed in Schedule I, which are particularly harmful and of extremely limited medical or therapeutic value") narcotic drug. The 1971 UN Convention on Psychotropic Substances (Substances presenting a high-risk of abuse, posing a particularly serious threat to public health which are of very little or no therapeutic value).

Most countries in Europe are parties to these conventions which govern international trade and domestic control of these substances, including cannabis. They may interpret and implement their obligations in a way that creates a legal obstacle to TOP obtaining manufacturing and/or marketing approval for its drugs in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit TOP's drug candidates to be manufactured and/or marketed, or achieving such amendments to the laws and regulations may take a prolonged period.

Some countries outside of the United States have a similar process that requires the submission of a clinical trial application ("CTA"), much like the submissions of an IND in the U.S. prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to the national health authority of each EU Member State in which the clinical trial is to be conducted and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

To obtain regulatory approval to commercialize a new drug under regulatory systems in the European Union, TOP must submit a marketing authorization application, or MAA. In the European Union, marketing authorization for a drug can be obtained through a centralized, mutual recognition, decentralized procedure, or the national procedure of an individual EU Member State. In accordance with the centralized procedure, the applicant may submit a single application for marketing authorization to the EMA. The agency will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization that permits the marketing of a drug in all 28 EU Member States and three of the four European Free Trade Associations ("EFTA") states: Iceland, Liechtenstein and Norway. The centralized procedure is mandatory for certain medicinal drugs, including orphan drugs derived from certain biotechnological processes, advanced therapy drugs and certain other drugs containing a new active substance for the treatment of certain diseases. This route is optional for certain other drugs, including drugs that are a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU Member State in which the drug is to be marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The applicable EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States.

The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the EU Member States of the marketing authorization of a drug by the competent authorities of other EU Member States. The holder of a national marketing authorization may submit an application to the competent authority of another EU Member State requesting that this authority recognize the marketing authorization delivered by the competent authority of the other EU Member State.

For countries outside of the European Union, including countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, drug licensing, pricing and reimbursement vary from country to country. Internationally, clinical trials are generally required to be conducted in accordance with GCP, applicable regulatory requirements of each jurisdiction and the medical ethics principles that have their origin in the Declaration of Helsinki.

In the European Union, if a marketing authorization is granted for a drug containing a new active substance, that drug benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that drug may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic drugs may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

### Orphan Drug Designation in the European Union

In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Union. Additionally, orphan drug designation is granted for drugs intended for the

diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug. The application for orphan designation must be submitted to the EMA and approved before an application is made for marketing authorization for the drug. Once authorized, orphan drugs are entitled to ten years of market exclusivity. During this ten-year period, with a limited number of exceptions, neither the competent authorities of the EU Member States, the EMA, or the European Commission are permitted to accept applications or grant marketing authorization for other similar drugs with the same therapeutic indication. However, marketing authorization may be granted to a similar medicinal drug with the same orphan indication during the ten-year period with the consent of the marketing authorization holder for the original orphan medicinal drug or if the manufacturer of the original orphan medicinal drug is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar drug with the same orphan indication if this latter drug is safer, more effective or otherwise clinically superior to the original orphan drug. The period of market exclusivity may, in addition, be reduced to six years if it can be demonstrated based on available evidence that the original orphan medicinal drug is sufficiently profitable not to justify maintenance of market exclusivity.

#### Accelerated Review

Under the Centralized Procedure in the European Union, the maximum timeframe for the evaluation of a MAA is 210 days (excluding "clock stops," when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal drug is expected to be of a major public health interest. Three cumulative criteria must be fulfilled in such circumstances: the seriousness of the disease (e.g., heavy disabling or life-threatening diseases) to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days.

## Well-Established Medicinal Use

Under Article 10a of Directive 2001/83/EC, an applicant may, in substitution for the results of its own preclinical and clinical research, present detailed references to published literature demonstrating that the active substance(s) of a drug have a well-established medicinal use within the community with recognized efficacy and an acceptable level of safety. The applicant is entitled to refer to a variety of different types of literature, including reports of clinical trials with the same active substance(s) and epidemiological studies that indicate that the constituent or constituents of the drug have an acceptable safety/efficacy profile for a particular indication. However, use of the published literature exemption is restricted because in no circumstances will constituents be treated as having a well-established use if they have been used for less than 10 years from the first systematic and documented use of the substance as a medicinal drug in the EU. Even after 10 years of systematic use, the threshold for well-established medicinal use might not be met. European pharmaceutical law requires the competent authorities to consider among other factors, the period over which a substance has been used, the amount of patient use of the substance, the degree of scientific interest in the use of the substance (as reflected in the scientific literature) and the coherence (consistency) of all the scientific assessments made in the literature. For this reason, different substances may reach the threshold for well-established use after different periods, but the minimum period is 10 years. If the applicant seeks approval of an entirely new therapeutic use compared with that to which the published literature refers, additional pre-clinical and/or clinical results are required.

## Informed Consent

Under Article 10c of Directive 2001/83/EC, following the grant of a marketing authorization the holder of such authorization may consent to a competent authority utilizing the pharmaceutical, preclinical and clinical documentation that it submitted to obtain approval for a medicinal drug to assess a subsequent application relating to a medicinal drug possessing the same qualitative and quantitative composition with respect to the active substances and the same pharmaceutical form.



## Law Relating to Pediatric Research

Regulation (EC) 1901/2006 (as amended by Regulation (EC) 1902/2006) governs the development of medicinal drugs for human use to meet the specific therapeutic needs of the pediatric population. It requires any application for marketing authorization made after July 26, 2008 in respect of a drug not authorized in the European Community on January 26, 2007 (the time the regulation entered into force), to include the results of all studies performed and details of all information collected in compliance with a pediatric investigation plan agreed by the Pediatric Committee of the EMA, unless the drug is subject to an agreed waiver or deferral or unless the drug is excluded from the scope of Regulation 1902/2006 (generics, hybrid medicinal drugs, biosimilars, homeopathic and traditional (herbal) medicinal drugs and medicinal drugs containing one or more active substances of wellestablished medicinal use). Waivers can be granted in certain circumstances where pediatric studies are not required or desirable. Deferrals can be granted in certain circumstances where the initiation or completion of pediatric studies should be deferred until appropriate studies in adults have been performed. Moreover, this regulation imposes the same obligation from January 26, 2009 on an applicant seeking approval of a new indication, pharmaceutical form or route of administration for a drug already authorized and still protected by a supplementary protection certificate granted under Regulation EC 469/2009 and its predecessor (EEC) 1768/92 or by a patent that qualifies for the granting of such a supplementary protection certificate. The pediatric Regulation 1901/2006 also provides, subject to certain conditions, a reward for performing such pediatric studies, regardless of whether the pediatric results provided resulted in the grant of a pediatric indication. This reward comes in the form of an extension of six months to the supplementary protection certificate granted in respect of the drug, unless the drug is subject to orphan drug designation, in which case the 10-year market exclusivity period for such orphan drugs is extended to 12 years. If any of the non-centralized procedures for marketing authorization have been used, the six-month extension of the supplementary protection certificate is only granted if the medicinal drug is authorized in all member states.

#### Post-Authorization Obligations

In the pre-authorization phase, the applicant must provide a detailed pharmacovigilance plan that it intends to implement post-authorization. An authorization to market a medicinal drug in the EU carries with it an obligation to comply with many post-authorization organizational and behavioral regulations relating to the marketing and other activities of authorization holders. These include requirements relating to post-authorization efficacy studies, post-authorization safety studies, adverse event reporting and other pharmacovigilance requirements, advertising, packaging and labeling, patient package leaflets, distribution and wholesale dealing. The regulations frequently operate within a criminal law framework and failure to comply with the requirements may not only affect the authorization, but also can lead to financial and other sanctions levied on the company in question and responsible officers. Because of the currently on-going overhaul of EU pharmacovigilance legislation, the financial and organizational burden on market authorization holders will increase significantly, including pursuant to the obligation to maintain a pharmacovigilance system master file that applies to all holders of marketing authorizations granted in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. Marketing authorization holders must also collect data on adverse events associated with use of the authorized drug outside the scope of the authorization. Pharmacovigilance for biological drugs and medicines with a new active substance will be strengthened by subjecting their authorization to additional monitoring activities. The EU is currently in the process of issuing implementing regulations for the new pharmacovigilance framework.

Any authorization granted by member state authorities, which within three years of its granting is not followed by the actual placing on the market of the authorized drug in the authorizing member state, ceases to be valid. When an authorized drug previously placed on the market in the authorizing member state is no longer actually present on the market for a period of three consecutive years, the authorization for that drug shall cease to be valid. The same two three-year periods apply to authorizations granted by the European Commission based on the centralized procedure.

#### Israel

TOP, with the cooperation of TOL, has been conducting in Israel pre-clinical trials and randomized, placebocontrolled clinical trials using cannabinoid-based compounds to develop unique, condition-specific formulas based on TOL products. To conduct clinical testing on humans in Israel, special authorization

must first be obtained from the ethics committee and general manager of the institution where the clinical studies are scheduled to be conducted, as required under the Guidelines for Clinical Trials in Human Subjects implemented pursuant to the Israeli Public Health Regulations (Clinical Trials in Human Subjects), as amended from time to time, and other applicable legislation. These regulations also require authorization from the Israeli Ministry of Health, except in certain circumstances, and in the case of genetic trials, special fertility trials and similar trials, an additional authorization of the overseeing institutional ethics committee. The institutional ethics committee must, among other things, evaluate the anticipated benefits that are likely to be derived from the project to determine if it justifies the risks and inconvenience to be inflicted on the human subjects, and the committee must ensure that adequate protection exists for the rights and safety of the participants as well as the accuracy of the information gathered from the clinical testing.

Israel's Ministry of Health ("Ministry of Health"), which regulates medical testing, has adopted protocols that correspond, generally, to those of the FDA and the EMA, making it comparatively straightforward for studies conducted in Israel to satisfy FDA and the EMA's requirements, thereby enabling medical technologies subjected to clinical trials in Israel to reach U.S. and EU commercial markets in an expedited fashion. Many members of Israel's medical community have earned international prestige in their chosen fields of expertise and routinely collaborate, teach and lecture at leading medical centers throughout the world. Israel also has free trade agreements with the United States and the European Union.

The cannabinoid-based drugs TOP intends to develop contain a controlled substance (cannabis) as defined in the Israeli Dangerous Drugs Ordinance [New Version], 5733 – 1973. The research facilities through which TOP and TOL conduct research are located, at present, in Israel, where licenses to cultivate, possess and supply cannabis for medical research are granted by the Ministry of Health on an ad-hoc basis. TOP has initially used TOL's research facilities but has not yet determined where any of its own research facilities, if any, may be located. TOP requires that the research facilities with which it enters into collaborative agreements maintain their existing licenses to conduct medical-based cannabinoid research. TOP may be required to obtain additional licenses and permits related to medical research for other prospect products if TOP enters into collaboration agreements with other hospitals or research institutes, which may include authorization from the ethics committee and general manager of each institution in which TOP intends to conduct its clinical trials, and in most cases, from the Ministry of Health.

## **Research and Development Activities**

TOP incurred expenses of \$431,013 and \$235,096 during the fiscal years ended December 31, 2018 and 2017, respectively, on research and development. None of these research or development costs are borne by any customers.

## Employees

TOP currently has one employee engaged in executive management, including supervising third parties conducting drug candidate development, as well as relationships with third-party firms and individuals. TOP has three consultants who serve as its interim management team. Our employees are not subject to any collective bargaining agreement.

# DESCRIPTION OF PROPERTY

TOP's principal office is located at 77 Water Street, 8<sup>th</sup> Floor, New York, New York 10005. TOP's telephone number is (303) 495-7583. TOP's offices consist of approximately 200 square feet of executive offices and TOP believes that these facilities will be sufficient for the next twelve months.

## LEGAL PROCEEDINGS

There are no pending legal proceedings to which TOP is a party, and TOP's property is not the subject of any pending legal proceedings.

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

The following discussion and analysis is intended to help prospective investors understand our business, financial condition, results of operations, liquidity and capital resources. You should read this discussion in conjunction with our combined financial statements and related notes thereto included elsewhere in this prospectus.

The statements in this discussion regarding industry outlook, expectations regarding our future performance, liquidity and capital resources and other non-historical statements are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Special Note Regarding Forward-Looking Statements." Actual results may differ materially from those contained in any forward-looking statements.

The AquaMed Financial Statements and unaudited Interim Condensed Financial Statements, discussed below, reflect the AquaMed financial condition, results of operations, and cash flows. The financial information discussed below and included in this prospectus, however, may not necessarily reflect what the AquaMed financial condition, results of operations, or cash flows would have been had AquaMed been operated as a separate, independent entity during the periods presented, or what the AquaMed financial condition, results of operations, and cash flows may be in the future.

#### Overview

We manufacture a high-water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. We believe that we are one of the leading manufacturers of high-performance gels in the United States. We specialize in custom gels by capitalizing on proprietary manufacturing technologies. We have historically served as a contract manufacturer, supplying our gels to third parties who incorporate them into their own products. Our contract manufacturing business provides custom hydrogels to the OEM market.

### Liquidity and Capital Resources

As of December 31, 2018, we had no cash and cash equivalents as we are a carve out of Alliqua's contract manufacturing business, all cash management and other treasury-related functions on a centralized basis for all of its divisions, were performed by Alliqua.

Net cash used in operating activities was \$1.5 million and \$0.8 million for the years ended December 31, 2018 and 2017, respectively.

Net cash used in investing activities was nominal for the years ended December 31, 2018, and 2017, respectively.

Net cash provided in financing activities for the years ended December 31, 2018 and 2017 consisted of the advances from the Parent, Alliqua.

At December 31, 2018, current assets totaled \$0.4 million and current liabilities totaled \$0.4 million, as compared to current assets totaling \$0.2 million and current liabilities totaling \$0.2 million at December 31, 2017. As a result, we had working capital deficit of \$0.046 million at December 31, 2018 compared to working capital of \$0 at December 31, 2017.

The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital to support ongoing operations.

Management is evaluating all options to raise sufficient funds to fund the Company's working capital requirements through equity offerings. There can be no assurances, however, that management will be able to obtain sufficient additional funds when needed, or that such funds, if available, will be obtained on terms satisfactory to the Company. The ability of the Company to continue as a going concern is dependent upon its ability to raise additional capital and achieve profitable operations. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern.



## **Results of Operations**

## Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017

**Revenues, net.** For the year ended December 31, 2018 revenues increased by \$0.2 million, or 11%, to \$2.2 million from \$2.0 million for the year ended December 31, 2017. The increase in our overall revenue was due to an increase in orders from contract manufacturing customers.

**Gross profit.** Our gross profit was \$0.514 million for the year ended December 31, 2018 compared to \$0.147 million for the year ended December 31, 2017. The improved results for the year ended December 31, 2018, as compared to the year ended December 31, 2017 was primarily due to a customer mix shifting toward higher margin projects and a stricter emphasis on manufacturing operating efficiency. Gross margin was approximately 23% for the year ended December 31, 2018. Gross margin was approximately 7% for the year ended December 31, 2018.

The components of cost of revenues are as follows for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended	Year Ended December 31,	
	2018	2017	
Cost of revenues			
Materials and finished products	\$ 620	\$ 674	
Stock-based compensation	33	45	
Compensation and benefits	387	481	
Depreciation and amortization	289	288	
Equipment, production and other expenses	370	357	
Total cost of revenues	\$ 1,699	\$ 1,845	

Selling, general and administrative expenses. The following table highlights selling, general and administrative expenses by type for the years ended December 31, 2018 and 2017 (in thousands):

	Year Ended	Year Ended December 31,	
	2018	2017	
Selling, general and administrative expenses			
Compensation and benefits	\$ 464	\$ 184	
Stock-based compensation	173	198	
Other expenses and professional fees	1,765	734	
Total selling, general and administrative expenses	\$ 2,402	\$ 1,116	

Selling, general and administrative expenses increased by \$1.3 million to \$2.4 million for the year ended December 31, 2018, as compared to \$1.1 million for the year ended December 31, 2017. The increase in selling, general and administrative expenses is directly attributable to higher professional fees related to legal and consulting fees.

Compensation and benefits increased by \$0.3 million to \$0.5 million for the year ended December 31, 2018, as compared to \$0.2 million for the year ended December 31, 2017. The increase in compensation and benefits was primarily due to the change in employees' roles and allocation in 2018 compared to 2017.

Stock-based compensation decreased by \$0.025 million, to \$0.173 million for the year ended December 31, 2018, as compared to \$0.198 million for the year ended December 31, 2017. The decrease in stock-based compensation is primarily due to a reduced amount of unvested employee stock options outstanding.

Other expenses and professional fees increased by \$1.031 million to \$1.765 million for the year ended December 31, 2018 from \$0.734 million for the year ended December 31, 2017. Other selling, general and administrative expenses consist of costs associated with our selling efforts and general management, including information technology, travel, training and recruiting. The increase is due to higher legal and consulting fees.

**Income tax benefit.** During the year ended December 31, 2018, we recorded income tax expense of \$0. During the year ended December 31, 2017, we recorded an income tax benefit of approximately \$16,000 which was primarily attributable to the impairment of goodwill assets.

The United States enacted the Tax Cuts and Jobs Act ("Act") on December 22, 2017, most provisions of which took effect in years beginning after December 31, 2017. The Act made substantial changes to U.S. taxation of corporations, including a reduction in the U.S. federal corporate income tax rate from 34% to 21% and changes to limitations on the deductibility of executive compensation. The effect on deferred tax assets and liabilities of a change in law or tax rates is recognized in income in the period that includes the enactment date.

After the enactment of the Act, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In our financial statements for the period ended December 31, 2017, we calculated an estimate of the impact of the Act related to the remeasurement of our net U.S. deferred tax asset due to the change in U.S. federal corporate income tax rate. As we have recorded a full valuation allowance against our net deferred tax assets as of December 31, 2017, these changes have no impact on the income tax benefit for year ending December 31, 2017. During the quarter ended December 31, 2018, the Company completed the accounting for the income tax effects of the Act, which resulted in an immaterial change in the net deferred tax asset, before valuation allowance, as of the enactment date. For additional discussion of the impact on the income tax provision, other income tax balances and related disclosures, see "Note 9—Income Taxes" in the Notes accompanying the audited Consolidated Financial Statements.

## **Off Balance Sheet Arrangements**

As of December 31, 2018, we had no off-balance sheet arrangements in the nature of guarantee contracts, retained or contingent interests in assets transferred to unconsolidated entities (or similar arrangements serving as credit, liquidity or market risk support to unconsolidated entities for any such assets), or obligations (including contingent obligations) arising out of variable interests in unconsolidated entities providing financing, liquidity, market risk or credit risk support to us, or that engage in leasing, hedging or research and development services with us.

#### **Critical Accounting Policies**

Our critical accounting policies are described in the notes to our financial statements for the year ended December 31, 2018 and included elsewhere herein.

#### **Recent Accounting Pronouncements**

Recently issued accounting pronouncements are addressed in Note 1 in the notes to our financial statements for the year ended December 31, 2018 and included elsewhere herein.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND PLAN OF OPERATION OF TOP

### Forward-Looking Statements

The following discussion contains management's discussion and analysis of TOP's financial condition and results of operations and TOP's plan of operation and should be read together with "Selected Historical Consolidated Financial Data for TOP" and the historical consolidated financial statements and the notes thereto included herein. This discussion contains forward-looking statements that reflect TOP's plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section hereof. Actual results may differ materially from those contained in any forward-looking statements. These statements are based on information available to us as of the date hereof and while we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. TOP's statements should not be read to indicate that it has conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely on these statements. You should not rely upon forward-looking statements or forward-looking information speak only as of the date hereof. Except as required by law, TOP undertakes no obligation to update any forward-looking statements or forward-looking information to reflect events or circumstances after the date of such statements. You should carefully read "Cautionary Statement Concerning Forward-Looking Statements" and "Risk Factors."

## Overview

TOP is an early stage company with no revenues from operations. There is substantial doubt that TOP can continue as an on-going business for the next twelve months without raising additional capital. TOP does not anticipate that it will generate revenues from its research and development activities related to its drug development projects in the near future, due to the protracted revenue model of pursuing pharmaceutical drug development in accordance with the pathway set forth by the FDA and non-U.S. regulatory authorities.

As a relatively new business engaged in start-up operations and activities, TOP will require substantial additional funding to successfully complete any of its drug development programs. At present, TOP cannot estimate the substantial capital requirements needed to secure regulatory approvals for its drug candidates. Nevertheless, TOP estimates that it will need to raise at a minimum \$2 million during the next 12 months to continue its drug development programs and fund the operating costs related to being a public company. Determining a budget is subject to a number of factors. In general, this estimate may be higher if our research efforts prove to be successful, or lower if the research efforts produce results that warrant a decision to cease ongoing research and development efforts. Failure to obtain this necessary capital at acceptable terms, if at all, when needed, may force TOP to delay, limit, or terminate its drug development efforts to secure regulatory approvals and would adversely impact its planned research and development efforts in connection with the Company's future drug candidates, which may make it more difficult for TOP to attain profitability.

Pursuant to the Merger Agreement, TOP will merge with and into Merger Sub with TOP as the surviving company and following the Merger, will become a wholly owned subsidiary of AquaMed, subject to the terms and conditions in the Merger Agreement. The current members of TOP and other third-party investors in AquaMed will receive approximately 90% of the total number of shares of AquaMed common stock outstanding immediately after the Merger and the proposed concurrent Private Placement, of which approximately 77% will be owned by the current members of TOP and approximately 13% will be owned by the third-party investors that participate in the Private Placement, assuming that no more than \$10 million is raised in such private placement and it is consummated on the terms currently proposed, before giving effect to any fees payable in equity to financial advisors or other intermediaries. After giving effect to the Merger and the proposed distribution to the stockholders of Alliqua, Inc. of the shares of common stock of AquaMed owned thereby, AquaMed expects to have a class of equity securities publicly traded on the Nasdaq Capital Market, which it believes will enhance its and TOP's access to capital; however, no assurance can be given that AquaMed or TOP will successfully raise capital on terms that will permit the successful execution of its business plan.

## Results of Operations for the years ended December 31, 2018 and 2017

Net loss from operations for the year ended December 31, 2018 was (\$1,171,494), an increase of \$433,824 or 59% from the net loss of (\$737,670) for the year ended December 31, 2017, as a result of an increase of \$195,917 or 83% in research and development expenses from the corresponding period in 2017 due to TOP's escalating research and development activities, and an increase of \$237,907 or 47% in selling, general and administrative expenses, which resulted entirely from increased professional fees.

Professional fees consisted primarily of legal fees to external counsel for patent and related development matters. During the year ended December 31, 2018, the Company's efforts were focused on filings with the U.S. and non-U.S. patent offices and the development of protocols and investigative brochures, and the payment of fees to members of the medical advisory board and consultants for scientific development.

## Liquidity and Capital Resources

At December 31, 2018, TOP had cash of \$359,189, which represented the remaining proceeds of its November 2018 issuance of \$500,000 principal amount of 5% convertible promissory notes due March 31, 2019 (the "Bridge Notes"). For the year ended December 31, 2018, TOP used net cash in operating activities of \$621,899, and for the year ended December 31, 2017, TOP used net cash in operating activities of \$625,393, which it funded by borrowing such amount from an affiliate pursuant to a master services agreement. On September 26, 2018, TOP agreed to permit the affiliate to convert its aggregate \$1,036,256 obligations under the master services agreement into up to six percent (6%) of the fully diluted equity of TOP. In December 2018, TOG exercised this conversion right in full for 39,721 Class A Units. In November 2018, TOP issued \$500,000 principal amount of Bridge Notes to four accredited investors. The Bridge Notes bear interest at a rate of 5% per annum, payable upon maturity at March 31, 2019. The Bridge Notes convert automatically upon consummation of the Merger at a conversion price equal to the lesser of (a) 80% of the per share price in the Private Placement, or (b) \$2.30 per share.

The Company entered into five agreements to conduct clinical trials in Israel, pursuant to which it is obligated to pay an aggregate of approximately \$610,000, of which approximately \$145,000 was paid as of December 31, 2018 and approximately \$465,000 remained owing as of such date.

TOP currently has no agreements, arrangements or understandings with any person to obtain funds through bank loans, lines of credit or any other sources.

Notwithstanding TOP's proposed capital raise from the private sale of equity securities concurrent with the Merger, there can be no assurance that TOP will continue to be successful in raising equity capital and have adequate capital resources to fund its operations or that any additional funds will be available to TOP on favorable terms or in amounts required by TOP. TOP estimates that it will need to raise at a minimum \$2 million during the next 12 months to continue its drug candidate development projects and fund the operating costs related to being a public company. Determining a budget is subject to a number of factors. In general, this estimate may higher if TOP's research efforts prove to be successful or lower if the research efforts produce results that warrant a decision to cease ongoing research and development efforts. If TOP determines that it is necessary to raise additional funds, it may choose to do so through public or private equity or debt financing, a bank or non-bank loan line of credit, or other arrangements. If TOP is unable to obtain adequate capital resources to fund its operations, it may be required to delay, scale back or eliminate some or all of its planned operations, which may have a material adverse effect on its business, results of operations and ability to operate as a going concern.

Any additional equity financing may be dilutive to stockholders, and new equity securities may have rights, preferences or privileges senior to those of existing common stockholders. Debt or equity financing may subject TOP to restrictive covenants and significant interest costs.

#### Capital Expenditure Plan During the Next Twelve Months

To date, TOP has not raised significant equity capital. TOP intends to utilize the capital that it raises to fund its ongoing research efforts and administrative costs, including the costs incurred by being a public reporting company. However, there can be no assurance that TOP will be successful in raising capital in

sufficient amounts and/or at terms and conditions satisfactory to TOP. TOP's revenues are expected to come from its drug candidate development programs. As a result, TOP expects to continue to incur operating losses unless and until it obtains regulatory approval with respect to one or more of its drug candidate development projects and is able to market and sell such approved products sufficient to generate sufficient cash flow to meet operating expenses. There can be no assurance that TOP will obtain regulatory approval or that the market will adopt its anticipated future drug products. In the event that TOP is not able to successfully: (i) raise equity capital and/or debt financing; or (ii) market its drugs after obtaining regulatory approval, its financial condition and results of operations will be materially and adversely affected.

#### **Going Concern Consideration**

For the fiscal year ended December 31, 2018, TOP recorded a net loss of (\$1,171,494) and used cash in operating activities of \$621,899. TOP has incurred losses since inception, resulting in a members' equity deficit of \$1,933,203 as of December 31, 2018. In light of, among other things, TOP's working capital deficit, lack of available cash and cash equivalents and history of operating losses, the report of TOP's independent registered public accounting firm with respect to its financial statements at December 31, 2018, and for the year ended December 31, 2018, contains an explanatory paragraph as to TOP's potential inability to continue as a going concern. This opinion indicates that substantial doubt exists regarding TOP's ability to remain in business. Such an opinion may adversely affect TOP's ability to obtain new financing on reasonable terms or at all.

## **Off-Balance Sheet Arrangements**

As of December 31, 2018, TOP did not have any off-balance sheet arrangements as defined in Item 303(a)(4) (ii) of Regulation S-K promulgated under the Securities Act of 1934.

## **Contractual Obligations and Commitments**

#### Management Agreements

TOP has entered into an offer letter agreement dated October 19, 2018 with Seth Yakatan to serve as its chief executive officer for an annual salary of \$150,000. Mr. Yakatan is also eligible to receive options for three percent (3%) of AquaMed's outstanding stock after giving effect to the Merger and the Private Placement.

TOP has entered into a consulting agreement dated as of November 1, 2018 with Broom Street Associates to provide the services of Dr. Mitchell Glass as TOP's chief medical officer, at an annual rate of \$120,000, payable half in cash and half in equity.

TOP entered into an employment agreement dated March 9, 2016 with Sidney Taubenfeld to serve as an executive vice president of TOP for an annual salary of \$168,000. TOP has also issued warrants to Mr. Taubenfeld to purchase 39,505 Class A Units, of which 28,218 are vested as of December 31, 2018, at an exercise price of \$12.40 per Class A Unit, which after the Merger will be exercisable for 735,036 shares of common stock, of which 525,026 are vested as of December 31, 2018, at an exercise price of \$0.66 per share.

TOP has issued a warrant to Bernard Sucher, a manager of TOP, which is exercisable for an aggregate of 11,187 Class A Units, half of which are exercisable at exercise prices of \$15.11 and \$45.32 per Class A Unit, which after the Merger will be exercisable for 208,150 shares of common stock, half of which are exercisable at exercise prices of \$.81 and \$2.43 per share.

## U.S. and Worldwide Pharmaceutical Licenses with TOL

Pursuant to the MOU (i) TOPUSA entered into the US Pharma License; and (ii) TOIP the WW Pharma License. Pursuant to the Pharma Licenses, TOL granted an exclusive, perpetual, non-revocable, royalty-free and sublicensable license to use TOL's intellectual property, whenever developed, in connection with the TOP's Pharmaceutical Business. TOPUSA is permitted to use such intellectual property solely in the United States and TOIP is permitted to use such intellectual property anywhere in the world excluding the United States.

#### Sublicenses

TOPUSA and Tikkun Pharma have entered into the TP USA Sublicense Agreement, and TOIP and Tikkun Pharma have entered into TP WW Sublicense Agreement, pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the TP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and license of their respective intellectual property, in their respective territories, in connection with the TP Limited Business. TOP received a 50% ownership interest in Tikkun Pharma. Tikkun Pharma has failed to fulfill certain of its obligations to TOP, with respect to which TOP has not exercised any remedial action.

TOPUSA and Jay Pharma have entered into the JP USA Sublicense Agreement, and TOIP and Jay Pharma have entered into (the JP WW Sublicense Agreement, pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the JP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and license of their respective intellectual property, in their respective territories, in connection with the JP Limited Business. TOP received a 50% ownership interest in Jay Pharma.

#### Clinical Trials Agreements

TOP has entered into the MOR Agreement to examine and use *Avidekel*, a proprietary cannabis plant of TOL to which TOP holds intellectual property rights, with respect to the treatment of patients with inflammatory bowel diseases ("IBD"). The goal of such examination and use is to achieve a written study that can be utilized to create an IBD-based treatment or drug approved by the applicable drug administration(s). Pursuant to the MOR Agreement, (a) TOP is obligated to pay to MOR (i) for the 80 subjects taking part in this study, an amount of US\$120,000 (US\$1,500 per subject), and (ii) an annual amount equal to 8% of TOP's net revenues generated and actually received by TOP from the sale of the IBD drug to the public for the treatment of IDB; and (b) TOP retains all right, title and interest in and to all intellectual property and derivatives, modifications, enhancements and improvements thereto.

TOP has entered into the Lanaido Agreement to conduct a study focused on evaluating the safety and efficacy of *Avidekel* oil for the treatment of subjects with agitation related to Alzheimer's and other forms of dementia. Pursuant to the Lanaido Agreement, (a) TOP is obligated to pay to Lanaido approximately \$100,000; (b) TOP retains all right, title and interest in and to all intellectual property subject to the Lanaido Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time.

TOP has entered into the Soroka Agreement to conduct a double-blind placebo controlled, randomized trial in order to assess the safety and efficacy of medical grade cannabis oil derived from the cannabis strain *Erez* in acute migraine patients. Pursuant to the Soroka Agreement, (a) TOP is obligated to pay to Soroka an amount equal to US\$200,000, which is due in installments based upon the achievement of certain thresholds, including a fee per subject of US\$1,927 for up to 88 subjects, (b) TOP retains all right, title and interest in and to all intellectual property subject to the Soroka Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time.

TOP has entered into the Assaf Harofeh Agreement to conduct a randomized, double-blind, placebo controlled, parallel-group, pilot study in order to investigate the safety and efficacy of medical grade cannabis oil derived from the strain *Midnight* in the maintenance hemodialysis patients with protein-energy wasting ("PEW"). Pursuant to the Assaf Harofeh Agreement, (a) TOP is obligated to pay to Assaf Harofeh an amount equal to approximately US\$140,000, (b) TOP retains all right, title and interest in and to all intellectual property subject to the Assaf Harofeh Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time.

TOP has entered into the Sheba Agreement to conduct a study in order to assess the use of THC in medical grade cannabis oil derived from the strain *Erez* in benign essential blepharospasm ("BEB"). Pursuant to the Sheba Agreement, (a) TOP is obligated to pay to Sheba Fund an amount equal to



US\$50,000, which is due on a per subject and per visit basis for up to 20 subjects, (b) TOP retains all right, title and interest in and to all intellectual property subject to the Sheba Agreement; and (c) TOP is permitted to publish the results of and information pertaining to the study, whether, for any scientific, commercial or promotional purposes, at any time.

# Contingencies

In the normal course of business, TOP may receive inquiries or become involved in legal disputes regarding various litigation matters. In the opinion of management, any potential liabilities resulting from such claims would not have a material adverse effect on TOP's consolidated financial statements.

## **Critical Accounting Policies**

Our significant accounting policies are described in the notes to our financial statements as of December 31, 2018 and included elsewhere herein.

#### LIQUIDITY AND CAPITAL RESOURCES FOLLOWING THE TRANSACTIONS

The following discussion and analysis intended to help prospective investors understand our liquidity and capital resources following the transactions. You should read this discussion in conjunction with our combined financial statements and related notes thereto included elsewhere in this prospectus.

The statements in this discussion are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Special Note Regarding Forward-Looking Statements." Actual results may differ materially from those contained in any forward-looking statements.

Immediately following the Merger, we expect to have no cash except the remaining proceeds of the Private Placement, which we believe will be sufficient to fund our operations for at least twelve months, including continued funding of its drug candidate development projects, any operating losses and funding the operating costs related to being a public company. For the year ended December 31, 2018, TOP used net cash in operating activities of \$621,899, which it funded by borrowing such amount from TOG. On September 26, 2018, TOP agreed to permit TOG to convert its aggregate \$1,036,256 obligations into up to six percent (6%) of the fully diluted equity of TOP. In December 2018, TOG exercised this conversion right in full for 39,721 Class A Units.

For the year ended December 31, 2018, AquaMed used net cash in operating activities of \$1.54 million, which was funded by Alliqua.

In November 2018, to fund its working capital needs and transaction expenses relating to the Merger, TOP issued \$500,000 principal amount of 5% convertible promissory notes (the "Bridge Notes") to four accredited investors. The Bridge Notes bear interest at a rate of 5% per annum, payable upon maturity at March 31, 2019. The Bridge Notes convert automatically upon consummation of the Merger at a conversion price equal to the lesser of (a) 80% of the per share price in the Private Placement, or (b) \$2.30 per share.

Neither TOP nor AquaMed has any material commitments for capital expenditures. TOP has entered into five agreements to conduct clinical trials in Israel, pursuant to which it is obligated to pay an aggregate of approximately \$610,000, of which approximately \$145,000 was paid as of December 31, 2018 and approximately \$465,000 remained owing as of such date. After giving effect to the Merger, these will be the primary obligations of the Company other than ordinary course expenses.

We currently have no agreements, arrangements or understandings with any person to obtain funds through bank loans, lines of credit or any other sources. Our ability to create sufficient working capital to sustain the Company over the next twelve-month period, and beyond, is dependent on raising additional equity or debt capital or entering into strategic arrangements with one or more third parties. While our management believes that we will be successful in our current and planned activities, there can be no assurance that sufficient capital will be available to us, that we will be successful in efforts to raise sufficient equity or debt capital, that the terms of any financing transaction will be favorable to us, or that we will engage in strategic relationships, in the aggregate sufficient to sustain our operations. There is also no assurance that our hydrogel manufacturing operations will operate profitably or that our drug candidate development activities will be successful in the short term or the long term in generating revenues from operations sufficient to sustain our operations.

In general, our estimated cash needs may be higher if our research efforts prove to be successful or lower if the research efforts produce results that warrant a decision to cease ongoing research and development efforts. If we determine that it is necessary to raise additional funds, we may choose to do so through public or private equity or debt financing, a bank or non-bank loan line of credit, or other arrangements. If we are unable to obtain adequate capital resources to fund our operations, we may be required to delay, scale back or eliminate some or all of our planned operations, which may have a material adverse effect on our business, results of operations and ability to operate as a going concern.

Any additional equity financing may be dilutive to stockholders, and new equity securities may have rights, preferences or privileges senior to those of existing common stockholders. Debt or equity financing may subject us to restrictive covenants and significant interest costs.

## Capital Expenditure Plan During the Next Twelve Months

To date, we have not raised significant equity capital. We intend to utilize any capital that we raise to fund our ongoing research efforts and administrative costs, including the costs incurred by being a public reporting company. However, there can be no assurance that we will be successful in raising capital in sufficient amounts and/or at terms and conditions satisfactory to us. Our revenues are expected to come from our hydrogel manufacturing business and drug candidate development programs. As a result, we expect to continue to incur operating losses unless and may be able to market and sell such approved products sufficient to generate sufficient cash flow, in addition to cash flow generated by the hydrogel manufacturing business, to meet operating expenses. There can be no assurance that we will obtain regulatory approval or that market will adopt our anticipated future drug products, or that our hydrogel manufacturing business will be profitable. In the event that we are not able to successfully: (i) raise equity capital and/or debt financing; or (ii) market our drugs after obtaining regulatory approval, or (iii) operate our hydrogel manufacturing business profitably, our financial condition and results of operations will be materially and adversely affected.

#### **Going Concern Consideration**

For the fiscal year ended December 31, 2018, TOP recorded a net loss of (\$1,171,494) and used cash in operating activities of \$621,899. For the fiscal year ended December 31, 2018, AquaMed used net cash in operating activities of \$1.54 million, which was funded by Alliqua, which funding will no longer be available. TOP has incurred losses since inception, resulting in a members' equity deficit of \$1,933,203 as of December 31, 2018. AquaMed has also historically generated losses from operations. In light of, among other things, TOP's and AquaMed's working capital deficits, lack of available cash and cash equivalents and history of operating losses, in order to remain in business and maintain its drug development activities, the Company must raise capital from sources other than the actual sale from any drugs that it may develop, as it is unlikely that profits from the Company's hydrogel manufacturing business, if any, would be sufficient to sustain the Company's cash flow needs. Accordingly, there is substantial doubt about whether the Company will be able to continue as a going concern. The reports of TOP's and AquaMed's independent registered public accounting firm with respect to their financial statements at December 31, 2018, and for the year ended December 31, 2018, each contain an explanatory paragraph as to TOP's and AquaMed's respective potential inability to continue as a going concern. These opinions indicate that substantial doubt exists regarding TOP's and AquaMed's ability to remain in business. Such an opinion may adversely affect the surviving company's ability to obtain new financing on reasonable terms or at all.

# DESCRIPTION OF MATERIAL INDEBTEDNESS

Neither AquaMed nor TOP has any material debt obligations.

# MANAGEMENT OF THE COMPANY FOLLOWING THE TRANSACTIONS

The following table presents information concerning the individuals who are expected to serve as our executive officers and directors, and their anticipated titles, following the Spin-Off and Merger, including a brief summary of the business experience of each of them.

Name	Age	Position
Executive Officers		
Seth Yakatan	48	Chief Executive Officer and Interim Chief Financial Officer
Mitchell Glass	67	Chief Medical Officer
Sidney Taubenfeld	58	Vice President
<b>Directors</b>		
David Johnson	60	Chairman of the Board of Directors
Berel Farkas	30	Director
Bernard Sucher	58	Director
Tsachi Cohen	41	Director
George Kegler	63	Director

# **Executive Officers**

## Seth Yakatan, Chief Executive Officer and Interim Chief Financial Officer

Mr. Yakatan has served as chief executive officer of TOP since October 2018. Mr Yakatan has served as a director of FitLife Brands, Inc. and iSatori, Inc., which was acquired by FitLife Brands, Inc., since September 2014. He also served as interim Chief Financial Officer of iSatori, Inc. from April 2015 until the its merger with FitLife Brands. Mr. Yakatan served as interim CEO of Kalytera Therapeutics, Inc. from December 2015 through January 2017, and also served as a director thereof from December 2015 through July 2017. Mr. Yakatan and is a founder of Katan Associates, a consulting firm. Mr. Yakatan brings more than 24 years of experience as a life sciences business development and corporate finance professional, actively supporting small cap and major companies in achieving corporate, financing, and asset monetization objectives. Mr. Yakatan began his career as a venture capital analyst with Ventana Growth Funds and Sureste Venture Management, where he gained significant experience in creating successful venture-backed life science and biotechnology companies. Prior to founding Katan Associates in 2001, Mr. Yakatan worked in merchant banking at Union Bank of California, N.A., in the Specialized Lending Media and Telecommunications Group. During his six years there, he completed the placement of subordinated debt and private equity investments, exceeding \$3 billion in transaction value. Mr. Yakatan holds an MBA in Finance from the University of California, Irvine, and a BA in History and Public Affairs from the University of Denver.

## Mitchell Glass, Chief Medical Officer

Dr. Mitchell Glass has served as TOP's chief medical officer since November 2018. Since November 2012, Dr. Glass has served as an executive director and as executive vice president of research and development of Invion Ltd (ASX: IVX). Since August 2013, Dr. Glass has served as the chairman of the board of Accolade Pharmaceuticals LLC, a privately held specialty pharmaceutical company. Since October 2017, Dr. Glass has served as the chief medical officer of Strados Labs LLC, a privately held medical device and services developer. Since 2010, Dr. Glass has also served as the manager of Broom Street Associates LLC, a consulting firm to early stage pharmaceutical and medical device companies. Dr. Glass holds an M.D (1977) and an A.B (1973), with special honors in biology, from the University of Chicago.



## Sidney Taubenfeld

Sidney Taubenfeld has served as President of TOP since March 2016. Mr. Taubenfeld started his career as a clinical pharmacist at Bellevue Hospital before becoming buy-side healthcare equities research analyst and portfolio manager. For more than three years prior thereto, he worked at Scopia Capital, PAW Partners, Balyasny Asset Management (BAM), RH Capital, and Celsion Corporation. Mr. Taubenfeld received a B.S. from the Brooklyn College of Pharmacy and did graduate work in Pharmacology at New York Medical College.

## **Board of Directors**

#### David I. Johnson, Chairman of the Board of Directors

Mr. Johnson has served on the board of directors of Alliqua since November 2012 and has served as the President and Chief Executive Officer of Alliqua since February 2013. Mr. Johnson was formerly President of the ConvaTec Division of Bristol-Myers Squibb, Inc. until 2008 when he orchestrated a sale of the division from its pharmaceutical parent to Avista Capital Partners and Nordic Capital in a deal valued at \$4.1 billion. Concurrently, he acquired and integrated the assets of Copenhagen-based Unomedical to expand ConvaTec Inc.'s manufacturing and infrastructure into Europe. From 2008 through 2012, Mr. Johnson served as the Chief Executive Officer of ConvaTec Inc. Prior to his tenure with ConvaTec Inc., Mr. Johnson held several senior positions in the U.S., Europe and Canada with Zimmer Inc., Fisher Scientific, and Baxter Corporation. He served as a member of ConvaTec Inc.'s board of directors and the board of the Advanced Medical Technology Association (AdvaMed), where he chaired the Global Wound Sector Team for four years. Mr. Johnson received an Undergraduate Business Degree in Marketing from the Northern Alberta Institute of Technology in Edmonton, Alberta, Canada, completed the INSEAD Advanced Management Program in Fontainbleau, France, and is a fellow from the Wharton School of the University of Pennsylvania. Mr. Johnson's extensive experience in the pharmaceutical and biotechnology fields, as well as his executive leadership experience, make him an asset that will serve as a bridge between the board of directors and our executive officers.

#### Berel ("Barry") Farkas, Director

Berel (Barry) Farkas has served as a Manager of TOP since July 2018, and as a Manager of TOG since June 2015, and as Chairman of the Board thereof since July 2016. Since 2011, Mr. Farkas has served as a partner of Lightstone Management, LLC, a real estate investment firm.

## **Bernard Sucher**, Director

Bernard Sucher has been the Chief Executive Officer of the TOG since July 2016. Mr. Sucher's management experience includes nine years as co-founder and managing director of a leading Russian investment banking firm, Troika Dialog. He was also for four years Chairman of the Board of Alfa Capital, a Moscow-based asset management firm. Mr. Sucher led Merrill Lynch's return to Russian securities trading before being named as Russia Country Head for Bank of America-Merrill Lynch. Since 2011, Mr. Sucher has served as an independent director on the boards of several companies. He currently the non-executive chairman of UFG Asset Management Limited and has served as a director of JKX, an oil and gas firm listed on the London Stock Exchange; Magnitogorsk Metal and Mining, a mineral extraction business listed on the London Stock Exchange; Eastern Property Holdings; a property holding business listed on the Swiss Stock Exchange; Credit Bank of Moscow; and ATON, an investment bank and asset manager. Other affiliations have included Goldman Sachs, the Aspen Institute and Venture for America. Mr. Sucher has lived and worked in Hong Kong, Tokyo, London, Moscow, Detroit, New York and Miami. Mr. Sucher received a BBA degree from the University of Michigan (1983).

#### Tsachi Cohen, Director

Yitzchak (Tsachi) Cohen is a founder and the sole director of TOL, and for more than five years he was the CEO of TOL. He has served as a manager of TOG since June 2015 and is a director of Medifarm PTY Ltd., and Australian company, and a director of Tikun Olan, Greece S.A., a Greek company. We believe that TOL is globally recognized as one of the leading medical cannabis companies in the world and a pioneer of the modern medical cannabis industry. Mr. Cohen serves as a consultant to Tikkun Pharma for equity compensation.

#### George Kegel, Director

George Kegler is the executive vice president and chief financial officer, interim, at Mallinckrodt Pharmaceuticals. He has executive responsibility for the global finance function and is a member of Mallinckrodt's executive committee. Mr. Kegler has 40 years of experience in financial planning and analysis, corporate finance, controllership and business development. Previously Mr. Kegler served as the vice president of commercial finance for various businesses within Mallinckrodt and was also interim president of the company's specialty generics business. Prior to joining Mallinckrodt he was the chief financial officer for Convatec a private equity-owned company that was purchased from Bristol-Myers Squibb. He worked in various finance roles within Bristol-Myers Squibb including commercial, International, technical operations, research & development as well as the assistant controller of internal controls. Mr. Kegler holds a bachelor's degree in accounting from the University of Missouri, an MBA from Saint Louis University and completed the Certified Public Accountant exam in Missouri

#### **Family Relationships**

There are no family relationships among any of combined company's directors or executive officers.

## Our Board of Directors Following the Spin-Off and Merger and Director Independence

Immediately following the Spin-Off and Merger, we expect that our Board of Directors will comprise five (5) directors. The corporate governance standards of the Nasdaq Capital Market require that the board have a majority of independent directors, and we expect our Board of Directors to include a majority of independent directors, and we expect our Board of Directors to include a majority of independent directors and board committees composed of the requisite number of independent directors at the time of the Spin-Off under the corporate governance standards of the Nasdaq Capital Market and the independence requirements of Rule 10A-3 of the Exchange Act. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, we have determined that all of the proposed directors, except Mr. Johnson due to his prior position as the chief executive officer and director of AquaMed, and Mr. Cohen due to his control of TOL are "independent" as that term is defined under the rules of Nasdaq Listing Rule 5605.

Effective upon the completion of the Spin-Off and the Merger, our Board of Directors will have the following committees, each of which will operate under a written charter that will be posted on our website immediately upon the closing of the Spin-Off and the Merger.

#### Audit Committee

The Audit Committee will be established in accordance with Section 3(a)(58)(A) and Rule 10A-3 under the Exchange Act. The Audit Committee is expected to consist of Barry Farkas, Bernard Sucher and George Kegler. The board of directors has determined each proposed member is independent under Nasdaq listing standards and Rule 10A-3(b)(1) under the Exchange Act. The chair of the audit committee is expected to be Mr. Kegler. The board of directors has determined that each of Mr. Sucher and Mr. Kegler is an "audit committee financial expert" within the meaning of SEC regulations. The board of directors has also determined that each member of the audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee of our Audit Committee will be more fully described in our Audit Committee charter. We anticipate that our Audit Committee will, among other duties:

- · oversee financial reporting, accounting, control and compliance matters;
- appoint and evaluate the independent auditor;
- review with the internal and independent auditors the scope, results and adequacy of their audits and effectiveness of internal controls;
- review material financial disclosures;
- pre-approve all audit and permitted non-audit services;
- annually review our compliance programs and receive regular updates about compliance matters;
- · annually review our disclosure controls and procedures; and
- · review and make recommendations to our Board of Directors about related-person transactions.

# **Compensation Committee**

The compensation committee is expected to consist of Barry Farkas, Bernard Sucher and George Kegler. The board of directors has determined each proposed member of the compensation committee is independent under Nasdaq listing standards, is a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and is an "outside director" as that term is defined in Section 162(m) of the Code. The chair of the compensation committee is expected to be Mr. Sucher. The responsibilities of our Compensation Committee will be more fully described in our Compensation Committee charter, and we anticipate that they will include, among other duties:

- approving and recommending full Board of Directors approval of the CEO's compensation based upon an evaluation of the CEO's performance by the independent directors;
- reviewing and approving senior management's compensation;
- administering incentive and equity compensation plans and, in consultation with senior management, approving compensation policies; and
- · reviewing executive compensation disclosures and the annual compensation risk assessment.

## Nominating/Corporate Governance Committee

The nominating and corporate governance committee is expected to consist of Barry Farkas and George Kegler. The chair of the nominating and corporate governance committee is expected to be Mr. Farkas. Each proposed member of the nominating and corporate governance committee is independent within the meaning of applicable listing standards, is a non-employee director and is free from any relationship that would interfere with the exercise of his or her independent judgment, as determined by the combined company's board of directors in accordance with the applicable Nasdaq listing standards. The responsibilities of our Nominating/Corporate Governance Committee charter, and we anticipate that they will include, among other duties:

- monitoring our Board of Directors' structure and operations;
- setting criteria for Board of Directors membership;
- searching for and screening candidates to fill Board of Directors vacancies and recommend candidates for election;
- evaluating director and Board of Directors performance and assess Board of Directors composition and size;
- · evaluating our corporate governance process; and
- recommending to our Board of Directors whether to accept the resignation of incumbent directors that fail to be re-elected in uncontested elections.



## **Compensation Committee Interlocks and Insider Participation**

None of our executive officers has served as a member of a compensation committee (or other committee serving an equivalent function) of any other entity whose executive officers served as one of our directors.

#### **Codes of Conduct**

We are committed to high standards of ethical conduct and professionalism. Immediately upon the completion of the Spin-Off and the Merger, we will adopt a Code of Business Conduct that confirms our commitment to ethical behavior in the conduct of all our activities. The Code of Business Conduct will apply to all our directors, all our officers (including our CEO, CFO and Principal Accounting Officer) and employees and it will set forth our policies and expectations on a number of topics including avoiding conflicts of interest, confidentiality, insider trading, protection of AquaMed and customer property and providing a proper and professional work environment. We expect to continue to follow the same corporate governance practices immediately following the Distribution.

#### **Director Nomination Process**

Our initial Board of Directors has been selected through a process involving TOP and us. We intend to adopt corporate governance principles designed to assure excellence in the execution of the Board of Directors' duties. These principles will be outlined in Corporate Governance Guidelines which, in conjunction with our Amended and Restated Articles of Incorporation, Amended and Restated Bylaws, Code of Business Conduct, Board of Directors committee charters and related policies will form the framework for the effective governance of AquaMed. Our Corporate Governance Guidelines will be available on our website immediately upon closing of the Spin-Off and the Merger.

## Communicating with the Board or Chairman

After the Spin-Off and Merger, stockholders and other interested parties may communicate with the Board of Directors, individual directors, the non-management directors as a group, or with the Chairman, by writing in care of the Corporate Secretary, AquaMed Technologies, Inc., 2150 Cabot Boulevard West, Suite B, Langhorne, PA 19047. The Corporate Secretary will review all submissions and forward to members of the Board of Directors all appropriate communications that in the Corporate Secretary's judgment are not offensive or otherwise objectionable and do not constitute commercial solicitations.



### EXECUTIVE COMPENSATION

#### Summary

This section discusses the anticipated compensation to be paid by us to our executive officers following the Spin-Off and Merger for our fiscal year beginning January 1, 2019 and ending December 31, 2019 ("Fiscal 2019").

## Historical Compensation of Executive Officers Prior to the Spin-Off

Mr. Johnson served as AquaMed's chief executive officer during its last completed fiscal year and Joseph Warusz served as its chief financial officer during its last completed fiscal year beginning on April 1, 2018. Mr. Warusz resigned as a director and officer of AquaMed effective March 18, 2019. From January 1, 2018 through March 30, 2018, Brian Posner served as the chief financial officer of AquaMed. None of Mr. Johnson, Mr. Warusz or Mr. Posner received any compensation for their service as executive officers of AquaMed during its last completed fiscal year. Mr. Yakatan, Dr. Glass and Mr. Taubenfeld were not employed by AquaMed prior to the Spin-Off and Merger and therefore none of their historical compensation is discussed in this section.

# **Executive Officers and Compensation Going Forward**

# Expected AquaMed Executive Officers

Following the Spin-Off and Merger, we expect the following individuals to become our executive officers:

- Seth Yakatan, who is currently the Chief Executive Officer of TOP, is expected to become our Chief Executive Officer and Interim Chief Financial Officer;
- Mitchell Glass, who is currently the Chief Medical Officer of TOP, is expected to serve as our Chief Medical Officer; and
- Sidney Taubenfeld, who is currently the President of TOP, is expected to serve as our vice president.

Following the Spin-Off, we will form our own board-level compensation committee (our "Compensation Committee") that will be responsible for approving and overseeing our executive compensation programs. We expect to adopt a long-term equity-based incentive program and to offer post-employment benefits and severance programs similar to the programs that existed at Alliqua prior to the Spin-Off. Following the Spin-Off, our Compensation Committee will review and monitor the effect of the Spin-Off and the Merger on our executive compensation programs, and may make any adjustments it deems appropriate based on the Spin-Off or Merger or any other factors.

# Fiscal 2019 Expected AquaMed Compensation

The recommended compensation levels for the individuals who are expected to become our named executive officers for periods after the Spin-Off and Merger are as follows:

Name and principal position	Salary	Annual Incentive Target <sup>(1)</sup>	Long Term Incentive Target <sup>(1)</sup>	Target Total Direct Compensation <sup>(1)</sup>
Seth Yakatan	\$150,000	_	_	_
Dr. Mitchell Glass	\$120,000	_	_	—
Sidney Taubenfeld	\$168,000	_	_	_

 Does not include options, warrants or other securities issued or granted to the named executive officers. See "Security Ownership of Certain Beneficial Owners, Directors and Executive Officers."



Following the Spin-off, our Board of Directors, with the assistance of the Compensation Committee, expects to consider appropriate annual and long-term incentive targets and total compensation packages for our executive officers.

### **Treatment of Outstanding Alliqua Equity Awards**

Any outstanding Alliqua employee equity awards will be unaffected by the Spin-Off and the Merger. Any Alliqua equity awards held by individuals who are or become our employees in connection with the Spin-Off (including Mr. Johnson) will not see any adjustment in connection with the Spin-Off and/or the Merger.

## AquaMed Employee Equity Plan

#### 2019 Long-Term Incentive Plan

On March 8, 2019, our stockholders approved the 2019 Long-Term Incentive Plan (the "2019 Plan"), which was adopted by our board of directors on March 8, 2019. The 2019 Plan provides for the granting of incentive stock options, nonqualified stock options, restricted stock, stock appreciation rights, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem, and which may be paid in cash, shares of our common stock, or a combination of cash and shares of our common stock. We have reserved a total of 2,000,000 shares of our common stock for awards under the 2019 Plan. The maximum number of shares of common stock that may be delivered pursuant to incentive stock options under the 2019 Plan is 2,000,000 shares and the maximum number of shares of common stock with respect to which stock options or stock appreciation rights may be granted to an executive officer during any calendar year is 115,000 shares of common stock.

The purpose of the 2019 Plan is to provide an incentive to attract and retain the services of key employees, key contractors, and outside directors whose services are considered valuable, to encourage a sense of proprietorship and to stimulate active interest of such persons in our development and financial success. The 2019 Plan is intended to serve as an "umbrella" plan for us and our subsidiaries worldwide. Therefore, if so required, appendices may be added to the 2019 Plan in order to accommodate local regulations in foreign countries that do not correspond to the scope of the 2019 Plan.

The 2019 Plan will become effective immediately prior to the consummation of the Spin-Off and the Merger. Unless terminated earlier by the board of directors, the 2019 Plan will expire on the tenth anniversary of its effective date. No award may be made under the 2019 Plan after its expiration date, but awards made prior thereto may extend beyond that date.

### **Employment Agreements**

We do not expect to enter into employment agreements with our executive officers. The expected terms of our executive compensation program for periods after the Spin-Off and Merger are set forth above under the heading "Fiscal 2019 Expected AquaMed Compensation." In addition, such compensation arrangements would be subject to review and approval of our Compensation Committee. Subject thereto:

TOP has entered into an offer letter agreement dated October 19, 2018 with Seth Yakatan to serve as its chief executive officer for an annual salary of \$150,000. Mr. Yakatan is also eligible to receive options for three percent (3%) of AquaMed's outstanding stock after giving effect to the Merger and the Private Placement.

TOP has entered into a consulting agreement dated as of November 1, 2018 with Broom Street Associates to provide the services of Dr. Mitchell Glass as TOP's chief medical officer, at an annual rate of \$120,000, payable half in cash and half in equity.

TOP entered into an employment agreement dated March 9, 2016 with Sidney Taubenfeld to serve as an executive vice president of TOP for an annual salary of \$168,000. TOP has also issued warrants to Mr. Taubenfeld to purchase 39,505 Class A Units, of which 28,218 are vested as of December 31, 2018, at an exercise price of \$12.40 per Class A Unit, which after the Merger will be exercisable for 735,036 shares of common stock, of which 525,026 are vested as of December 31, 2018, at an exercise price of \$0.66 per share.

TOP has issued a warrant to Bernard Sucher, a manager of TOP, which is exercisable for an aggregate of 11,187 Class A Units, half of which are exercisable at exercise prices of 15.11 and \$45.32 per Class A Unit, which after the Merger will be exercisable for 208,150 shares of common stock, half of which are exercisable at exercise prices of \$.81 and \$2.43 per share.

## **Director Compensation**

Mr. Johnson is the sole current member of our board of directors. Mr. Warusz served as a director of AquaMed from April 1, 2018 through March 18, 2019. Neither Mr. Johnson or Mr. Warusz received any compensation from AquaMed for his service as a director of AquaMed. The following table summarizes the anticipated annual cash compensation to our non-employee directors for Fiscal 2019, subject to approval by the Compensation Committee.

## **Cash Compensation**

Position	Cash retainer amount*
Member of Board of Directors	\$35,000
Chairman of the Board of Directors	\$25,000
Audit Committee Chair	\$10,000
Compensation Committee Chair	\$ 7,500
Nominating and Governance Committee Chair	\$ 7,500
Committee Member	\$ 2,500

\* Board chair and committee chair or member fees are in addition to the payment for serving as a member of the board of directors.

# Equity Compensation

For Fiscal 2019, we expect that each non-employee director will receive an annual equity grant equal to \$10,000 of shares of common stock as of the grant date, which will vest annually in equal amounts for serving on our board of directors. These equity awards will be reviewed annually by our compensation committee and are subject to change following such review.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

## AquaMed Agreements with Alliqua

Following the Distribution, Alliqua will not own any of our shares and we will operate independently of Alliqua. In addition, we do not expect to depend on Alliqua to conduct our business following the Distribution. In order to govern the ongoing relationships between us and Alliqua after the Spin-Off, we and Alliqua intend to enter into agreements providing for various rights following the Spin-Off and under which we and Alliqua will agree to indemnify each other against certain liabilities arising from our respective businesses. For a summary of the terms of the material agreements we expect to enter into with Alliqua, see "The Asset Contribution and Separation Agreement and the Ancillary Agreements". Following the Distribution, our Chairman, Mr. David Johnson will continue serving as a director of Alliqua. Accordingly, transactions with Alliqua may continue to constitute related party transactions under SEC rules and under our related party transactions policy.

#### TOP

## T.O. Global LLC

Until July 13, 2018, TOP was a wholly-owned subsidiary of TOG ("TOG"), which provided funding to TOP pursuant to a master intercompany service agreement (the "Master Services Agreement"), under which TOG advanced funds on behalf of or otherwise extended loans to TOP sufficient to fund TOP's operations. As of December 31, 2017 and 2016, TOP owed to T.O Global LLC \$2,154,310 and \$1,528,917, respectively, thereunder. These obligations were unsecured and due on demand with no interest. On September 26, 2018, TOP agreed to permit TOG to convert its aggregate \$1,036,256 obligations under the Master Services Agreement into up to six percent (6%) of the fully diluted equity of TOP. In December 2018, TOG exercised this conversion right in full for 39,721 Class A Units.

TOP leases its offices on a month to month basis from TOG. The terms of the lease call for monthly base payments of \$1,000. Total rent expense for the years ended December 31, 2017 and 2016 amounted to \$12,000, for each of the years.

## Management Agreements

TOP has entered into an offer letter agreement dated October 19, 2018 with Seth Yakatan to serve as its chief executive officer for an annual salary of \$150,000. Mr. Yakatan is also eligible to receive options for three percent (3%) of AquaMed's outstanding stock after giving effect to the Merger and the Private Placement.

TOP has entered into a consulting agreement dated as of November 1, 2018 with Broom Street Associates to provide the services of Dr. Mitchell Glass as TOP's chief medical officer, at an annual rate of \$120,000, payable half in cash and half in equity.

TOP entered into an employment agreement dated March 9, 2016 with Sidney Taubenfeld to serve as an executive vice president of TOP for an annual salary of \$168,000. TOP has also issued warrants to Mr. Taubenfeld to purchase 39,505 Class A Units, of which 28,218 are vested as of December 31, 2018, at an exercise price of \$12.40 per Class A Unit, which after the Merger will be exercisable for 735,036 shares of common stock, of which 525,026 are vested as of December 31, 2018, at an exercise price of \$0.66 per share.

TOP has issued a warrant to Bernard Sucher, a manager of TOP, which is exercisable for an aggregate of 11,187 Class A Units, half of which are exercisable at exercise prices of \$15.11 and \$45.32 per Class A Unit, which after the Merger will be exercisable for 208,150 shares of common stock, half of which are exercisable at exercise prices of \$.81 and \$2.43 per share.

## U.S. and Worldwide Pharmaceutical Licenses with TOL

Pursuant to the MOU, TOL, which is expected to beneficially own approximately 12% of our outstanding common stock after giving effect to the Merger and the Private Placement, entered into (i) the US Pharma License with TOPUSA; and (ii) the WW Pharma License with TOIP. Pursuant to the Pharma

Licenses, TOL granted an exclusive, perpetual, non-revocable, royalty-free and sublicensable license to use TOL's intellectual property, whenever developed, in connection with the TOP's Pharmaceutical Business. TOPUSA is permitted to use such intellectual property solely in the United States (except the State of New York) and TOIP is permitted to use such intellectual property anywhere in the world excluding the United States. Pursuant to the Pharma Licenses, TOP paid or caused to be paid to TOL an aggregate of \$500,000 on behalf of TOPUSA and TOIP. No royalties or other payments are required under the Pharma Licenses except a two percent (2%) royalty payable to TOL with respect to TOIP's sale of over-the-counter pharmaceutical products outside the U.S. which reasonably compete with a non-pharmaceutical medical cannabis product with substantially similar composition of active components sold by TOL or any licensee of TOL (other than TOIP) conducting business in the applicable jurisdiction pursuant to an effective legal license, permit or similar authority.

#### Sublicenses

TOPUSA has entered into the TP USA Sublicense Agreement, and TOIP has entered into the TP WW Sublicense Agreement, pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the TP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and license of their respective intellectual property, in their respective territories, in connection with the TP Limited Business. TOP received a 50% ownership interest in Tikkun Pharma; however, prior to effecting the Merger, TOP's ownership interest in Tikkun Pharma will be distributed pro rata to its members. Tikkun Pharma has failed to fulfill certain of its obligations to TOP, with respect to which TOP has not exercised any remedial action.

TOPUSA has entered into the JP USA Sublicense Agreement, and TOIP has entered into the JP WW Sublicense Agreement, pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the JP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and license of their respective intellectual property, in their respective territories, in connection with the JP Limited Business. TOP initially received a 50% ownership interest in Jay Pharma, and owns approximately 40% of Jay Pharma as of the date hereof; however, prior to effecting the Merger, TOP's ownership interest in Jay Pharma will be distributed pro rata to its members.

## **Related Party Transaction Policy**

Our Board of Directors intends to adopt a written policy requiring the approval by the Nominating/Corporate Governance Committee of all transactions in excess of \$120,000 between AquaMed and any related person. For the purposes of this policy, a related person is any person who was in any of the following categories at any time during the fiscal year: (i) a director or executive officer of AquaMed; (ii) any nominee for director; (iii) any immediate family member of a director or executive officer, or of any nominee for director (immediate family members are any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law of such director, executive officer or nominee for director, and any person (other than a tenant or employee) sharing the household of such director, executive officer or nominee for director and any person who was in any of the following categories when a transaction in which such person had a direct or indirect material interest occurred or existed); (iv) any beneficial owner of more than 5% of AquaMed's common stock; or (v) any immediate family member of any such beneficial owner. A transaction includes, but is not limited to, any financial transaction, arrangement or relationship (including any indebtedness or guarantee of indebtedness) or any series of similar transactions, arrangements or relationships. In determining whether to approve an interested transaction, the Nominating/Corporate Governance Committee will take into account, among other factors it deems appropriate, whether the interested transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related party's interest in the transaction. No director will participate in any discussion or approval of an interested transaction for which he or she (or an immediate family member) is a related party, except that the director will provide all material information concerning the interested transaction to the Nominating/Corporate Governance Committee. For as long as there are any members of our Board of Directors associated with or employed by Alliqua, each will recuse himself or herself from decisions by our Board of Directors regarding matters relating to Alliqua including matters relating to the agreements between us and Alliqua described above.

# SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS, DIRECTORS AND EXECUTIVE OFFICERS

As of the date of this prospectus, Alliqua beneficially owns all the outstanding shares of our common stock. After the Spin-Off, Alliqua will not own any shares of our common stock. The following table provides information regarding the anticipated beneficial ownership of our common stock following consummation of the Spin-Off, the Merger, and all transactions to be consummated in connection therewith or conditioned thereon, by:

- each of our stockholders who we believe (based on the assumptions described below) will beneficially
  own more than 5% of our outstanding common stock;
- · each of our directors following the Spin-Off and Merger;
- · each of our executive officers following the Spin-Off and Merger; and
- all of our directors and executive officers following the Spin-Off and Merger as a group.

Except as otherwise noted below, we based the share amounts on each person's beneficial ownership of Alliqua common stock on March 25, 2019 or TOP membership units as of March 11, 2019, after giving effect to the exchange ratio set forth in the Merger Agreement and the consummation of the Merger and the transactions contemplated thereby, including the Private Placement and the assumed conversion of \$500,000 principal amount of convertible notes issued by TOP.

To the extent our directors and executive officers own Alliqua common stock at the Record Date of the Spin-Off, they will participate in the Distribution on the same terms as other holders of Alliqua common stock.

Except as otherwise noted in the footnotes below, each person or entity identified in the table has sole voting and investment power with respect to the securities he, she or it holds.

Immediately following the Spin-Off, the Merger, and the transactions contemplated thereby, including the Private Placement and the assumed conversion of \$500,000 principal amount of convertible notes issued by TOP, we estimate that 17,189,183 shares of our common stock will be issued and outstanding, based on the approximately 5,005,210 shares of Alliqua common stock outstanding on March 25, 2019.

Name and Address of Beneficial Owner <sup>(1)</sup>	Number of Shares Beneficially Owned <sup>(2)</sup>	Percentage Beneficially Owned <sup>(2)</sup>
5% Owners		
Tikun Olam Ltd. 183 Ibn Gabirol Street Tel Aviv, 6200715, Israel	2,112,568 <sup>(3)</sup>	12.3%
Tsachi Cohen 183 Ibn Gabirol Street Tel Aviv, 6200715, Israel	2,112,568 <sup>(3)</sup>	12.3%
Menachem Silber 77 Water Street, 8 <sup>th</sup> Floor New York, NY 10005	1,171,941	6.8%
Eric Lerner 77 Water Street, 8 <sup>th</sup> Floor New York, NY 10005	910,126	5.3%
Officers and Directors		
Berel Farkas	1,633,119 <sup>(4)</sup>	9.5%
Tsachi Cohen	2,112,568 <sup>(3)</sup>	12.3%
Bernard Sucher	611,180 <sup>(5)</sup>	3.6%

Name and Address of Beneficial Owner <sup>(1)</sup>	Number of Shares Beneficially Owned <sup>(2)</sup>	Percentage Beneficially Owned <sup>(2)</sup>
George Kegler	_	_
David I. Johnson	119,847 <sup>(6)</sup>	*
Seth Yakatan <sup>(7)</sup>	_	_
Mitchell Glass	4,667	*
Sidney Taubenfeld	525,026 <sup>(8)</sup>	3.0%
All executive officers and directors of the Company, as a group	5,006,407	29.1%

Represents ownership of less than 1%

- Unless otherwise indicated, the address of each person or group is c/o TO Pharmaceuticals, LLC, 77 Water Street, 8<sup>th</sup> Floor, New York, New York 10005.
- (2) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assumes the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 25, 2019. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person, but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.
- (3) Comprised of 2,112,568 shares of our common stock owned directly by TOL, of which Mr. Tsachi Cohen is deemed to have voting and investment power through Mr. Cohen's control of TOL.
- (4) Comprised of (i) 307,005 shares of our common stock owned directly by Mr. Farkas, and (ii) 1,326,114 shares of our common stock owned by two limited liability companies (after giving effect to the distribution by a member of TOP of its membership interests in TOP to its members, to be effective immediately prior to the consummation of the Merger).
- (5) Comprised of (i) 396,201 shares of our common stock owned directly by Mr. Sucher, (ii) 6,829 shares of our common stock owned by a trust in which Mr. Sucher is deemed to have voting and investment power as trustee, and (iii) 208,150 shares of our common stock issuable upon exercise of a warrant issued by TOP to Mr. Sucher, of which approximately 208,150 are exercisable as of March 25, 2019, half of which are exercisable at exercise prices of \$.81 and \$2.43 per share, respectively.
- (6) Based upon 342,814 shares of Alliqua common stock beneficially owned by Mr. Johnson as of December 31, 2018. The address for Mr. Johnson is c/o Alliqua BioMedical, Inc., 2150 Cabot Boulevard, West, Suite B, Langhorne, PA 19067.
- (7) This table does not include options that Mr. Yakatan is eligible to receive, exercisable for three percent (3%) of AquaMed's outstanding stock after giving effect to the Merger and the Private Placement, which is expected to be an amount equal to approximately 525,000 shares of our common stock and which are not exercisable within 60 days.
- (8) Comprised of 735,036 shares of our common stock issuable upon exercise of a warrant issued by TOP to Mr. Taubenfeld, of which 525,026 are exercisable as of March 25, 2019, at an exercise price of \$0.66 per share.

#### DESCRIPTION OF OUR CAPITAL STOCK

### General

Prior to the Distribution, Alliqua, as our sole stockholder, will approve and adopt our Amended and Restated Certificate of Incorporation, and our Board of Directors will approve and adopt our Amended and Restated Bylaws. The following summarizes information concerning our capital stock, including material provisions of our Amended and Restated Certificate of Incorporation, our Amended and Restated Bylaws and certain provisions of Delaware law. You are encouraged to read our form of Amended and Restated Certificate of Incorporation and our form of Amended and Restated Bylaws, which are filed as exhibits to our Registration Statement on Form S-1, of which this prospectus is part, for greater detail with respect to these provisions.

## Authorized Capital Stock

Immediately following the Spin-Off, our authorized capital stock will consist of 100,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of "blank check" preferred stock, par value \$0.001 per share.

## **Shares Outstanding**

Immediately following the Spin-Off, the Merger, and the transactions contemplated thereby, including the Private Placement, we estimate that 17,189,183 shares of our common stock will be issued and outstanding, based on approximately 5,005,210 shares of Alliqua common stock outstanding as of December 31, 2018.

#### **Common Stock**

## **Dividend Rights**

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our 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. See "Dividend Policy."

## Voting Rights

Except as required by law or matters relating solely to the terms of preferred stock, each outstanding share of common stock will be entitled to one vote on all matters submitted to a vote of stockholders. Holders of shares of our common stock shall have no cumulative voting rights. Except in respect of matters relating to the election and removal of directors on our Board of Directors and as otherwise provided in our Amended and Restated Certificate of Incorporation or required by law, all matters to be voted on by our stockholders must be approved by a majority of the shares present in person or by proxy at the meeting and entitled to vote on the subject matter. In the case of election of directors, all matters to be voted on by our stockholders must be approved by a plurality of the voting power of the shares present in person or by proxy at the meeting and entitled to vote thereon.

#### Liquidation

In the event of the liquidation, dissolution or winding up of our company, holders of our common stock are 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 and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

## **Rights and Preferences**

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there is no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our 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 we may designate in the future.

#### **Preferred Stock**

The Board of Directors is authorized, subject to any limitations prescribed by law, without further vote or action by the shareholders, to issue from time to time shares of preferred stock in one or more series. Preferred stock may be convertible into shares of our common stock or other series of preferred stock. Each such series of preferred stock shall have such number of shares, designations, preferences, voting powers, qualifications, and special or relative rights or privileges as shall be determined by the Board of Directors, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights. Issuance of preferred stock by our Board of Directors may result in such shares having dividend or liquidation preferences senior to the rights of the holders of our common stock and could dilute the voting rights of the holders of our common stock.

Prior to the issuance of shares of each series of preferred stock, the Board of Directors is required by the Delaware General Corporation Law and our certificate of incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions. Once designated by our Board of Directors, each series of preferred stock may have specific financial and other terms.

# Delaware Anti-Takeover Law and Provisions of our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

#### Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business
  combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation which has the effect, directly or indirectly, of increasing the proportionate share of the stock of any class or series, or securities convertible into the stock of any class or series, of the corporation or of any such subsidiary which is owned by the interested stockholder; or

 the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation or any entity or person affiliated with, or controlling, or controlled by, the entity or person. The term "owner" is broadly defined to include any person that, individually, with or through that person's affiliates or associates, among other things, beneficially owns the stock, or has the right to acquire the stock, whether or not the right is immediately exercisable, under any agreement or understanding or upon the exercise of warrants or options or otherwise or has the right to vote the stock under any agreement or understanding, or has an agreement or understanding with the beneficial owner of the stock for the purpose of acquiring, holding, voting or disposing of the stock.

The restrictions in Section 203 do not apply to corporations that have elected, in the manner provided in Section 203, not to be subject to Section 203 of the Delaware General Corporation Law or, with certain exceptions, which do not have a class of voting stock that is listed on a national securities exchange or authorized for quotation on the Nasdaq Stock Market or held of record by more than 2,000 stockholders. Our Amended and Restated Certificate of Incorporation and Bylaws do not opt out of Section 203.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

## Certificate of Incorporation and Bylaws

Provisions of our Amended and Restated Certificate of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which shareholders might otherwise receive a premium for their shares, or transactions that our shareholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Amended and Restated Certificate of Incorporation and Bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, without further action by the shareholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;
- provide that the authorized number of directors may be changed only by resolution of a majority of the total number of authorized directors whether or not there exist any vacancies in the previously authorized directorships (the "Whole Board");
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our shareholders may be called only by the the Board of Directors acting
  pursuant to a resolution adopted by a majority of the Whole Board or holders of a majority of the
  outstanding voting power of the shares of capital stock of the Company; and
- set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors and with regard to business to be brought before a meeting of shareholders.

## Limitation on Liability and Indemnification of Directors and Executive Officers

Our Amended and Restated Certificate of Incorporation will limit our directors' liability to the fullest extent permitted under Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:



- · for any breach of a director's duty of loyalty to us and our stockholders;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (unlawful payment of dividends or redemption of shares); or
- for any breach of a director's duty of loyalty to us or our stockholders.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

Delaware law provides, and our Amended and Restated Bylaws will provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses in advance of the final disposition of the proceeding.

We intend to maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for certain actions taken in their capacities as directors and officers. We believe that these provisions in our Amended and Restated Certificate of Incorporation and Bylaws and any such insurance policy are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock are available for future issuance without your approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

## **Choice of Forum**

Our Amended and Restated Bylaws will provide that the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any director or officer or other employee to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee arising pursuant to any provision of the Delaware General Corporation Law, our Amended and Restated Certificate of Incorporation or our Amended and Restated Bylaws (in each case, as may be amended from time to time); (iv) any action asserting a claim against us or any director or officer or other employee of governed by the internal affairs doctrine; or (v) any other internal corporate claim as defined in Section 115 of the Delaware General Corporation Law or any successor provision, shall be in the Court of Chancery of the State of Delaware, or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the Superior Court of the State of Delaware, or, if the Superior Court of the State of Delaware not have jurisdiction over the indispensable parties named therein. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could rule that these types of provisions to be inapplicable or unenforceable.

## Stock Exchange Listing

We intend to list our common stock on the Nasdaq Capital Market under the symbol "TOPP."

# **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be Action Stock Transfer Corporation.

## Direct Registration System

Our common stock will be registered in book-entry form through the direct registration system. Under this system, ownership of our common stock is reflected in account statements periodically distributed to stockholders by Action Stock Transfer Corporation, our transfer agent, who holds the book-entry shares on behalf of our common stockholders.

#### SHARES ELIGIBLE FOR FUTURE SALE

There is currently no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect the market price of our common stock prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

#### Sale of Restricted Securities

The shares of our common stock distributed to Alliqua stockholders will be freely transferable, except for shares received by individuals who are our affiliates. Individuals who may be considered our affiliates after the Spin-Off include individuals who control, are controlled by or are under common control with us, as those terms generally are interpreted for federal securities law purposes. These individuals may include some or all of our directors and executive officers. Individuals who are our affiliates will be permitted to sell their shares of our common stock only pursuant to an effective registration statement under the Securities Act, or an exemption from the registration requirements of the Securities Act, such as those afforded by Section 4(1) of the Securities Act or Rule 144 thereunder.

## Rule 144

In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated), including an affiliate, who beneficially owns "restricted securities" of a "reporting company" may not sell these securities until the person has beneficially owned them for at least six months. Thereafter, affiliates may not sell within any three-month period a number of shares in excess of the greater of: (i) 1% of the then outstanding shares of common stock as shown by the most recent report or statement published by the issuer; and (ii) the average weekly reported trading volume in such securities during the four preceding calendar weeks.

Sales under Rule 144 by our affiliates will also be subject to restrictions relating to manner of sale, notice and the availability of current public information about us and may be affected only through unsolicited brokers' transactions.

Persons not deemed to be affiliates who have beneficially owned "restricted securities" for at least six months but for less than one year may sell these securities, provided that current public information about the Company is "available," which means that, on the date of sale, we have been subject to the reporting requirements of the Exchange Act for at least 90 days and are current in our Exchange Act filings. After beneficially owning "restricted securities" for one year, our non-affiliates may engage in unlimited re-sales of such securities.

Shares received by our affiliates in the Distribution or upon exercise of stock options or upon vesting of other equity-linked awards may be "controlled securities" rather than "restricted securities." "Controlled securities" are subject to the same volume limitations as "restricted securities" but are not subject to holding period requirements.

#### LEGAL MATTERS

The validity of the common stock to be distributed in the Spin-Off will be passed upon for the Company by Haynes & Boone, LLP, New York, New York.

# EXPERTS

The financial statements of each of AquaMed and TOP as of December 31, 2018 and 2017 and for each of the two years ended December 31, 2018 and 2017 included in this prospectus have been so included in reliance on the reports of Marcum LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

# WHERE YOU CAN FIND MORE INFORMATION

We have filed a Registration Statement on Form S-1 with the SEC with respect to the shares of our common stock that Alliqua's stockholders will receive in the Distribution as contemplated by this prospectus. This prospectus is a part of and does not contain all the information set forth in, the Registration Statement and the other exhibits and schedules to the Registration Statement. For further information with respect to us and our common stock, please refer to the Registration Statement including its other exhibits and schedules. Statements we make in this prospectus relating to any contract or other document are not necessarily complete and you should refer to the exhibits attached to the Registration Statement for copies of the actual contract or document. You may review a copy of the Registration Statement including its exhibits and schedules at the SEC's public reference room, located at 100 F Street, N.E., Washington, D.C. 20549, as well as on the Internet website maintained by the SEC at www.sec.gov. Please call the SEC at 1-800-SEC-0330 for more information on the public reference room. Information contained on, or hyperlinked from, any website we refer to in this prospectus does not and will not constitute a part of this prospectus or the Registration Statement on Form S-1 of which this prospectus is a part.

As a result of the Spin-Off, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with the Exchange Act, we will file periodic reports, proxy statements and other information with the SEC.

You may request a copy of any of our filings with the SEC at no cost by writing us at the following address:

Before the Spin-Off, at:

Investor Relations Alliqua BioMedical, Inc. 2150 Cabot Boulevard West Suite B Langhorne, PA 19047 Phone: 215-702-8550

After the Spin-Off, at:

Investor Relations AquaMed Technologies, Inc. 2150 Cabot Boulevard West Suite B Langhorne, PA 19047 Phone: 215-702-8550

We intend to furnish holders of our common stock with annual reports containing combined financial statements prepared in accordance with U.S. generally accepted accounting principles and audited and reported on by an independent registered public accounting firm.



# INDEX TO FINANCIAL STATEMENTS

AUDITED FINANCIAL STATEMENTS OF AQUAMED:	
Report of Independent Registered Public Accounting Firm	<u>F-2</u>
Balance Sheets	<u>F-3</u>
Statements of Operations	<u>F-4</u>
Statements of Changes in Parent's Net Investment	<u>F-5</u>
Statements of Cash Flows	<u>F-6</u>
Notes to the Financial Statements	<u>F-7</u>

# AUDITED CONSOLIDATED FINANCIAL STATEMENTS OF TOP:

Report of Independent Registered Public Accounting Firm	<u>F-20</u>
Consolidated Balance Sheets	<u>F-21</u>
Consolidated Statements of Operations	<u>F-22</u>
Consolidated Statements of Member's Deficit	<u>F-23</u>
Consolidated Statements of Cash Flows	<u>F-24</u>
Notes to the Consolidated Financial Statements	<u>F-25</u>

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Alliqua BioMedical, Inc.

#### **Opinion on the Financial Statements**

We have audited the accompanying balance sheets of AquaMed Technologies, Inc. (a segment of Alliqua BioMedical, Inc.) (the "Company"), as of December 31, 2018 and 2017, the related statements of operations, changes in parent's net investment and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

# Explanatory Paragraph — Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 3, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

#### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP Marcum LLP

We have served as the Company's auditor since 2010.

New York, NY March 11, 2019

BALANCE SHEETS (in thousands)

	December 31, 2018	December 31, 2017
ASSETS:		
Current Assets:		
Accounts receivable, net	\$ 34	\$ 99
Inventory, net	101	93
Prepaid expenses and other current assets	226	7
Total current assets	361	199
Improvements and equipment, net	200	522
Other assets	178	173
Total assets	\$739	\$894
LIABILITIES AND PARENT'S NET INVESTMENT		
Current Liabilities:		
Accounts payable	\$157	\$ 63
Accrued expenses and other current liabilities	250	147
Total current liabilities	407	210
Other long-term liabilities	51	59
Total liabilities	458	269
Commitments and Contingencies		
Parent's net investment	281	625
Total Parent's net investment	281	625
Total liabilities and Parent's net investment	\$739	\$894

The accompanying notes are an integral part of these financial statements.

**STATEMENTS OF OPERATIONS** *(in thousands)* 

Years Ended	Years Ended December 31,		
2018	2017		
\$ 2,213	\$1,992		
1,699	1,845		
514	147		
2,402	1,116		
2,402	1,116		
(1,888)	(969)		
_	16		
\$(1,888)	\$ (953)		
	2018 \$ 2,213 1,699 514 2,402 2,402 (1,888) —		

The accompanying notes are an integral part of these financial statements.

# AQUAMED TECHNOLOGIES, INC. (A SEGMENT OF ALLIQUA BIOMEDICAL, INC.) STATEMENTS OF CHANGES IN PARENT'S NET INVESTMENT (in thousands)

	Years Ended	Years Ended December 31,		
	2018	2017		
Parent's net investment, beginning of year	\$ 625	\$ 794		
Net Loss	(1,888)	(953)		
Advances from Parent	1,544	\$ 784		
Parent's net investment, end of year	\$ 281	\$ 625		

The accompanying notes are an integral part of these financial statements.

**STATEMENTS OF CASH FLOWS** (in thousands)

	Years Ended December 31,		
	2018	2017	
Operating Activities			
Net loss	\$(1,888)	\$(953)	
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	322	316	
Amortization of deferred lease incentive	(8)	(8)	
Deferred income tax expense	_	(16)	
Provision for doubtful accounts	(1)	2	
Provision for excess and slow moving inventory	(5)	5	
Changes in operating assets and liabilities:			
Accounts receivable	66	(27)	
Inventory	(3)	60	
Prepaid expenses and other assets	(224)	18	
Accounts payable	94	(84)	
Accrued expenses and other liabilities	103	(90)	
Net Cash Used in Operating Activities	(1,544)	(777)	
Investing Activities			
Purchase of improvements and equipment		(7)	
Net Cash Used in Investing Activities		(7)	
Financing Activities			
Advances from parent	1,544	784	
Net Cash Provided by Financing Activities	1,544	784	
Net Increase (Decrease) in Cash and Cash Equivalents		_	
Cash and Cash Equivalents – Beginning of year	_	_	
Cash and Cash Equivalents – End of year	\$ —	\$ —	
Supplemental Disclosure of Cash Flows Information			
Cash paid during the year for:			
Interest	\$ —	\$ —	
Taxes	_	_	

The accompanying notes are an integral part of these financial statements.

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

# 1. Description of Business and Basis of Presentation

AquaMed Technologies, Inc. ("AquaMed" or the "Company") manufactures high water content, electron beam cross-linked, aqueous polymer hydrogels, or gels, used for wound care, medical diagnostics, transdermal drug delivery and cosmetics. The Company specializes in custom gels by capitalizing on proprietary manufacturing technologies. The Company has, historically, served as a contract manufacturer, supplying its gels to third parties who incorporate them into their own products.

#### **Recent Developments**

On November 27, 2018, AquaMed, a wholly-owned subsidiary of Alliqua BioMedical, Inc. ("Alliqua" or the "Parent"), AQ TOP, LLC, a Delaware limited liability company and a wholly-owned subsidiary of AquaMed ("Merger Sub"), and TO Pharmaceuticals, LLC, a Delaware limited liability company ("TOP"), entered into an Agreement and Plan of Merger (the "Merger Agreement"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into TOP, with TOP becoming a wholly-owned subsidiary of the AquaMed and the surviving company of the merger (the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free contribution under the provisions of Section 351(a) of the Internal Revenue Code of 1986, as amended.

The Merger will occur after the consummation by Alliqua of the following steps:

- Pursuant to an Asset Contribution and Separation Agreement to be entered into by and between Alliqua and AquaMed (the "Separation Agreement") prior to consummation of the Merger, Alliqua will transfer certain assets and liabilities utilized primarily in connection with its custom hydrogels contract manufacturing business to AquaMed (the "Separation"),
- (2) AquaMed will issue a to be determined number of shares of common stock to Alliqua in consideration of the contribution of assets pursuant to the Separation Agreement (the "Distribution Consideration"),
- (3) Alliqua will distribute to its stockholders all of the issued and outstanding shares of common stock, par value \$0.001 per share, of AquaMed by way of a pro rata dividend (the "Distribution"), and
- (4) Alliqua will consummate the previously announced reverse merger transaction with Adynxx, Inc. ("Adynxx"), pursuant to that certain Agreement and Plan of Merger and Reorganization, dated as of October 11, 2018, by and among Alliqua, Embark Merger Sub, Inc. and Adynxx.
- (5) Effective post-Merger and share distribution, the merged entity will issue 4.99% of its outstanding shares to a third party for consulting services related to the business combination.

At the effective time of the Merger, all of the outstanding membership units of TOP will be converted into the right to receive, in the aggregate, merger consideration consisting of shares of AquaMed common stock. Immediately after the effective time of the Merger and consummation of the Private Placement (as defined below), before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis).

The consummation of the Merger is subject to certain customary and other conditions, including (i) the completion of the Separation and the Distribution, (ii) the effectiveness of the registration statement on Form S-1 filed with the SEC with respect to, and the approval for listing on the NASDAQ Capital Market of, the shares of AquaMed common stock to be issued in the Distribution and the Merger, (iii) receipt of binding commitments from third-party investors to consummate a private placement of AquaMed's



# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation – (continued)

common stock in a minimum aggregate amount of \$10 million immediately prior to the effective time of the Merger (the "Private Placement") (iv) the accuracy of the parties' representations and warranties and the performance of their respective covenants contained in the Merger Agreement, and (v) receipt of an independent third-party valuation of the AquaMed common stock to be issued in the Distribution.

The Merger Agreement contains customary and other representations, warranties and covenants, including a covenant for AquaMed to use (i) commercially reasonable efforts to consummate and make effective the Separation and payment of the Distribution Consideration contemplated by the Distribution Agreement in accordance with its terms and (ii) reasonable best efforts to consummate the Private Placement.

#### **Basis of Presentation**

The Company is being presented as a carve out of the Contract Manufacturing segment of Alliqua, which includes AquaMed and certain other accounts of Alliqua and collectively presents the Company on a standalone basis.

Management believes the assumptions underlying the Company's standalone financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas.

Alliqua used a centralized approach to cash management and financing its operations, including the operations of the Company. Accordingly, none of the cash and cash equivalents of Alliqua have been allocated to the Company in the financial statements. Transactions between Alliqua and the Company are accounted for through Parent's Net Investment.

#### Significant Accounting Policies and Estimates

#### Use of Estimates in the Financial Statements

The preparation of the financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates and assumptions include valuing the allowance for doubtful accounts, inventory reserves, deferred taxes and related valuation allowances, and the fair values of long-lived assets. Actual results could differ from the estimates.

# Trade Accounts Receivable

Trade accounts receivable are stated at the amount the Company expects to collect and do not bear interest. The Company evaluates the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to the Company, a provision to the allowances for doubtful accounts is recorded against amounts due to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowances for doubtful accounts is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience.

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation - (continued)

Provisions to the allowances for doubtful accounts are recorded to selling, general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered. The allowance for doubtful accounts was nominal as of December 31, 2018 and \$2,000 as of December 31, 2017.

#### Inventory

Inventory is stated at the lower of cost, the value determined by the first-in, first-out method, or net realizable value. At each balance sheet date, the Company evaluates inventories for excess quantities, obsolescence or shelf life expiration. This evaluation includes analysis of historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions, and a review of the shelf life expiration dates for products. To the extent that management determines there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value.

#### Improvements and Equipment

Improvements and equipment are recorded at cost. Depreciation of equipment is computed utilizing the straight-line method over the estimated useful lives of the assets. Amortization of leasehold improvements is computed utilizing the straight-line method over the lesser of the lease term or the estimated useful life. Repairs and maintenance costs are expensed as incurred. The cost of major additions and improvements is capitalized, while maintenance and repair costs that do not improve or extend the lives of the respective assets are charged to operations as incurred.

# Cost of Goods Sold and Selling, General and Administrative Expenses

Costs associated with the production and procurement of product are included in cost of goods sold, including shipping and handling costs such as inbound freight costs, purchasing and receiving costs, inspection costs and other product procurement related charges. All other expenses are included in selling, general and administrative expenses, as the predominant expenses associated therewith are general and administrative in nature.

# Shipping and Handling

Amounts billed to customers for shipping and handling are included in revenues. The related shipping and freight charges incurred by the Company are included in cost of goods sold and were not material for either the years ended December 31, 2018 or 2017.

#### Income Taxes

Income taxes are accounted for under the asset and liability method as if the Company were a separate taxpayer during the period that its operations were included as part of a federal consolidated tax return filing group with its parent company. Under this method, deferred tax assets and liabilities are recognized for the expected future tax consequences attributable to temporary differences between the financial statement carrying amounts and their respective tax bases of assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period enacted. A valuation allowance is provided when it is more likely



# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation – (continued)

than not that a portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the reversal of deferred tax liabilities during the period in which related temporary differences become deductible.

The Company adopted the provisions of Accounting Standards Codification Topic 740 ("ASC 740") related to the accounting for uncertainty in income taxes recognized in an enterprise's consolidated financial statements. ASC 740 prescribes a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns.

The benefit of tax positions taken or expected to be taken in the Company's income tax returns are recognized in the financial statements if such positions are more likely than not of being sustained upon examination by taxing authorities. Differences between tax positions taken or expected to be taken in a tax return and the benefit recognized and measured pursuant to the interpretation are referred to as "unrecognized benefits". A liability is recognized (or amount of net operating loss carryover or amount of tax refundable is reduced) for an unrecognized tax benefit because it represents an enterprise's potential future obligation to the taxing authority for a tax position that was not recognized as a result of applying the provisions of ASC 740. Interest costs and related penalties related to unrecognized tax benefits are required to be calculated, if applicable. The Company's policy is to classify assessments, if any, for tax related interest as interest expense and penalties as selling, general and administrative expenses. No interest or penalties were recorded during the years ended December 31, 2018, and 2017. As of December 31, 2018, and December 31, 2017, no liability for unrecognized tax benefits was required to be reported. The Company does not expect any significant changes in its unrecognized tax benefits in the next year.

Under the separate entity method, the Company is assumed to file a separate return with the taxing authority, thereby reporting its taxable income or loss and paying the applicable tax to or receiving the appropriate refund from its parent. However, since there is no tax-sharing agreement in place between the Company and its parent, any taxes payable or receivable on current taxable income or loss at the end of each reporting date is treated as a capital contribution or dividend.

#### Parent's Net Investment

The Company's equity on the Balance Sheet represents Alliqua's net investment in the Company's business and is presented as "Parent's Net Investment" in lieu of stockholder's equity. The Statement of Changes in Parent's Net Investment includes net cash transfers between Alliqua and the Company. Alliqua performs cash management and other treasury-related functions on a centralized basis for all of its divisions, which includes the Company. Liabilities recorded by Alliqua, whose related expenses have been pushed down to the Company, are included in the Parent's Net Investment.

All transactions reflected in the Parent's Net Investment in the accompanying Balance Sheets have been considered cash receipts and payments for purposes of the Statements of Cash Flows and are reflected in the financing activities in the accompanying Statements of Cash Flows.

Earnings per share data has not been presented in the accompanying Financial Statements because the Company did not operate as a separate legal entity with its own capital structure during the periods presented.

#### Subsequent Events

The Company evaluates events and/or transactions occurring after the balance sheet date and before the issue date of the carve-out financial statements to determine if any of those events and/or transactions requires adjustment to or disclosure in the carve-out financial statements.

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation - (continued)

# **Recent Accounting Principles**

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" and ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company expects to adopt ASU 2016-02 effective January 1, 2019 upon adoption of Topic 842, the Company expects recognition of additional assets and corresponding liabilities pertaining to its operating leases on its balance sheets. The Company does not expect the adoption of the new standard to have a significant impact on its statements of operations and cash flows.

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement". The amendments in this update is to improve the effectiveness of disclosures in the notes to the financial statements by facilitating clear communication of the information required by GAAP that is most important to users of each entity's financial statements. The amendments in this update apply to all entities that are required, under existing GAAP, to make disclosures about recurring or nonrecurring fair value measurements. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company does not expect that this guidance will have a material impact on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, "Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting". The amendments in this update is to maintain or improve the usefulness of the information provided to the users of financial statements while reducing cost and complexity in financial reporting. The areas for simplification in this Update involve several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, to include share-based payment transactions for acquiring goods and services from nonemployees. Some of the areas for simplification apply only to nonpublic entities. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. The Company does not expect that this guidance will have a material impact on its consolidated financial statements.

On December 22, 2017 the U.S. government enacted significant changes to federal tax law following the passage of the Tax Cuts and Jobs Act ("the Act"). Following the enactment of the Act, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act ("SAB 118"). The Company follows the guidance in SAB 118, which provides additional clarification regarding the application of US GAAP in situations where the Company does not have the necessary

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation – (continued)

information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the Act for the reporting period in which the Act was enacted. SAB 118 provides for a measurement period beginning in the reporting period that includes the Act's enactment date and ending when the Company has obtained, prepared, and analyzed the information needed in order to complete the accounting requirements but in no circumstances should the measurement period extend beyond one year from the enactment date. During the quarter ended December 31, 2018, the Company completed the accounting for the income tax effects of the Act, which resulted in an immaterial change in the net deferred tax asset, before valuation allowance, as of the enactment date. These impacts are disclosed in "Note 8 — Income Taxes" in the Notes accompanying the audited Financial Statements.

In May 2014 the FASB issued Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (Topic 606), in August 2015 the FASB issued ASU No. 2015-14, Deferral of the Effective Date, in March 2016 the FASB issued ASU No. 2016-08, Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net), in April 2016, the FASB issued ASU No. 2016-10, Identifying Performance Obligations and Licensing, in May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606) — Narrow Scope Improvements and Practical Expedients, in December 2016 the FASB issued ASU No. 2017-09, Revenue from Contracts with Customers, in September 2017 the FASB issued ASU No. 2017-13 Amendments to SEC Paragraphs Pursuant to the Staff Announcement at the July 20, 2017 EITF Meeting and Rescission of Prior SEC Staff Announcements and Observer Comments, and in November 2017 the FASB issued and made effective ASU 2017-14, Income Statement — Reporting Comprehensive Income (Topic 220), Revenue Recognition (Topic 605), and Revenue from Contracts with Customers (Topic 606). These standards and their effect on the Company's financial statements and related disclosures are discussed below under Revenue Recognition.

# **Carve-Out Assumptions and Allocations**

The expenses of AquaMed for the years ended December 31, 2018 and 2017, including executive compensation, have been allocated by management between AquaMed and Alliqua, based either on specific attribution of those expenses or, where necessary and appropriate, based on management's best estimate of an appropriate proportional allocation.

The following expenses included in the accounting records of AquaMed have been attributed by management to the operations being retained by AquaMed, accordingly:

.....

	Year Ended I	Year Ended December 31,		
	2018	2017		
Selling, general and administrative expenses				
Compensation and benefits	\$ 464	\$ 184		
Stock-based compensation	173	198		
Other expenses and professional fees	1,765	734		
Total selling, general and administrative expenses	\$ 2,402	\$ 1,116		

#### **Revenue Recognition**

On January 1, 2018, the Company adopted Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). The core principle of ASC 606 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation - (continued)

services. ASC 606 defines a five-step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing accounting principles generally accepted in the United States of America ("U.S. GAAP") including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation.

The Company adopted ASC 606 for all applicable contracts using the modified retrospective method, which would have required a cumulative-effect adjustment, if any, as of the date of adoption. The adoption of ASC 606 did not have a material impact on the Company's financial statements as of the date of adoption. As a result, a cumulative-effect adjustment was not required.

The Company recognizes revenue predominately from one type of revenue, contract manufacturing. Revenue from contract manufacturing is recognized at the point where the customer obtains control of the goods and the Company satisfies its performance obligation, which generally is at the time it ships the product to the customer. To achieve this core principle, the Company applies the following five steps:

Step 1 — Identify the Contract with the Customer — A contract exists when (a) the parties to the contract have approved the contract and are committed to perform their respective obligations, (b) the entity can identify each party's rights regarding the goods or services to be transferred, (c) the entity can identify the payment terms for the goods or services to be transferred, (d) the contract has commercial substance and it is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Step 2 — Identify Performance Obligations in the Contract — Upon execution of a contract, the Company identifies as performance obligations each promise to transfer to the customer either (a) goods or services that are distinct or (b) a series of distinct goods or services that are substantially the same and have the same pattern of transfer to the customer. To the extent a contract includes multiple promised goods or services, the Company must apply judgement to determine whether the goods or services are capable of being distinct within the contract. If these criteria are not met, the goods or services are accounted for as a combined performance obligation.

Step 3 — Determine the Transaction Price — The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring products or services to the customer. Generally, all contracts include fixed consideration. If a contract did include variable consideration, the Company would determine the amount of variable consideration that should be included in the transaction price based on expected value method. Variable consideration would be included in the transaction price, if in the Company's judgement, it is probable that a significant future reversal of cumulative revenue under the contract would not occur.

Step 4 — Allocate the Transaction Price — After the transaction price has been determined, the next step is to allocate the transaction price to each performance obligation in the contract. If the contract only has one performance obligation, the entire transaction price will be applied to that obligation. If the contract has multiple performance obligations, the transaction price is allocated to the performance obligations based on the relative standalone selling price (SSP) at contract inception.

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 1. Description of Business and Basis of Presentation - (continued)

Step 5 — Satisfaction of the Performance Obligations (and Recognize Revenue) — When the customer obtains control of the asset (or the services are rendered), the Company recognizes revenue. At contract inception, the Company determines if each performance obligation is satisfied at a point in time or over time. Revenue from contract manufacturing is recognized at the point where the customer obtains control of the goods and the Company satisfies its performance obligation, which generally is at the time it ships the product to the customer.

# **Disaggregation of Revenue**

The Company recognizes revenue from contract manufacturing. Revenue from contract manufacturing is recognized at the point where the customer obtains control of the goods and the Company satisfies its performance obligation, which generally is at the time it ships the product to the customer.

As of December 31, 2018, or December 31, 2017, the Company did not have any contract assets or contract liabilities from contracts with customers. During the years ended December 31, 2018 and 2017, there was no revenue recognized from performance obligations satisfied (or partially satisfied) in previous periods. As of December 31, 2018, there were no remaining performance obligations that the Company had not satisfied.

# 2. Going Concern

The Company's financial statements are prepared using accounting principles generally accepted in the United States of America applicable to a going concern that contemplates the realization of assets and liquidation of liabilities in the normal course of business.

The Company has experienced recurring losses since its merger with Alliqua BioMedical, Inc. in 2010. As of December 31, 2018, the Company had a \$0 cash balance. For the years ended December 31, 2018 and 2017, the Company incurred net losses of \$1.9 million and \$1.0 million, respectively. These factors raise substantial doubt as to the Company's ability to continue as a going concern within one year from the date these financial statements are issued.

The Company expects to continue incurring losses for the foreseeable future and will need to raise additional capital to support ongoing operations.

Management is evaluating all options to raise sufficient funds to fund the Company's working capital requirements through equity offerings. There can be no assurances, however, that management will be able to obtain sufficient additional funds when needed, or that such funds, if available, will be obtained on terms satisfactory to the Company. The ability of the Company to continue as a going concern is dependent upon its ability to raise additional capital and achieve profitable operations. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets and liabilities that might be necessary should the Company be unable to continue as a going concern.

# 3. Inventory

Inventory consists of the following (in thousands):

	December 31, 2018	December 31, 2017
Raw materials	\$ 101	\$98
Less: Inventory reserve for excess and slow moving inventory		(5)
Total	\$ 101	\$93

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

# 4. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	December 31, 2018	December 31, 2017
Salaries, benefits and incentive compensation	\$108	\$ 92
Professional fees	95	28
Other	47	27
Total accrued expenses and other current liabilities	\$250	\$ 147

# 5. Operating Leases

The Company leases one commercial manufacturing facility through an operating lease agreement for this facility located in Langhorne, Pennsylvania, through 2026. Tenant improvements are included in leasehold improvements on the balance sheet.

Future minimum lease payments, excluding expense reimbursements, under noncancelable operating leases at December 31, 2018 are as follows (in thousands):

2019	207
2020	207
2021	207
2022	207
2023	207
Thereafter	434
Total	\$1,469

# 6. Concentration of Risk

Revenue for the years ended December 31, 2018 and 2017, and accounts receivable as of December 31, 2018 and 2017 from the Company's largest customers, were as follows:

	% of Total Revenue		% of Total Revenue		Accounts Receivable	Accounts Receivable
Customer	2018	2017	December 31, 2018	December 31, 2017		
A	63%	65%	0%	100%		
В	14%	16%	0%	0%		

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

# 7. Improvements and Equipment, net

Improvements and equipment consist of the following (in thousands):

	Useful Life	e December 31,		
	(Years)	2018	2017	
Machinery and equipment	3 - 10	\$ 2,893	\$ 2,893	
Office furniture and equipment	3 - 10	49	56	
Leasehold improvements	(A)	228	228	
		3,170	3,177	
Less: Accumulated depreciation and amortization		(2,970)	(2,655)	
Improvements and equipment, net		\$ 200	\$ 522	

(A) Leasehold improvements are amortized over the shorter of the remaining lease term or estimated useful life.

Depreciation and Amortization expense was \$315,000 and \$316,000 for the years ended December 31, 2018 and 2017, respectively.

# 8. Income Taxes

The Company files corporate income tax returns in U.S. federal, state and local jurisdictions, including Pennsylvania, and has tax returns subject to examination by tax authorities generally beginning in the year ended December 31, 2015 and through December 31, 2018. However, to the extent we utilize our net operating loss ("NOL") carryforwards in the future, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state tax authorities of the future period tax return in which the attribute is utilized.

The income tax (benefit) provision consists of the following:

	For The Years E	For The Years Ended December 31	
	2018	2017	
Federal:			
Current	\$ —	\$ —	
Deferred	—	(13)	
State and local:			
Current	—		
Deferred	—	(3)	
Income tax provision	\$	\$(16)	

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 8. Income Taxes – (continued)

For the years ended December 31, 2018 and 2017, the expected tax benefit based on the statutory rate reconciled with the actual benefit is as follows:

	For The Years End	For The Years Ended December 31,	
	2018	2017	
U.S. federal statutory rate	21.0%	34.0%	
State tax rate, net of federal benefit	1.1%	0.1%	
Permanent differences			
- Change in fair value of warrant liability	0.0%	0.0%	
- Change in fair value of contingent consideration	0.0%	0.0%	
— Intangible impairment	0.0%	0.0%	
— Other	0.0%	0.0%	
State tax change	4.2%	0.0%	
Tax Reform – Federal Rate Change	0.0%	(139.1)%	
Tax Reform - Change in valuation allowance	0.0%	139.1%	
Change in valuation allowance	(26.3)%	(32.4)%	
Income tax provision	0.0%	1.7%	

For the years ended December 31, 2018 and 2017, differences between the expected tax expense based on the federal statutory rate and the actual tax expense is primarily attributable to losses for which no benefit is recognized.

The United States enacted the Tax Cuts and Jobs Act ("Act") on December 22, 2017, most provisions of which took effect in years beginning after December 31, 2017. The Act made substantial changes to U.S. taxation of corporations, including a reduction in the U.S. federal corporate income tax rate from 34% to 21% and changes to limitations on the deductibility of executive compensation. The effect on deferred tax assets and liabilities of a change in law or tax rates is recognized in income in the period that includes the enactment date.

After the enactment of the Act, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. In our financial statements for the period ended December 31, 2017, we calculated an estimate of the impact of the Act related to the remeasurement of our net U.S. deferred tax asset due to the change in U.S. federal corporate income tax rate. The provisional amount recorded was deferred tax expense of \$1.3 million, but which was fully and equally offset by a deferred tax benefit related to a corresponding reduction in our valuation allowance. During the quarter ended December 31, 2018, the Company completed the accounting for the income tax effects of the Act, which resulted in an immaterial change in the net deferred tax asset, before valuation allowance, as of the enactment date.

# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

#### 8. Income Taxes – (continued)

As of December 31, 2018 and 2017, the Company's deferred tax assets consisted of the effects of temporary differences attributable to the following:

	As of Dec	As of December 31,	
	2018	2017	
Deferred tax assets:			
Net operating loss carryforwards	\$ 3,110	\$ 2,752	
Intangible Assets	28	233	
Goodwill and Tradename	—	29	
Accruals	12	21	
Other	18	2	
Total deferred tax assets	3,168	3,037	
Valuation allowance	(3,151)	(2,957)	
Deferred tax assets, net of valuation allowance	\$ 17	\$ 80	
Deferred tax liabilities:			
Property and equipment	(17)	(80)	
Intangible assets	—	—	
Goodwill and Trade Name	—	—	
Total deferred tax liabilities	(17)	(80)	
Net deferred tax liabilities	\$	\$	

The deferred tax assets associated with net operating losses included in the table above reflect proforma net operating losses as if the Company were a separate taxpayer during the periods presented. The corporate income tax returns of the subsidiary which owns the contract manufacturing assets, for years ended December 31, 2018 and 2017, reported approximately \$7.8 million and \$8.2 million of federal NOL carryovers, respectively, which substantially begin to expire in 2028 and through 2035. Similarly, the subsidiary's Pennsylvania state returns reported state NOL carryovers of approximately \$7.7 million and \$7.7 million, as of December 31, 2018 and December 31, 2017, respectively. However, these loss carryforwards on a separate company basis may be subject to limitations on the amounts that may be utilized pursuant to Internal Revenue Code section 382 and applicable state law. The Company will need to determine the amounts that may be utilized on a separate company basis in the future as necessary.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of the deferred tax assets is dependent upon the future generation of taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in making this assessment. After consideration of all the evidence, both positive and negative, management has recorded a full valuation allowance against net deferred tax assets at December 31, 2018 and December 31, 2017 because management has determined that it is more likely than not that these deferred tax assets will not be realized. The valuation allowance increased by \$0.2 million and decreased by \$1.1 million during the years ended



# NOTES TO FINANCIAL STATEMENTS FOR YEARS ENDED DECEMBER 31, 2018 AND 2017

# 8. Income Taxes – (continued)

December 31, 2018 and December 31, 2017, respectively. The increase in tax year ended December 31, 2018 is primarily related to the increase in net operating losses. The decrease in tax year ended December 31, 2017 is primarily related to the decrease in the corporate tax rate from 34% to 21% due to the enactment of the Act.

# 10. Subsequent Event

On January 9, 2019, the Company filed an S-1 statement with the Securities and Exchange Commission regarding the proposed merger with TO Pharmaceuticals, LLC.

# **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Members and Board of Managers of TO Pharmaceuticals LLC and Subsidiaries

# **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of TO Pharmaceuticals LLC and Subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, members' deficit and cash flows for each of two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

# Explanatory Paragraph — Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has experienced recurring net losses and negative cash flows from operations since its inception. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

# **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum LLP Marcum LLP

We have served as the Company's auditor since 2018.

New York, NY March 11, 2019



# TO PHARMACEUTICALS LLC AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS As of December 31, 2018 and 2017

		2018		2017
ASSETS				
Current Assets				
Cash	\$	359,189	\$	_
Other current assets		4,255		_
Other receivables-related party		116,558		17,000
Total Current Assets	_	480,002		17,000
Intangible Assets				
Licenses, net of accumulated amortization		429,250		454,500
Total Assets	\$	909,252	\$	471,500
LIABLILITIES				
Current Liabilities				
Accounts payable	\$	294,422	\$	65,155
Accrued expenses		448,891		50,000
Convertible promissory notes payable		500,000		_
Due to affiliate		1,599,142		2,154,310
Total Current Liabilities	_	2,842,455		2,269,465
Commitments and Contingencies				
MEMBERS' DEFICIT				
Members' Deficit	(	1,933,203)	(	1,797,965)
Total Liabilities and Members' Deficit	\$	909,252	\$	471,500

The accompanying notes are an integral part of these consolidated financial statements

# TO PHARMACEUTICALS LLC AND SUBSIDIARIES CONDSOLIDATED STATEMENTS OF OPERATIONS For the Years Ended December 31, 2018 and 2017

	2018	2017
Operating Expenses		
Selling, general & administrative	\$ 740,481	\$ 502,574
Research & development	431,013	235,096
Total Operating Expenses	1,171,494	737,670
Net Loss from Operations	(1,171,494)	\$(737,670)
Net Loss	\$(1,171,494)	\$(737,670)

The accompanying notes are an integral part of these consolidated financial statements

# TO PHARMACEUTICALS LLC AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF MEMBERS' DEFICIT For the Years Ended December 31, 2018 and 2017

	2018	2017
Balance, Beginning of Year	\$(1,797,965)	\$(1,060,295)
Due to Affiliate converted to equity	1,036,256	—
Net Loss	(1,171,494)	(737,670)
Balance, End of Year	\$(1,933,203)	\$(1,797,965)

The accompanying notes are an integral part of these consolidated financial statements F-23

# TO PHARMACEUTICALS LLC AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS For the Years Ended December 31, 2018 and 2017

	2018	2017
Cash Flow from Operating Activities:		
Net loss	\$(1,171,494	\$(737,670
Adjustments to reconcile net loss to net cash used in operating activities:	)	)
Amortization	25,250	25,250
Changes in operating assets and liabilities:		
Other asset	(4,255)	_
Due from affiliate	(99,558)	(17,000)
Accounts payable	229,267	54,027
Accrued expenses	398,891	50,000
Net cash used in operating activities	(621,899)	(625,393)
Cash Flows from Financing Activities		
Due to affiliate	481,088	625,393
Proceeds received from convertible notes	500,000	
Net cash provided by financing activities	981,088	625,393
Net Increase in cash and cash equivalents	359,189	
Cash and cash equivalents, Beginning of the Year		
Cash and cash equivalents, End of the Year	\$ 359,189	\$
Supplemental disclosure of cash flow information:		
Cash paid for interest	<u>\$                                    </u>	\$
Income taxes paid	\$	\$ —
Non-cash investing activities:		
Due to affiliate converted to equity	\$ 1,036,256	<u>\$                                    </u>

The accompanying notes are an integral part of these consolidated financial statements

# 1. Nature of Organization

TO Pharmaceuticals LLC (the "Company"), is a limited liability company formed in the state of Delaware. The Company was formed on October 21, 2015 with an unlimited duration or until dissolved. The Company's equity is represented by Class A membership interest units ("Class A Units") and Class B profit sharing interests. The Company is an early stage biopharmaceutical company engaged in the business of discovering, developing and commercializing drugs containing cannabinoids, which are based on a proprietary cannabinoid product platform, for the treatment of various diseases, disorders and medical conditions. The Company operates primarily through two wholly-owned subsidiaries, TO Pharmaceuticals USA LLC, a Delaware limited liability company ("TOPUSA") in the United States, and Tikun Olam IP Ltd., a Cayman Islands corporation ("TOIP"), outside the United States. The Company's subsidiaries own exclusive licenses to intellectual property rights of certain cannabinoids throughout the world (except the State of New York) for pharmaceutical products in their respective territories. (see Note 3).

# 2. Summary of Significant Accounting Policies

#### **Basis of Presentation**

Through July 13, 2018, the Company was a wholly owned subsidiary of T.O. Global LLC ("TOG"). These consolidated financial statements have been derived from the accounting records of TOG, through and until July 13, 2018 and present the Company and its consolidated subsidiaries on a standalone basis. On July 13, 2018, all of the outstanding membership interests in the Company were distributed by TOG, the Company's former sole beneficial owner, to its members on a pro rata basis.

Management believes the assumptions underlying the Company's stand-alone financial statements are reasonable. Nevertheless, the financial statements may not include all of the actual expenses that would have been incurred had the Company operated as a standalone company during the periods presented, and may not reflect the Company's results of operations, financial position and cash flows had the Company operated as a standalone company during the periods presented. Actual costs that would have been incurred if the Company had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas.

TOG used a centralized approach to cash management and financing its operations, including the operations of the Company. Accordingly, none of the cash or cash equivalents of TOG have been allocated to the Company in the consolidated financial statements. Transactions between TOG and the Company are accounted for through Due to Affiliate. For the period from July 14, 2018 through December 31, 2018, the Company operated separately from TOG.

#### **Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries. All significant inter-company transactions and accounts have been eliminated in consolidation.

#### Use of estimates

The preparation of the Company's consolidated financial statements is in conformity with generally accepted accounting principles of the United States of America which requires management to makes estimates that affect the amounts reported in the consolidated financial statements and accompanying notes. These estimates include the fair values of long-lived assets. Actual results could differ from those estimates.

# Cash and cash equivalents

The Company considers all instruments with the maturity of three months or less when purchased as cash equivalents. The Company maintains its cash balances with one financial institution. The account is insured by the Federal Deposit Insurance Corporation up to \$250,000. During the year ended



#### 2. Summary of Significant Accounting Policies - (continued)

December 31, 2018, the Company had cash balances in excess of the insured limit. As of December 31, 2018, the Company's cash balance of \$176,535 was fully insured.

#### **Intangible Assets**

Intangible assets consist of licenses and related costs. Costs related to licenses are capitalized and amortized over their estimated useful lives using the straight-line method.

#### Impairment of Long-lived assets

Management reviews long-lived assets for potential impairment whenever significant events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment exists when the estimated undiscounted cash flows expected to result from the use of an asset and its eventual disposition are less than the carrying amount. If an impairment exists, the resulting write-down would be the difference between the fair market value of the long-lived asset and the related net book value. No material impairments related to long-lived assets or amortized intangible assets were recorded for the years ended December 31, 2018 and 2017.

# **Research and Development Expenses**

The Company charges research and development costs to operations as incurred. Research and development expenses consist of the costs of clinical trials and the Company's medical advisory board and does not include other personnel or other costs.

#### Income taxes

The consolidated financial statements do not include a provision for income taxes, as the Company has not incurred federal or state income taxes since inception. The Company's loses are included in the respective members' income tax returns.

U.S. GAAP requires entities to evaluate measure, recognize and disclose any uncertain income tax positions taken on their income tax returns. Management has evaluated the impact of this standard on it financial statements and believes that there are no uncertain tax positions and the effects of adopting this standard are not material to the Company's financial position or results of operations. At December 31, 2018 and 2017, no interest or penalties were required to be recorded. Management's conclusions regarding uncertain tax positions may be subject to review and adjustment at a later date upon ongoing analysis of tax laws, regulations, and interpretations thereof, as well as other factors.

# **Going concern**

The Company's consolidated financial statements are prepared using accounting principles generally accepted in the United States of America applicable to a going concern that contemplates the realization of assets and liquidation of liabilities in the normal course of business.

The Company is an early stage company with no operating revenue to date. On November 14, 2018, the Company received \$500,000 in proceeds from issuance of convertible promissory notes, and had a remaining cash and cash equivalents balance of \$359,189 as of December 31, 2018. The Company has experienced recurring net losses and negative cash flows from operations since its inception. The Company incurred a net loss of \$1,171,494 and used \$621,899 of cash in its operations for the year ended December 31, 2018 and had a members' deficit of \$1,933,203 as of December 31, 2018. The Company incurred a net loss of \$737,670 and used \$625,393 of cash in its operations for the year ended Decembers' deficit of \$1,797,965 as of December 31, 2017. As of February 28, 2019, the Company had a cash balance of \$207,996.



#### 2. Summary of Significant Accounting Policies - (continued)

In the near term, the Company expects its net losses and cash used in operating activities will increase as compared to prior periods. Additionally, continued investments will be required to support planned activities in research and development conducting pre-clinical and clinical trials of new drug candidates. The Company does not expect to recognize any revenue, within the next twelve months. Consequently it will need to raise additional capital through equity or debt financing, to finance operations. There are no assurances that sufficient capital can be secured.

The Company will seek to raise funding through private placements, public offerings or debt financing, which may result in high interest expense and would increase the liabilities and cash obligations of the Company. Additionally, any financing, if available, may be on unfavorable terms, and the Company may be forced to relinquish rights to its proprietary technology or marketing rights and could be in default on its obligations in connection with its licensed intellectual property, which could negatively impact future revenue or profitability, and could impair the Company's ability to generate positive cash flow to support on-going operations. If adequate funds are not obtained, the Company may be required to reduce, curtail, or discontinue operations. There is no assurance that the Company's cash flow will be adequate to satisfy its existing operating expenses and capital requirements. In addition, if the Company issues equity or convertible debt securities to raise additional funds, its existing members may experience substantial dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of the Company's existing members.

These factors raise substantial doubt as to the Company's ability to continue as a going concern within one year from the date these consolidated financial statements are issued. The ability of the Company to continue as a going concern is dependent upon the Company's successful efforts to raise additional capital or other financing. These consolidated financial statements do not include any adjustments for this uncertainty.

# **Recent Accounting Principles**

In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820): Disclosure Framework — Changes to the Disclosure Requirements for Fair Value Measurement". The amendments in this update improve the effectiveness of disclosures in the notes to the financial statements by facilitating clear communication of the information required by GAAP that is most important to users of each entity's financial statements. The amendments in this Update apply to all entities that are required, under existing GAAP, to make disclosures about recurring or nonrecurring fair value measurements. The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The Company does not expect that this guidance will have a material impact on its consolidated financial statements.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" and ASU

No. 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) — Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition



#### 2. Summary of Significant Accounting Policies - (continued)

method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company expects to adopt ASU 2016-02 effective January 1, 2019. The Company is currently evaluating the adoption of this guidance and does not expect that this guidance will have a material impact on its consolidated financial statements.

In November 2015, the FASB issued Accounting Standards Update 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes" ("ASU 2015-07"), an update to accounting guidance to simplify the presentation of deferred income taxes. The guidance requires an entity to classify all deferred tax liabilities and assets, along with any valuation allowance, as noncurrent in the balance sheet. The guidance is effective for public companies with annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. Early application is permitted. The Company has elected to early adopt ASU 2015-17 during the year ended December 31, 2016 with retrospective application. The adoption of ASU 2015-17 did not have a material impact on the Company's consolidated financial statements.

#### 3. Related Party Transactions

The Company rents its offices on a month to month basis from TOG, its former parent. The monthly rental rate is \$1,000. Total rent expense for the years ended December 31, 2018 and 2017 amounted to \$12,000, for each of the years.

Due to Affiliate totaled \$1,599,142 and \$2,154,310 at December 31, 2018 and 2017, respectively owed to TOG, the Company's former parent. These unsecured loans are due on demand with no interest. In September 2018 the Company agreed to permit TOG to convert its then aggregate \$1,036,256 of these obligations into up to six (6%) of the fully diluted equity of the Company and in December 2018 TOG exercised this conversion right in full.

Pursuant to a 2015 agreement ("MOU"), a principal equityholder of the Company's parent (until July 13, 2018) and Tikun Olam Ltd., an Israeli corporation ("TOL"), an unrelated third party which pursuant to such agreement became a principal equityholder of the parent, (i) TOPUSA and TOL entered into a license agreement dated as of April 13, 2017, as amended (the "US Pharma License") relating to the Company's U.S. pharmaceutical business (the "U.S. Pharmaceutical Business"); and (ii) TOIP and TOL entered into a license agreement dated as of April 13, 2017, as amended (the "WW Pharma License", and together with the US Pharma License, the "Pharma Licenses") relating to the Company's non-U.S. pharmaceutical business (the "Worldwide Pharmaceutical Business"; and together with the U.S. Pharmaceutical Business, the "Pharmaceutical Business"). Pursuant to the Pharma Licenses, TOL granted an exclusive worldwide (other than the State of New York), perpetual, nonrevocable, and sublicensable license to use TOL's intellectual property, whenever developed, in connection with the Company's Pharmaceutical Business. TOPUSA is permitted to use such intellectual property solely in the United States (except the State of New York) and TOIP is permitted to use such intellectual property anywhere in the world excluding the United States. Pursuant to the MOU, TOG and the Company paid or caused to be paid to TOL an aggregate of \$500,000 on behalf of TOPUSA and TOIP. No royalties or other payments are required under the Pharma Licenses except a two percent (2%) royalty payable to TOL with respect to TOIP's sale of overthe-counter pharmaceutical products outside the U.S. which reasonably compete with a non-pharmaceutical medical cannabis product with substantially similar composition of active components sold by TOL or any licensee of TOL (other than TOIP) conducting business in the applicable jurisdiction pursuant to an effective legal license, permit or similar authority. The Company capitalized the costs associated with the Pharma Licenses, including certain costs of acquisition.

In connection with the Company's ownership interest in and sublicense to Tikkun Pharma, Inc. a Delaware corporation ("Tikkun Pharma"), in 2018 and 2017 the Company incurred \$99,558 and \$17,000, respectively of expenses for the account of Tikkun Pharma, for which it is entitled to be reimbursed. The



#### 3. Related Party Transactions - (continued)

amount outstanding as of December 31, 2018 and 2017 was \$116,558 and \$17,000, respectively, and is recorded in other receivables-related party. (See note 8)

# 4. Intangible Assets

The Company purchased the Pharma Licenses in 2015 for \$505,000 including cost of acquisition and began utilizing them in 2016. At December 31, 2018 and 2017, the Company had net capitalized costs of licenses of \$429,250 and \$454,500, respectively. The Company amortizes its licenses over their useful lives of 20 years. The Company had accumulated amortization of \$75,750 and \$50,500. at December 31, 2018 and 2017, respectively. The Company recognized \$25,250 of amortization expense related to the licenses for each of the years ended December 31, 2018 and 2017. See Note 3, Related Party Transactions.

The weighted average amortization period is 17 years and future amortization expense is as follows:

2019	\$ 25,250
2020	25,250
2021	25,250
2022	25,250
2023	25,250
Thereafter	303,000
	\$429,250

# 5. Convertible Promissory Notes

In November 2018, the Company issued \$500,000 principal amount of convertible promissory notes to four accredited investors. These Notes bear interest at a rate of 5% per annum, are payable upon maturity at March 31, 2019, and convert automatically upon consummation of the Merger (see Note 8) at a conversion price equal to the lesser of (a) 80% of the per share price in the Private Placement, or (b) \$2.30 per share, at which time the contingent beneficial feature will be recognized.

# 6. Accrued Expenses

The following table sets forth the components of accrued expenses at December 31, 2018 and 2017, respectively.

	Decem	December 31,	
	2018	2017	
Clinical trials	\$350,085	\$50,000	
Professional Fees	94,450		
Interest	4,356		
	\$448,891	\$50,000	

# 7. Commitments

The Company entered into an employment agreement dated March 9, 2016 with Sidney Taubenfeld to serve as an executive vice president of the Company for an annual salary of \$168,000. The Company has issued warrants to Mr. Taubenfeld to purchase 39,505 Class A Units, of which 28,218 are vested as of December 31, 2018, at an exercise price of \$12.40 per Class A Unit, which after the Merger will be exercisable for 735,036 shares of common stock, of which 525,026 are vested as of December 31, 2018, at an exercise price of \$.66 per share.

#### 7. Commitments – (continued)

The Company has issued a warrant to Bernard Sucher, a manager of TOP, for services to TOG which is exercisable for an aggregate of 11,187 Class A Units, half of which are exercisable at exercise prices of \$15.11 and \$45.32 per Class A Unit, which after the Merger will be exercisable for 208,150 shares of common stock, half of which are exercisable at exercise prices of \$.81 and \$2.43 per share. The value of this warrant was not material.

At December 31, 2018, the Company had only the two aforementioned warrants outstanding.

The Company has entered into an offer letter agreement dated October 19, 2018 with Seth Yakatan to serve as its chief executive officer for an annual salary of \$150,000. Mr. Yakatan is also eligible to receive options for three percent (3%) of AquaMed's outstanding stock after giving effect to the Merger and the Private Placement, (see Note 8).

The Company has entered into a consulting agreement dated as of November 1, 2018 with Broom Street Associates to provide the services of Dr. Mitchell Glass as the Company's chief medical officer, at an annual rate of \$120,000, payable half in cash and half in equity.

Through December 31, 2018, the Company entered into five agreements to conduct clinical trials in Israel, pursuant to which it is obligated to pay an aggregate of approximately \$610,000, of which approximately \$564,000 was incurred and approximately \$145,000 was paid as of December 31, 2018, respectively, and approximately \$465,000 remained owing as of December 31, 2018.

As of January 2018, TOPUSA entered into an exclusive sublicense agreement (the "TP USA Sublicense Agreement") with Tikkun Pharma, Inc., a Delaware corporation ("Tikkun Pharma"), and TOIP entered into an exclusive sublicense agreement (the "TP WW Sublicense Agreement"; and together with the TP USA Sublicense Agreement, the "TP Sublicense Agreements") with Tikkun Pharma, pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the TP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and licenses of their own respective intellectual property, in their respective territories, in connection with the production, research, development, promotion, marketing, sale, distribution and commercialization of pharmaceutical products derived from such intellectual property relating to the prevention, management and treatment of autoimmune diseases, disorders or symptoms related thereto, other than (1) Crohn's Disease, coeliac diseases, any type of colitis (including without limitation microscopic and ulcerative colitis), any and all digestive and irritable bowel disorders, together with any diseases, disorders or symptoms related thereto, and (2) all diseases and disorders, and symptoms thereof, using glatiramer acetate (also known as Copaxone), whether alone or in a combination with any product, including not limited to, CBD. The Company received a 50% ownership interest in Tikkun Pharma, which does not constitute a controlling economic interest, Tikkun Pharma has failed to fulfill certain of its obligations to the Company, with respect to which the Company has not exercised any remedial action.

As of January 2018, TOPUSA entered into an exclusive sublicense agreement (the "JP USA Sublicense Agreement") with Jay Pharma, Inc., a Canadian corporation ("Jay Pharma"), and TOIP entered into an exclusive sublicense agreement with Jay Pharma (the "JP WW Sublicense Agreement"; and together with the JP USA Sublicense Agreement, the "JP Sublicense Agreements"), pursuant to which TOPUSA and TOIP each have granted a perpetual, non-revocable (subject to the terms of the JP Sublicense Agreements), fully paid, royalty-free, exclusive sublicense of TOL's intellectual property and licenses of their own respective intellectual property, in their respective territories, in connection with the production, research, development, promotion, marketing, sale, distribution and commercialization of pharmaceutical products derived from such intellectual property relating to the prevention, management and treatment of cancer and diseases, disorders or symptoms related thereto. TOP initially received a 50% ownership interest in Jay Pharma, which as of December 31, 2018 represented an approximately 40% ownership interest, which does not constitute a controlling economic interest.

Both Tikkun Pharma and Jay Pharma are early stage entities with minimal assets exclusive of these Sublicense Agreements, therefore, the Company has assigned a minimal value to these agreements.



#### 8. Proposed Merger

On November 27, 2018, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with AquaMed Technologies, Inc. ("AquaMed"), a wholly-owned subsidiary of Alliqua BioMedical, Inc. ("Alliqua" or the "Parent") and AQ TOP, LLC, a Delaware limited liability company and a wholly-owned subsidiary of AquaMed ("Merger Sub"), pursuant to which, among other things, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into the Company, with the Company becoming a wholly-owned subsidiary of AquaMed and the surviving company of the merger (the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free contribution under the provisions of Section 351(a) of the Internal Revenue Code of 1986, as amended.

The Merger will occur after the consummation by Alliqua of the following steps:

- (1) Pursuant to an Asset Contribution and Separation Agreement to be entered into by and between Alliqua and AquaMed (the "Separation Agreement") prior to consummation of the Merger, Alliqua will transfer certain assets and liabilities utilized primarily in connection with its custom hydrogels contract manufacturing business to AquaMed (the "Separation"),
- (2) AquaMed will issue a to be determined number of shares of common stock to Alliqua in consideration of the contribution of assets pursuant to the Separation Agreement (the "Distribution Consideration"),
- (3) Alliqua will distribute to its stockholders all of the issued and outstanding shares of common stock, par value \$0.001 per share, of AquaMed by way of a pro rata dividend (the "Distribution"), and
- (4) Alliqua will consummate its previously announced reverse merger transaction with Adynxx, Inc. ("Adynxx"), pursuant to that certain Agreement and Plan of Merger and Reorganization, dated as of October 11, 2018, by and among Alliqua, Embark Merger Sub, Inc. and Adynxx.
- (5) Effective post-Merger and share distribution, the merged entity will issue 4.99% of its outstanding shares to a third party for consulting services related to the business combination.

At the effective time of the Merger, all of the outstanding membership units of the Company will be converted into the right to receive, in the aggregate, merger consideration consisting of shares of AquaMed common stock. Immediately after the effective time of the Merger and consummation of the Private Placement (as defined below), before giving effect to any fees payable in equity to financial advisors or other intermediaries, the current members of TOP and the third-party investors that participate in the Private Placement are expected to hold approximately 90% of the total number of shares of AquaMed common stock outstanding (on a fully diluted basis). The Merger will be accounted for as a reverse business combination with the Company being the accounting acquirer.

The consummation of the Merger is subject to certain customary and other conditions, including (i) the completion of the Separation and the Distribution, (ii) the effectiveness of the registration statement on Form S-1 to be filed with the SEC with respect to, and the approval for listing on the NASDAQ Capital Market of, the shares of AquaMed common stock to be issued in the Distribution and the Merger, (iii) receipt of binding commitments from third-party investors to consummate a private placement of AquaMed's common stock in a minimum aggregate amount of \$10 million immediately prior to the effective time of the Merger (the "Private Placement") (iv) the accuracy of the parties' representations and warranties and the performance of their respective covenants contained in the Merger Agreement, and (v) receipt of an independent third-party valuation of the AquaMed common stock to be issued in the Distribution.

# 9. Subsequent Events

Management has evaluated subsequent events through March 11, 2019 the date when financial statements were available to be issued.

Prior to effecting the Merger, TOP's ownership interest in each of Tikkun Pharma and Jay Pharma will be distributed pro rata to its members.

### PART II

# INFORMATION NOT REQUIRED IN PROSPECTUS

## Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than the underwriting discounts, payable by the registrant in connection with the registration of its common stock. All amounts are estimates except the Securities and Exchange Commission registration fee.

Item	Amount to Be Paid
Securities and Exchange Commission registration fee	\$ 65.33
Blue Sky fees and expenses	
Legal fees and expenses	600,000
Accounting fees and expenses	30,000
Printing expenses	20,000
Miscellaneous*	76,800
Total	\$726,865

\* Expenses include Nasdaq listing fee and transfer agent and registrar fees

#### Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement in connection with any threatened, pending or completed actions, suit or proceeding, whether civil, criminal, administrative or investigative, in which such person is made a party by reason of the fact that the person is or was a director, officer, employee or agent of the corporation (other than an action by or in the right of the corporation — a "derivative action"), if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe such person's conduct was unlawful. A similar standard is applicable in the case of derivative actions, except that indemnification extends only to expenses (including attorneys' fees) incurred in connection with the defense or settlement of such action, and the statute requires court approval before there can be any indemnification where the person seeking indemnification has been found liable to the corporation. The statute provides that it is not exclusive of other indemnification that may be granted by a corporation's bylaws, disinterested director vote, stockholder vote, agreement or otherwise.

Our Amended and Restated Certificate of Incorporation will limit our directors' liability to the fullest extent permitted under Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability:

- for any breach of a director's duty of loyalty to us and our stockholders;
- for any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- under Section 174 of the Delaware General Corporation Law (unlawful payment of dividends or redemption of shares); or
- for any breach of a director's duty of loyalty to us or our stockholders.

If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of our directors shall be eliminated or limited to the fullest extent permitted by the Delaware General Corporation Law, as so amended.

# II-1

Delaware law provides, and our Amended and Restated Bylaws will provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to payment or reimbursement of reasonable expenses in advance of the final disposition of the proceeding.

We intend to maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for certain actions taken in their capacities as directors and officers. We believe that these provisions in our Amended and Restated Certificate of Incorporation and Bylaws and any such insurance policy are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

#### Item 15. Recent Sales of Unregistered Securities

None.

# Item 16. Exhibits and Financial Statement Schedules

# (a) Exhibits

See the Exhibit Index immediately preceding the signature page to this registration statement, which is incorporated by reference herein.

### (b) Financial Statement Schedules:

No financial statement schedules are provided because the information called for is not required or is shown either in the financial statements or the notes thereto.

# Item 17. Undertakings.

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933; (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the effective registration statement; and (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.
- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such posteffective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act to any purchaser, if such registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on



Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of such undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant or its movided by or on behalf of the undersigned registrant or its movided by or on behalf of the undersigned registrant; and (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the 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.

Exhibit Number	Exhibit Description
<u>2.1</u>	Agreement and Plan of Merger, dated November 27, 2018, by and among AquaMed Technologies, Inc., TO Pharmaceuticals, LLC and AQ TOP, LLC (incorporated by reference to Exhibit 2.1 to Alliqua BioMedical Inc.'s Form 8-K, filed with the SEC on November 28, 2018) <sup>∞</sup> *
<u>2.2</u>	Amendment No. 1, dated January 8, 2019 to Agreement and Plan of Mergerss
<u>2.3</u>	Form of Asset Contribution and Separation Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc.∞*
<u>2.4</u>	Form of Tax Matters Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc.∞*
<u>2.5</u>	Form of Bill of Sale and Assignment and Assumption Agreement between Alliqua BioMedical, Inc. and AquaMed Technologies, Inc.
<u>3.1</u>	Certificate of Incorporation of AquaMed Technologies, Inc. (as currently in effect) 2
<u>3.2</u>	Certificate of Amendment to Certificate of Incorporation of AquaMed Technologies, Inc.oo
<u>3.3</u>	Form of Amended and Restated Certificate of Incorporation of AquaMed Technologies, Inc.
<u>3.4</u>	Bylaws of AquaMed Technologies, Inc. (as currently in effect)∞
<u>3.5</u>	Form of Amended and Restated Bylaws of AquaMed Technologies, Inc.
<u>5.1</u>	Opinion of Haynes and Boone, LLP
<u>10.1</u>	Assignment and Amended and Restated Lease, dated as of January 25, 2002, by and between 2150 Cabot LLC, Embryo Development Corporation and Hydrogel Design Systems, Inc.∞
<u>10.2</u>	Amendment to Lease, dated as of February 23, 2007, by and between 2150 Cabot LLC and Hydrogel Design Systems, $Inc.\infty$
<u>10.3</u>	Third Amendment to Lease, dated as of February 27, 2009, by and between Exeter 2150 Cabot, L.P and Hydrogel Design Systems, Inc.∞
<u>10.4</u>	Assignment and Assumption of Lease Agreement, dated as of February 27, 2009, by and among Exeter 2150 Cabot, L.P., Hydrogel Design Systems, Inc. and Aquamed Technologies, Inc
<u>10.5</u>	Fourth Amendment to Lease, dated as of July 24, 2013, by and between Exeter 2150 Cabot, L.P and Aquamed Technologies, Inc.∞
<u>10.6</u>	License Agreement, dated as of April 13, 2017, by and between Tikun Olam Ltd. and TO Pharmaceuticals USA LLC <sup>\$\infty\$</sup>
<u>10.7</u>	Amendment dated December 9, 2018, to License Agreement, dated as of April 13, 2017, by and between Tikun Olam Ltd. and TO Pharmaceuticals USA $LLC\infty$
<u>10.8</u>	License Agreement, dated as of April 13, 2017, by and between Tikun Olam Ltd. and Tikun Olam IP Ltd. $\infty$
<u>10.9</u>	<u>Amendment dated December 9, 2018, to License Agreement, dated as of April 13, 2017, by and between Tikun Olam Ltd. and Tikun Olam IP Ltd.<math>\infty</math></u>
<u>10.10</u>	<u>Amended and Restated Sublicense Agreement, dated as of January 12, 2018, by and between TO</u> <u>Pharmaceuticals USA LLC and Tikkun Pharma, Inc.</u> $\infty$
<u>10.11</u>	Amended and Restated Sublicense Agreement, dated as of January 12, 2018, by and between Tikun Olam IP Ltd. and Tikkun Pharma, Inc.∞
<u>10.12</u>	Sublicense Agreement, dated as of January 12, 2018, by and between TO Pharmaceuticals USA LLC and Jay Pharma, $Inc.\infty$

# EXHIBIT INDEX

Exhibit Number	Exhibit Description
<u>10.13</u>	Sublicense Agreement, dated as of January 12, 2018, by and between Tikun Olam IP Ltd. and Jay Pharma, Inc. $\infty$
<u>10.14</u>	Master Intercompany Services Agreement, dated as of January 1, 2018, by and among T.O. Global LLC, TO Holding Group LLC, Tikun Olam LLC, TO Pharmaceuticals LLC and Israel Liaison Holding Group Ltd. <sup>®</sup>
<u>10.15</u>	Letter Agreement, dated September 26, 2018, by and between T.O. Global LLC and TO Pharmaceuticals $LLC\infty$
<u>10.16</u>	Employment Agreement, dated as of March 9, 2016, by and between TO Pharmaceuticals LLC and Sidney Taubenfeld <sup>\$\Delty\$</sup>
<u>10.17</u>	Management Consulting Agreement dated October 19, 2018 between TO Pharmaceutical LLC and Seth Yakatan®
<u>10.18</u>	Consulting Agreement dated as of November 1, 2018 between TO Pharmaceuticals LLC and Broom Street Associates, LLC <sup>∞</sup>
<u>10.19</u>	Warrant, dated March 9, 2016 issued to Sidney Taubenfeldoo
<u>10.20</u>	Warrant, dated November 1, 2018, issued to Bernard Sucher, exercisable at \$15.11 per Class A Unitso
<u>10.21</u>	Warrant, dated November 1, 2018, issued to Bernard Sucher, exercisable at \$45.32 per Class A Unit <sup>∞</sup>
<u>10.22</u>	Form of 2019 Incentive Plan∞
<u>10.23</u>	Form of Incentive Option Agreement under 2019 Incentive Plan∞
<u>10.24</u>	Form of Nonqualified Stock Option Agreement under 2019 Incentive Plans
<u>10.25</u>	Form of Restricted Stock Award Agreement under 2019 Incentive Plan∞
<u>21.1</u>	List of Subsidiaries of AquaMed Technologies, Inc.∞
23.1	Consent of Marcum, LLP with respect to the financial statements of AquaMed Technologies, Inc.
23.2	Consent of Marcum, LLP with respect to the financial statements of TO Pharmaceuticals, LLC
23.3	Consent of Haynes and Boone, LLP (contained in Exhibit 5.1)
<u>24.1</u>	Powers of Attorney (included on the signature page of this Registration Statement)
<u>99.1</u>	Consent of Barry Farkas pursuant to Rule 43800
<u>99.2</u>	Consent of Bernard Sucher pursuant to Rule 438∞
<u>99.3</u>	Consent of George Kegler pursuant to Rule 438∞
<u>99.4</u>	Consent of Tsachi Cohen pursuant to Rule 438∞
<u>99.5</u>	Consent of David Johnson pursuant to Rule 438 <sup>∞</sup>

 $\infty$  Previously filed.



<sup>\*</sup> Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The registrant hereby undertakes to furnish copies of any of the omitted schedules and exhibits upon request by the U.S. Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 2 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, hereunto duly authorized, in the City of Langhorne, State of Pennsylvania, on March 25, 2019.

## AQUAMED TECHNOLOGIES, INC.

By: /s/ DAVID I. JOHNSON

Name: David I. Johnson Title: *Chief Executive Officer* 

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date	
/s/ DAVID I. JOHNSON David I. Johnson	Director and Chief Executive Officer (Principal Executive Officer and Principal Financial and Accounting Officer)	March 25, 2019	

II-6

#### AMENDED AND RESTATED

## CERTIFICATE OF INCORPORATION OF

## AQUAMED TECHNOLOGIES, INC.

AquaMed Technologies, Inc., a corporation organized and existing under the laws of the State of Delaware (the 'Corporation'), certifies that:

A. The name of the Corporation is AquaMed Technologies, Inc. The Corporation's original Certificate of Incorporation was filed with the Secretary of State of the State of Delaware on January 13, 2009. The Corporation was originally incorporated under the name AquaMed Technologies, Inc.

B. This Amended and Restated Certificate of Incorporation was duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, and has been duly approved by the written consent of the stockholders of the Corporation in accordance with Section 228 of the General Corporation Law of the State of Delaware.

C. The text of the Certificate of Incorporation is amended and restated to read as forth in EXHIBIT A attached hereto.

IN WITNESS WHEREOF, AquaMed Technologies, Inc. has caused this Amended and Restated Certificate of Incorporation to be signed by \_\_\_\_\_, a duly authorized officer of the Corporation, on \_\_\_\_\_\_, 2019.

Chief Executive Officer

#### EXHIBIT A

## AMENDED AND RESTATED

## CERTIFICATE OF INCORPORATION OF

## AQUAMED TECHNOLOGIES, INC.

#### ARTICLE I

The name of the corporation is AquaMed Technologies, Inc. (hereinafter referred to as the 'Corporation').

## ARTICLE II

The address of the Corporation's registered office in the State of Delaware is 251 Little Falls Drive, in the City of Wilmington, County of New Castle, 19808. The name of the registered agent at such address is Corporation Service Company.

## ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law (the "DGCL").

## ARTICLE IV

A. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 105,000,000, consisting of 100,000,000 shares of Common Stock, \$0.001 par value per share (the "**Common Stock**"), and 5,000,000 shares of Preferred Stock, \$0.001 par value per share (the "**Preferred Stock**").

B. All shares of Common Stock shall be identical and entitle the holders thereof to the same preferences, limitations and relative rights. Each holder of Common Stock shall be entitled to one vote for each share of Common Stock standing in the holder's name on the books of the Corporation on each matter submitted to a vote by the stockholders of the Corporation and shall, except as otherwise specifically noted in this Certificate of Incorporation, as amended from time to time, be entitled to receive the net assets of the Corporation upon the dissolution of the Corporation. For so long as any shares of Common Stock are outstanding, subject the rights, if any, of holders of outstanding shares of Preferred Stock, the holders of shares of Common Stock shall be entitled to receive dividends, if any, when, as and if declared by the Board of Directors or any duly authorized committee of the Board of Directors, out of funds legally available therefor.

C. The Preferred Stock may be issued from time to time in one or more series pursuant to a resolution or resolutions providing for such issue duly adopted by the Board of Directors (authority to do so being hereby expressly vested in the Board of Directors). The Board of Directors is further authorized, subject to any limitations prescribed by law, to fix by resolution or resolutions the designation, powers, preferences, and rights of the shares of each such series and any qualifications, limitations or restrictions thereof. The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any series then outstanding) the number of shares of any series, the number of which was fixed by it, subject to the powers, preferences and rights, and the qualifications, limitations and restrictions thereof stated in this Amended and Restated Certificate of Incorporation or the resolution of the Board of Directors originally fixing the number of shares of such series.

D. The number of authorized shares of Preferred Stock or Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of all of the outstanding shares of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL (or any successor provisions thereto), voting together as a single class, without a separate vote of the holders of the class or classes the number of authorized shares of which are being increased or decreased, unless a vote by any holders of one or more series of Preferred Stock is required by the express terms of any series of Preferred Stock as provided for or fixed pursuant to the provisions of Section C of this Article IV (or any certificate of designation with respect thereto). Except as otherwise required by law or provided in this Section D, holders of Common Stock shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more other such affected series are entitled, either separately or together as a class with the holders of one or more other such asries, to vote thereon pursuant to this Amended and Restated Certificate of Incorporation (including any series of Preferred Stock) and series as a class with the holders of one or more other such asries, to vote thereon pursuant to this Amended and Restated Certificate of Incorporation (including any certificate of Incorporation (including any certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) and the series of Preferred Stock is of one or more other such asries, to v

### ARTICLE V

Subject to the rights of holders of Preferred Stock, the number of directors that constitutes the entire Board of Directors of the Corporation shall be fixed solely by resolution of the majority of the Whole Board. For purposes of this Amended and Restated Certificate of Incorporation, the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies in the previously authorized directorships. At each annual meeting of stockholders, directors of the Corporation shall be elected to hold office until the next annual meeting of stockholders and until their successors have been duly elected and qualified or until their earlier resignation or removal; except that if any such meeting shall not be so held, such election shall take place at a stockholders' meeting called and held in accordance with the DGCL or by written consent in lieu of an annual meeting pursuant to Section 211(b) of the DGCL and Article VIII hereof.

### ARTICLE VI

Except as otherwise provided for or fixed by or pursuant to the provisions of Article IV hereof in relation to the rights of the holders of Preferred Stock to elect directors under specified circumstances or as provided by resolution of the Board of Directors, newly created directorships resulting from any increase in the number of directors, created in accordance with the Bylaws of the Corporation, and any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other cause shall be filled only by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders. If the directors are divided into classes, a person so elected by the Board of Directors to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen until his or her successor shall have been duly elected and qualified, or until such director's earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any increase in the number of director.

### ARTICLE VII

A. The Corporation is to have perpetual existence.

B. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authority expressly conferred upon them by statute or by this Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation.

C. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, alter, amend or repeal the Bylaws of the Corporation. The affirmative vote of at least a majority of the Whole Board shall be required in order for the Board of Directors to adopt, amend, alter or repeal the Corporation's Bylaws. The Corporation's Bylaws may also be adopted, amended, altered or repealed by the stockholders of the Corporation. Notwithstanding the above or any other provision of this Amended and Restated Certificate of Incorporation, the Bylaws of the Corporation may not be amended, altered or repealed except in accordance with Article X of the Bylaws. No Bylaw hereafter legally adopted, amended, altered or repealed shall invalidate any prior act of the directors or officers of the Corporation that would have been valid if such Bylaw had not been adopted, amended, altered or repealed.

D. The election of the directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

E. No stockholder will be permitted to cumulate votes at any election of directors.

### ARTICLE VIII

A. Any action required or permitted to be taken at an annual or special meeting of stockholders may be taken without a meeting if a consent or consents in writing, setting forth the action so taken, shall be signed by holders of record on the record date (established in the manner provided in Section B of this Article VIII) of outstanding shares of the Corporation having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted, but only if such action is taken in accordance with the provisions of this Article VIII, the Bylaws of the Corporation and applicable law; *provided, however*, that in the case of the election or removal of directors by written consent, such consent shall be effective only if signed by the holders of all outstanding shares entitled to vote for the election of directors.

B. In order that the Corporation may determine the stockholders entitled to consent to corporate action in writing without a meeting, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than ten days after the date upon which the resolution fixing the record date is adopted by the Board of Directors. Any stockholder of record seeking to have the stockholders authorize or take corporate action by written consent shall, by written notice to the attention of the Secretary of the Corporation, request the Board of Directors to fix a record date. The Board of Directors shall promptly, but in all events within ten days after the date on which such a request is received, adopt a resolution fixing the record date (unless a record date has previously been fixed by the Board of Directors pursuant to the first sentence of this Section B of Article VIII). If no record date has been fixed by the Board of Directors is required by applicable law, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery to its registered office in the State of Delaware, its principal place of business, or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded. If no record date has been fixed by the Board of Directors is required by applicable law, the record date for determining stockholders entitled to consent to corporate action in writing without a meeting shall be at the close of business on the date on which the Board of Directors adopts the record date for determining stockholders entitled to consent to corporate action in writing without a meeting shall be at the close of business on the date on which the Board of Directors adopts the record date for determining stockholders entitled to consent to corpor

### ARTICLE IX

A. Special meetings of stockholders of the Corporation may be called only by the Chairperson of the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board, and any power of stockholders to call a special meeting of stockholders is specifically denied. Only such business shall be considered at a special meeting of stockholders as shall have been stated in the notice for such meeting.

B. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner and to the extent provided in the Bylaws of the Corporation.

## ARTICLE X

A. To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director. If the DGCL is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

B. The Corporation shall indemnify, to the fullest extent permitted by applicable law, any director or officer of the Corporation who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "**Proceeding**") by reason of the fact that he or she is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding. The Corporation shall be required to indemnify a person in connection with a Proceeding (or part thereof) initiated by such person only if the Proceeding (or part thereof) was authorized by the Board of Directors.

C. The Corporation shall have the power to indemnify, to the extent permitted by applicable law, any employee or agent of the Corporation who was or is a party or is threatened to be made a party to any Proceeding by reason of the fact that he or she is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any such Proceeding.

D. Neither any amendment nor repeal of this Article X, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation inconsistent with this Article X, shall eliminate or reduce the effect of this Article X, in respect of any matter occurring, or any action or proceeding accruing or arising or that, but for this Article X, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

### ARTICLE XI

Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of this Corporation may provide. The books of this Corporation may be kept (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of this Corporation.

## ARTICLE XII

The Corporation reserves the right to amend or repeal any provision contained in this Amended and Restated Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; *provided, however*, that notwithstanding any other provision of this Amended and Restated Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, the Board of Directors acting pursuant to a resolution adopted by a majority of the Whole Board and the affirmative vote of sixty-six and two-thirds percent (66 2/3%) of the voting power of the then outstanding voting securities of the Corporation, voting together as a single class, shall be required for the amendment, repeal or modification of the provisions of, or adoption of any provision inconsistent with, Section C of Article IV, Article VI, Section E of Article VII, Article VII, Article IX or this Article XII of this Amended and Restated Certificate of Incorporation.

## AMENDED AND RESTATED BYLAWS OF

# AQUAMED TECHNOLOGIES, INC.

(as amended and restated on [DATE], 2019, and effective immediately as of the closing of the corporation's merger with TO Pharmaceuticals, LLC)

		Page
	- CORPORATE OFFICES	1
1.1	REGISTERED OFFICE	1
1.2	OTHER OFFICES	1
ARTICLE II -	— MEETINGS OF STOCKHOLDERS	1
2.1	PLACE OF MEETINGS	1
2.2	ANNUAL MEETING	1
2.3	SPECIAL MEETING	1
2.4	ADVANCE NOTICE PROCEDURES	2
2.5	NOTICE OF STOCKHOLDERS' MEETINGS	5
2.6	QUORUM	6
2.7	ADJOURNED MEETING; NOTICE	6
2.8	CONDUCT OF BUSINESS	6
2.9	VOTING	6
2.10	STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING	7
2.11	RECORD DATES	7
2.12	PROXIES	8
2.13	LIST OF STOCKHOLDERS ENTITLED TO VOTE	8
2.14	INSPECTORS OF ELECTION	8
ARTICLE III	— DIRECTORS	9
3.1	POWERS	9
3.2	NUMBER OF DIRECTORS	9
3.3	ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS	9
3.4	RESIGNATION AND VACANCIES	9
3.5	PLACE OF MEETINGS; MEETINGS BY TELEPHONE	10
3.6	REGULAR MEETINGS	10
3.7	SPECIAL MEETINGS; NOTICE	10
3.8	QUORUM; VOTING	11
3.9	BOARD ACTION BY WRITTEN CONSENT WITHOUT A MEETING	11
3.10	FEES AND COMPENSATION OF DIRECTORS	11
3.11	REMOVAL OF DIRECTORS	11
ARTICLE IV	T — COMMITTEES	11
4.1	COMMITTEES OF DIRECTORS	11
4.2	COMMITTEE MINUTES	12
4.3	MEETINGS AND ACTION OF COMMITTEES	12
4.4	SUBCOMMITTEES	12
ARTICLE V	— OFFICERS	12
5.1	OFFICERS	12
5.2	APPOINTMENT OF OFFICERS	12
5.4		15

## TABLE OF CONTENTS (Continued)

		Page
5.3	SUBORDINATE OFFICERS	13
5.4	REMOVAL AND RESIGNATION OF OFFICERS	13
5.5	VACANCIES IN OFFICES	13
5.6	REPRESENTATION OF SHARES OR INTERESTS OF OTHER CORPORATIONS OR ENTITIES	13
5.7	AUTHORITY AND DUTIES OF OFFICERS	13
ARTICLE VI	- STOCK	14
6.1	STOCK CERTIFICATES; PARTLY PAID SHARES	14
6.2	SPECIAL DESIGNATION ON CERTIFICATES	14
6.3	LOST, STOLEN OR DESTROYED CERTIFICATES	14
6.4	DIVIDENDS	15
6.5	TRANSFER OF STOCK	15
6.6	STOCK TRANSFER AGREEMENTS	15
6.7	REGISTERED STOCKHOLDERS	15
ARTICLE VI	— MANNER OF GIVING NOTICE AND WAIVER	15
7.1	NOTICE OF STOCKHOLDERS' MEETINGS	15
7.2	NOTICE BY ELECTRONIC TRANSMISSION	15
7.3	NOTICE TO STOCKHOLDERS SHARING AN ADDRESS	16
7.4	NOTICE TO PERSON WITH WHOM COMMUNICATION IS UNLAWFUL	16
7.5	WAIVER OF NOTICE	17
ARTICLE VI	I — INDEMNIFICATION	17
8.1	INDEMNIFICATION OF DIRECTORS AND OFFICERS IN THIRD PARTY PROCEEDINGS	17
8.2	INDEMNIFICATION OF DIRECTORS AND OFFICERS IN ACTIONS BY OR IN THE RIGHT OF THE CORPORATION	17
8.3	SUCCESSFUL DEFENSE	18
8.4	INDEMNIFICATION OF OTHERS; ADVANCE PAYMENT TO OTHERS	18
8.5	ADVANCE PAYMENT OF EXPENSES	18
8.6	LIMITATION ON INDEMNIFICATION	18
8.7	DETERMINATION; CLAIM	19
8.8	NON-EXCLUSIVITY OF RIGHTS	19
8.9	INSURANCE	19
8.10	SURVIVAL	19
8.11	EFFECT OF REPEAL OR MODIFICATION	19
8.12	CERTAIN DEFINITIONS	19
ARTICLE IX	— GENERAL MATTERS	20
9.1	EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS	20
9.2	FISCAL YEAR	20
9.3	SEAL	20

ii

# 9.4 CONSTRUCTION; DEFINITIONS

ARTICLE X — AMENDMENTS

**Page** 20

20

#### AMENDED AND RESTATED BYLAWS OF AQUAMED TECHNOLOGIES, INC.

## ARTICLE I - CORPORATE OFFICES

1.1 Registered Office. The registered office of AquaMed Technologies, Inc. shall be fixed in the corporation's certificate of incorporation. References in these bylaws to the certificate of incorporation shall mean the certificate of incorporation, as amended from time to time, including the terms of any certificates of designation of any series of Preferred Stock.

1.2 Other Offices. The corporation may at any time establish other offices at any place or places.

#### ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 *Places of Meetings*. Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors. The board of directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a)(2) of the General Corporation Law of the State of Delaware (the "<u>DGCL</u>"). In the absence of any such designation or determination, stockholders' meetings shall be held at the corporation's principal executive office.

2.2 Annual Meeting. The annual meeting of stockholders shall be held on such date, at such time, and at such place (if any) within or without the State of Delaware as shall be designated from time to time by the board of directors and stated in the corporation's notice of the meeting. At the annual meeting, directors shall be elected and any other proper business, brought in accordance with Section 2.4 of these bylaws, may be transacted.

### 2.3 Special Meeting

(i) A special meeting of the stockholders, other than those required by statute, may be called at any time only by the affirmative vote of a majority of the Whole Board. A special meeting of the stockholders may not be called by any other person or persons. The board of directors, by the affirmative vote of a majority of the Whole Board, may cancel, postpone or reschedule any previously scheduled special meeting at any time, before or after the notice for such meeting has been sent to the stockholders. For purposes of these bylaws, the term "Whole Board" shall mean the total number of authorized directors whether or not there exist any vacancies in previously authorized directorships.

(ii) The notice of a special meeting shall include the purpose for which the meeting is called. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting by or at the direction of the board of directors, the chairperson of the board of directors, the chief executive officer or the president. Nothing contained in this Section 2.3(ii) shall be construed as limiting, fixing or affecting the time when a meeting of stockholders called by action of the board of directors may be held.

#### 2.4 Advance Notice Procedures.

(i) Advance Notice of Stockholder Business. At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be brought: (A) pursuant to the corporation's proxy materials with respect to such meeting, (B) by or at the direction of the board of directors, or (C) by a stockholder of the corporation who (1) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(i) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this Section 2.4(i). In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these bylaws and applicable law. Except for proposals properly made in accordance with Rule 14a-8 under the Securities and Exchange Act of 1934, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations, the "<u>Exchange Act</u>"), clause (C) above shall be the exclusive means for a stockholder to bring business before an annual meeting of stockholders.

(a) To comply with clause (C) of Section 2.4(i) above, a stockholder's notice must set forth all information required under this Section 2.4(i) and must be timely received by the secretary of the corporation. To be timely, a stockholder's notice must be received by the secretary at the principal executive offices of the corporation not later than the 45th day nor earlier than the 75th day before the one-year anniversary of the date on which the corporation first mailed its proxy materials or a notice of availability of proxy materials (whichever is earlier) for the preceding year's annual meeting; *provided*, *however*, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting is advanced by more than 30 days prior to or delayed by more than 60 days after the one-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the secretary not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting, or (ii) the tenth day following the day on which Public Announcement (as defined below) of the date of such annual meeting is first made. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described in this Section 2.4(i)(a). "Public Announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable national news service or in a document publicly filed by the corporation with the Section 13, 14 or 15(d) of the Exchange Act.

To be in proper written form, a stockholder's notice to the secretary must set forth as to each matter of business the stockholder intends to (b) bring before the annual meeting: (1) a brief description of the business intended to be brought before the annual meeting, the text of the proposed business (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the annual meeting, (2) the name and address, as they appear on the corporation's books, of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (3) the class and number of shares of the corporation that are held of record or are beneficially owned by the stockholder or any Stockholder Associated Person and any derivative positions held or beneficially held by the stockholder or any Stockholder Associated Person as of the date of delivery of such notice, (4) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit from share price changes for, or to increase or decrease the voting power of, such stockholder or any Stockholder Associated Person with respect to any securities of the corporation, (5) any material interest of the stockholder or a Stockholder Associated Person in such business, and (6) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the voting power of the corporation's voting shares required under applicable law to carry the proposal (such information provided and statements made as required by clauses (1) through (6), a "Business Solicitation Statement"). In addition, to be in proper written form, a stockholder's notice to the secretary must be supplemented not later than ten days following the record date for notice of the meeting to disclose the information contained in clauses (3) and (4) above as of the record date for notice of the meeting. For purposes of this Section 2.4, a "Stockholder Associated Person" of any stockholder shall mean (i) any person controlling, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the corporation owned of record or beneficially by such stockholder and on whose behalf the proposal or nomination, as the case may be, is being made, or (iii) any person controlling, controlled by or under common control with such person referred to in the preceding clauses (i) and (ii).

(c) Without exception, no business shall be conducted at any annual meeting except in accordance with the provisions set forth in this Section 2.4(i) and, if applicable, Section 2.4(ii). In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that business was not properly brought before the annual meeting and in accordance with the provisions of this Section 2.4(i), and, if the chairperson should so determine, he or she shall so declare at the annual meeting that any such business not properly brought before the annual meeting shall not be conducted.

(ii) Advance Notice of Director Nominations at Annual Meetings. Notwithstanding anything in these bylaws to the contrary, only persons who are nominated in accordance with the procedures set forth in this Section 2.4(ii) shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election or re-election to the board of directors of the corporation shall be made at an annual meeting of stockholders only (A) by or at the direction of the board of directors or (B) by a stockholder of the corporation who (1) was a stockholder of record at the time of the giving of the notice required by this Section 2.4(ii) and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has complied with the notice procedures set forth in this Section 2.4(ii). In addition to any other applicable requirements, for a nomination to be made by a stockholder, the stockholder must have given timely notice thereof in proper written form to the secretary of the corporation.

(a) To comply with clause (B) of Section 2.4(ii) above, a nomination to be made by a stockholder must set forth all information required under this Section 2.4(ii) and must be received by the secretary of the corporation at the principal executive offices of the corporation at the time set forth in, and in accordance with, the final three sentences of Section 2.4(i)(a) above; *provided additionally, however*, that in the event the number of directors to be elected to the board of directors is increased and there is no Public Announcement naming all of the nominees for director or specifying the size of the increased board made by the corporation at least ten (10) days before the last day a stockholder may deliver notice of nomination pursuant to the foregoing provisions, a stockholder's notice required by this Section 2.4(ii) shall also be considered by such increase, if it shall be received by the secretary at the principal executive offices of the corporation not later than the close of business on the tenth day following the date on which such Public Announcement is first made by the corporation.

#### (b) To be in proper written form, such stockholder's notice to the secretary must set forth:

(1) as to each person (a "<u>nominee</u>") whom the stockholder proposes to nominate for election or re-election as a director: (A) the name, age, business address and residence address of the nominee, (B) the principal occupation or employment of the nominee, (C) the class and number of shares of the corporation that are held of record or are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (D) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of the nominee with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee, (E) a description of all arrangements or understandings between or among the stockholder and each nominee and any other person or persons (naming such person or persons) pursuant to which the nomineitons are to be made by the stockholder or concerning the nominee's potential service on the board of directors, (F) a written statement executed by the nominee acknowledging that as a director of the corporation, the nominee will owe fiduciary duties under Delaware law with respect to the corporation and its stockholders, and (G) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election or re-election of the nominee as a director, or that is otherwise required, in each case pursuant to Regulation 14A under the Exchange Act (including without limitation the nominee's written consent to being named in the proxy statement, if any, as a nominee and to serving as a director if elected or re-elected, as the case may be); and

(2) as to such stockholder giving notice, (A) the information required to be provided pursuant to clauses (2) through (5) of Section 2.4(i) (b) above, and the supplement referenced in the second sentence of Section 2.4(i)(b) above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), and (B) a statement whether either such stockholder or Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of voting power of the corporation's voting shares reasonably believed by such stockholder or Stockholder Associated Person to be necessary to elect or re-elect such nominee(s) (such information provided and statements made as required by clauses (A) and (B) above, a "Nominee Solicitation Statement").

(c) At the request of the board of directors, any person nominated by a stockholder for election or re-election as a director must furnish to the secretary of the corporation (1) that information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given, (2) such other information as may reasonably be required by the corporation to determine the eligibility of such proposed nominee to serve as an independent director or audit committee financial expert of the corporation under applicable law, securities exchange rule or regulation, or any publicly disclosed corporate governance guideline or committee charter of the corporation and (3) such other information that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee; in the absence of the furnishing of any such information of the kind specified in this Section 2.4(ii)(c) if requested, such stockholder's nomination shall not be considered in proper form pursuant to this Section 2.4(ii).

(d) Without exception, no person shall be eligible for election or re-election as a director of the corporation at an annual meeting of stockholders unless nominated in accordance with the provisions set forth in this Section 2.4(ii). In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or if the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The chairperson of the annual meeting shall, if the facts warrant, determine and declare at the annual meeting that a nomination was not made in accordance with the provisions prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the annual meeting, and the defective nomination shall be disregarded.

#### (iii) Advance Notice of Director Nominations for Special Meetings.

(a) If the board of directors has authorized in the specific case that stockholders may fill a vacancy or newly created directorship at a special meeting of stockholders, and a special meeting has been properly called for such purpose, nominations of persons for election or appointment to the board of directors at such special meeting shall be made only (1) by or at the direction of the board of directors or (2) by any stockholder of the corporation who (A) is a stockholder of record at the time of the giving of the notice required by this Section 2.4(iii) and on the record date for the determination of stockholders entitled to vote at the special meeting and (B) delivers a timely written notice of the nomination to the secretary of the corporation that includes the information set forth in Sections 2.4(ii)(b) and (ii)(c) above. To be timely, such notice must be received by the secretary at the principal executive offices of the corporation not later than the close of business on the later of the 90th day prior to such special meeting or the tenth day following the day on which Public Announcement is first made of the date of the special meeting and of the nominees proposed by the board of directors or (i) by a stockholder in accordance with the notice procedures set forth in this Section 2.4(iii). In addition, a nominee shall not be eligible for election or appointment if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee contains an untrue statement of a material fact or omity to state a material fact necessary to make the statements therein not misleading. Any person nominated in accordance with this Section 2.4(iii) is subject to, and must comply with, the provisions of Section 2.4(iii) c.

(b) The chairperson of such special meeting shall, if the facts warrant, determine and declare at the meeting that a nomination or business was not made in accordance with the procedures prescribed by these bylaws, and if the chairperson should so determine, he or she shall so declare at the meeting, and the defective nomination or business shall be disregarded.

(iv) Other Requirements and Rights. In addition to the foregoing provisions of this Section 2.4, a stockholder must also comply with all applicable requirements of state law and of the Exchange Act with respect to the matters set forth in this Section 2.4. Nothing in this Section 2.4 shall be deemed to affect any rights of:

(a) a stockholder to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under

the Exchange Act; or

(b) the corporation to omit a proposal from the corporation's proxy statement pursuant to Rule 14a-8 (or any successor provision) under the

Exchange Act.

2.5 Notice of Stockholders' Meetings. Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting, if such date is different from the record date for determining stockholders entitled to notice of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. Except as otherwise provided in the DGCL, the certificate of incorporation or these bylaws, the written notice of any meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting.

2.6 Quorum. The holders of a majority of the voting power of the stock issued, outstanding and entitled to vote, present in person or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders, unless otherwise required by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange. Where a separate vote by a class or series or classes or series is required, a majority of the voting power of the then-issued and outstanding shares of such class or series or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter, except as otherwise required by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange.

If a quorum is not present or represented at any meeting of the stockholders, then either (i) the chairperson of the meeting, or (ii) the stockholders entitled to vote at the meeting, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. The chairperson of the meeting shall have the authority to adjourn a meeting of the stockholders in all other events. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.7 Adjourned Meeting; Notice. When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the board of directors shall fix a new record date for notice of such adjourned meeting in accordance with Section 213(a) of the DGCL and Section 2.11 of these bylaws, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such adjourned meeting.

2.8 Conduct of Business. The chairperson of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including such regulation of the manner of voting and the conduct of business. The chairperson of any meeting of stockholders shall be designated by the board of directors; in the absence of such designation, the chairperson of the board, if any, the chief executive officer (in the absence of the chairperson) or the president (in the absence of the chairperson of the board and the chief executive officer), or in their absence any other executive officer of the corporation, shall serve as chairperson of the stockholder meeting.

2.9 Voting. The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

Except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange, in all matters other than the election of directors, the affirmative vote of a majority of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the subject matter shall be the act of the stockholders. Except as otherwise required by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange, directors shall be elected by a plurality of the voting power of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Where a separate vote by a class or series or classes or series is required, in all matters other than the election of directors, the affirmative vote of the majority of the voting power of shares of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series present in person or represented by proxy at the meeting shall be the act of such class or series or classes or series, except as otherwise provided by law, the certificate of incorporation, these bylaws or the rules of any applicable stock exchange.

2.10 Stockholder Action by Written Consent Without a Meeting. Unless otherwise provided in the certificate of incorporation, any action required by statute to be taken at any annual or special meeting of the stockholders, or any action which may be taken at an annual or special meeting of stockholders, may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be (i) signed by the holders of record on the record date (established in the manner set forth in Section 2.11 and Article VIII of the corporation's certificate of incorporation) of outstanding shares of the corporation having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted; shares entitled to vote for the election of directors, and (ii) delivered to the corporation in accordance with Section 228 of the DGCL.

2.11 *Record Dates.* In order that the corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the board of directors and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If the board of directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the board of directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination.

If no record date is fixed by the board of directors, the record date for determining stockholders entitled to notice of and to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting*provided*, *however*, that the board of directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance with the provisions of Section 213 of the DGCL and this Section 2.11 at the adjourned meeting.

In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the board of directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

2.12 *Proxies.* Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A written proxy may be in the form of a telegram, cablegram, or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram, or other means of electronic transmission was authorized by the stockholder.

2.13 List of Stockholders Entitled to Vote. The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting; provided, however, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the meeting date, the list shall reflect the stockholders entitled to vote as of the tenth day before the meeting date. The stockholder list shall be arranged in alphabetical order and show the address of each stockholder and the number of shares registered in the name of each stockholder. The corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the corporation's principal place of business. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held at a place (as opposed to solely by means of remote communication), then a list shall also be open to the examination of any stockholder whole is provided with the notice of the meeting. The stock ledger of the corporation shall be the only evidence as to the identity of the information required to access such list shall be provided with the notice of the meeting. The stock ledger of the corporation shall be the only evidence as to the identity of the stockholders entitled to examine th

2.14 Inspectors of Election. Before any meeting of stockholders, the board of directors shall appoint an inspector or inspectors of election to act at the meeting or its adjournment. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting shall appoint a person to fill that vacancy.

Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. The inspector or inspectors so appointed and designated shall (i) ascertain the number of shares of capital stock of the corporation outstanding and the voting power of each share, (ii) determine the shares of capital stock of the corporation represented at the meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors, and (v) certify their determination of the number of shares of capital stock of the corporation represented at the meeting and such inspector or inspectors' count of all votes and ballots.

In determining the validity and counting of proxies and ballots cast at any meeting of stockholders of the corporation, the inspector or inspectors may consider such information as is permitted by applicable law. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all.

## ARTICLE III - DIRECTORS

3.1 *Powers*. The business and affairs of the corporation shall be managed by or under the direction of the board of directors, except as may be otherwise provided in the DGCL or the certificate of incorporation.

3.2 Number of Directors. The board of directors shall consist of one or more members, each of whom shall be a natural person. Unless the certificate of incorporation fixes the number of directors, the number of directors shall be determined from time to time solely by resolution of the Whole Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 *Election, Qualification and Term of Office of Directors.* Except as provided in Section 3.4 of these bylaws, each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

3.4 Resignation and Vacancies. Any director may resign at any time upon notice given in writing or by electronic transmission to the corporation, provided, however, that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the director. A resignation is effective when the resignation is delivered unless the resignation specifies a later effective date or an effective date determined upon the happening of an event or events. Unless otherwise specified in the notice of resignation, acceptance of such resignation shall not be necessary to make it effective. A resignation which is conditioned upon the director failing to receive a specified vote for reelection as a director may provide that it is irrevocable. Unless otherwise provided in the certificate of incorporation or these bylaws, when one or more directors resign from the board of directors, effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective.

Unless otherwise provided in the certificate of incorporation or these bylaws or if authorized by resolution of the board of directors, vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class shall be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and not by the stockholders. If the directors are divided into classes, a person so elected by the directors then in office to fill a vacancy or newly created directorship shall hold office until the next election of the class for which such director shall have been chosen and until his or her successor shall have been duly elected and qualified.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the Whole Board (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least 10% of the voting power of the capital stock of the corporation at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the DGCL as far as applicable.

3.5 Places of Meetings; Meetings by Telephone. The board of directors may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors may participate in a meeting of the board of directors by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 *Regular Meetings*. Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board of directors.

3.7 Special Meetings; Notice. Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairperson of the board of directors, the chief executive officer, the president, the secretary or a majority of the authorized number of directors, at such times and places as he or she or they shall designate.

Notice of the time and place of special meetings shall be:

- (i) delivered personally by hand, by courier or by telephone;
- (ii) sent by United States first-class mail, postage prepaid;
- (iii) sent by facsimile; or
- (iv) sent by electronic mail,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, as the case may be, as shown on the corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or (iii) sent by electronic mail, it shall be delivered or sent at least 24 hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the corporation's principal executive office) nor the purpose of the meeting.

3.8 *Quorum; Voting.* At all meetings of the board of directors, a majority of the total authorized number of directors shall constitute a quorum for the transaction of business. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

The affirmative vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the board of directors, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws.

If the certificate of incorporation provides that one or more directors shall have more or less than one vote per director on any matter, every reference in these bylaws to a majority or other proportion of the directors shall refer to a majority or other proportion of the directors.

3.9 Board Action by Written Consent Without a Meeting Unless otherwise restricted by the certificate of incorporation, these bylaws or statute, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a meeting if all members of the board of directors or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the board of directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Any person (whether or not then a director) may provide, whether through instruction to an agent or otherwise, that a consent to action will be effective at a future time (including a time determined upon the happening of an event), no later than 60 days after such instruction is given or such provision is made and such consent shall be deemed to have been given for purposes of this Section 3.9 at such effective time so long as such person is then a director and did not revoke the consent prior to such time. Any such consent shall be revocable prior to its becoming effective.

3.10 *Fees and Compensation of Directors*. Unless otherwise restricted by the certificate of incorporation, these bylaws or statute, the board of directors shall have the authority to fix the compensation of directors.

3.11 Removal of Directors. A director may be removed from office by the stockholders of the corporation with or without cause.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

## ARTICLE IV — COMMITTEES

4.1 *Committees of Directors*. The board of directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the board of directors to act at the meeting in the place of all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the corporation.

- 4.2 Committee Minutes. Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.
- 4.3 Meetings and Action of Committees. Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:
  - (i) Section 3.5 (place of meetings and meetings by telephone);
  - (ii) Section 3.6 (regular meetings);
  - (iii) Section 3.7 (special meetings; notice);
  - (iv) Section 3.8 (quorum; voting);
  - (v) Section 3.9 (action without a meeting); and
  - (vi) Section 7.5 (waiver of notice)

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members.

- (i) the time of regular meetings of committees may be determined by resolution of the committee;
- (ii) special meetings of committees may also be called by resolution of the committee; and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors or a committee may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

Any provision in the certificate of incorporation providing that one or more directors shall have more or less than one vote per director on any matter shall apply to voting in any committee or subcommittee, unless otherwise provided in the certificate of incorporation or these bylaws.

4.4 *Subcommittees*. Unless otherwise provided in the certificate of incorporation, these bylaws or the resolutions of the board of directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

### ARTICLE V — OFFICERS

5.1 *Officers.* The officers of the corporation shall be a president and a secretary. The corporation may also have, at the discretion of the board of directors, a chairperson of the board of directors, a chief executive officer, a chief financial officer or treasurer, one or more vice presidents, one or more assistant treasurers, one or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 *Appointment of Officers*. The board of directors shall appoint the officers of the corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment. A vacancy in any office because of death, resignation, removal, disqualification or any other cause shall be filled in the manner prescribed in this Article V for the regular election to such office.

5.3 Subordinate Officers. The board of directors may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

5.4 *Removal and Resignation of Officers*. Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the board of directors or by any officer upon whom such power of removal may be conferred by the board of directors, except that, unless specifically approved by the board, officers may not remove other officers chosen by the board of directors.

Any officer may resign at any time by giving written or electronic notice to the corporation: *provided, however*, that if such notice is given by electronic transmission, such electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the officer. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

5.5 Vacancies in Offices. Any vacancy occurring in any office of the corporation shall be filled by the board of directors or as provided in Section 5.3.

5.6 *Representation of Shares or Interests of Other Corporations or Entities.* The chairperson of the board of directors, the president, any vice president, the treasurer, the secretary or any assistant secretary of this corporation, or any other person authorized by the board of directors or the president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares or equity interests of any other corporation or corporations or entity or entities standing in the name of this corporation, including the right to act by written consent. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 Authority and Duty of Officers. All officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the board of directors.

### ARTICLE VI - STOCK

6.1 *Stock Certificates; Partly Paid Shares.* The shares of the corporation shall be represented by certificates, provided that the board of directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Every holder of stock represented by certificates shall be entitled to have a certificate signed by, or in the name of the corporation by the chairperson of the board of directors or vice-chairperson of the board of directors, or the president or a vice-president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the corporation registrar who has signed or whose facismile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue. The corporation shall not have power to issue a certificate in bearer form.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly-paid shares, or upon the books and records of the corporation in the case of uncertificated partly-paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully-paid shares, the corporation shall declare a dividend upon partly-paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

6.2 Special Designation on Certificates. If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to this Section 6.2 or Sections 151, 156, 202(a) or 218(a) of the DGCL or with respect to this Section 6.2 a statement that the corporation will furnish without charge to each stock preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of uncertificated stock and the rights and obligations of such preferences of such preferences and relative, participating, optional or other special functions, limitations or restrictions of such preferences and/or rights. Except as otherwise expressly provided by law, the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of uncertificated stock and the rights and obligations of the holders of uncertificated

6.3 Lost, Stolen or Destroyed Certificates. Except as provided in this Section 6.3, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

6.4 *Dividends*. The board of directors, subject to any restrictions contained in the certificate of incorporation or applicable law, may declare and pay dividends upon the shares of the corporation's capital stock. Dividends may be paid in cash, in property, or in shares of the corporation's capital stock, subject to the provisions of the certificate of incorporation.

The board of directors may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve.

6.5 *Transfer of Stock*. Transfers of record of shares of stock of the corporation shall be made only upon its books by the holders thereof, in person or by an attorney duly authorized, and, if such stock is certificated, upon the surrender of a certificate or certificates for a like number of shares, properly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer; *provided, however*, that such succession, assignment or authority to transfer is not prohibited by the certificate of incorporation, these bylaws, applicable law or contract.

6.6 *Stock Transfer Agreements.* The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

## 6.7 Registered Stockholders. The corporation:

owner:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such

(ii) shall be entitled (to the fullest extent permitted by law) to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(iii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

## ARTICLE VII - MANNER OF GIVING NOTICE AND WAIVER

7.1 Notice of Stockholders' Meetings. Notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the corporation's records. An affidavit of the secretary or an assistant secretary of the corporation or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

7.2 *Notice by Electronic Transmission*. Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any such consent shall be deemed revoked if:

- (i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent; and
- (ii) such inability becomes known to the secretary or an assistant secretary of the corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

- (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;
- (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and

(iv) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be *prima facie* evidence of the facts stated therein.

An "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved, and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

7.3 Notice to Stockholders Sharing an Address. Except as otherwise prohibited under the DGCL, without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation under the provisions of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any stockholder who fails to object in writing to the corporation, within 60 days of having been given written notice by the corporation to send the single notice, shall be deemed to have consented to receiving such single written notice.

7.4 Notice to Person with whom Communication is Unlawful. Whenever notice is required to be given, under the DGCL, the certificate of incorporation or these bylaws, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the corporation is such as to require the filing of a certificate under the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

7.5 *Waiver of Notice*. Whenever notice is required to be given to stockholders, directors or other persons under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders or the board of directors, as the case may be, need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

## ARTICLE VIII — INDEMNIFICATION

8.1 Indemnification of Directors and Officers in Third Party Proceedings. Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding") (other than an action by or in the right of the corporation) by reason of the fact that such person is or was a director of the corporation or an officer of the corporation, or while a director of the corporation or officer of the corporation is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such Proceeding if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that such person reasonably believed to be in or not opposed to the best interests of the corporation and manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and manner which such person reasonably believed to be in or not opposed to the best interests of the corporation, and manner which such person reasonably believed to be in o

8.2 Indemnification of Directors and Officers in Actions by or in the Right of the Corporation. Subject to the other provisions of this Article VIII, the corporation shall indemnify, to the fullest extent permitted by the DGCL, as now or hereinafter in effect, any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that such person is or was a director or officer of the corporation, or while a director or officer of the corporation is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

8.3 *Successful Defense*. To the extent that a present or former director or officer of the corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding described in Section 8.1 or Section 8.2, or in defense of any claim, issue or matter therein, such person shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith.

8.4 Indemnification of Others; Advance Payment to Others. Subject to the other provisions of this Article VIII, the corporation shall have power to advance expenses to and indemnify its employees and its agents to the extent not prohibited by the DGCL or other applicable law. The board of directors shall have the power to delegate the determination of whether employees or agents shall be indemnified or receive an advancement of expenses to such person or persons as the board of directors determines.

8.5 *Advance Payment of Expenses*. Expenses (including attorneys' fees) incurred by an officer or director of the corporation in defending any Proceeding shall be paid by the corporation in advance of the final disposition of such Proceeding upon receipt of a written request therefor (together with documentation reasonably evidencing such expenses) and an undertaking by or on behalf of the person to repay such amounts if it shall ultimately be determined that the person is not entitled to be indemnified under this Article VIII or the DGCL. Such expenses (including attorneys' fees) incurred by former directors and officers or other employees and agents may be so paid upon such terms and conditions, if any, as the corporation deems reasonably appropriate and shall be subject to the corporation's expense guidelines. The right to advancement of expenses shall not apply to any claim for which indemnity is excluded pursuant to these bylaws, but shall apply to any Proceeding referenced in Section 8.6(ii) or 8.6(iii) prior to a determination that the person is not entitled to be indemnified by the corporation.

8.6 *Limitation of Indemnification*. Subject to the requirements in Section 8.3 and the DGCL, the corporation shall not be obligated to indemnify any person pursuant to this Article VIII in connection with any Proceeding (or any part of any Proceeding):

(i) for which payment has actually been made to or on behalf of such person under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(ii) for an accounting or disgorgement of profits pursuant to Section 16(b) of the Exchange Act, or similar provisions of federal, state or local statutory law or common law, if such person is held liable therefor (including pursuant to any settlement arrangements);

(iii) for any reimbursement of the corporation by such person of any bonus or other incentive-based or equity-based compensation or of any profits realized by such person from the sale of securities of the corporation, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the corporation pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "<u>Sarbanes-Oxley Act</u>"), or the payment to the corporation of profits arising from the purchase and sale by such person of securities in violation of Section 306 of the Sarbanes-Oxley Act), if such person is held liable therefor (including pursuant to any settlement arrangements);

(iv) initiated by such person against the corporation or its directors, officers, employees, agents or other indemnitees, unless (a) the board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (b) the corporation provides the indemnification, in its sole discretion, pursuant to the powers vested in the corporation under applicable law, (c) otherwise required to be made under Section 8.7 or (d) otherwise required by applicable law; or

(v) if prohibited by applicable law; *provided, however*, that if any provision or provisions of this Article VIII shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (1) the validity, legality and enforceability of the remaining provisions of this Article VIII (including, without limitation, each portion of any paragraph or clause containing any such provision held to be invalid, illegal or unenforceable, that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; and (2) to the fullest extent possible, the provisions of this Article VIII (including, without limitation, each such portion of any paragraph or clause containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.

8.7 **Determination; Claim.** If a claim for indemnification or advancement of expenses under this Article VIII is not paid in full within 90 days after receipt by the corporation of the written request therefor, the claimant shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of expenses. The corporation shall indemnify such person against any and all expenses that are incurred by such person in connection with any action for indemnification or advancement of expenses from the corporation under this Article VIII, to the extent such person is successful in such action, and to the extent not prohibited by law. In any such suit, the corporation shall, to the fullest extent not prohibited by law, have the burden of proving that the claimant is not entitled to the requested indemnification or advancement of expenses.

8.8 Non-Exclusivity of Rights. The indemnification and advancement of expenses provided by, or granted pursuant to, this Article VIII shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under the certificate of incorporation or any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office. The corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advancement of expenses, to the fullest extent not prohibited by the DGCL or other applicable law.

8.9 *Insurance*. The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against any liability asserted against such person and incurred by such person in any such capacity, or arising out of such person's status as such, whether or not the corporation would have the power to indemnify such person against such liability under the provisions of the DGCL.

8.10 Survival. The rights to indemnification and advancement of expenses conferred by this Article VIII shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of the heirs, executors and administrators of such a person.

8.11 *Effect of Repeal or Modification.* Any amendment, alteration or repeal of this Article VIII shall not adversely affect any right or protection hereunder of any person in respect of any act or omission occurring prior to such amendment, alteration or repeal.

8.12 *Certain Definitions.* For purposes of this Article VIII, references to the "corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Article VIII with respect to the resulting or surviving corporation as such person would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article VIII, references to "other enterprises" shall include any excise taxes assessed on a person with respect to an employee benefit plan (excluding any "parachute payments" within the meanings of Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended); and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner "not opposed to the best interests of the corporation" as referred to in this Article VIII.

### ARTICLE IX — GENERAL MATTERS

9.1 *Execution of Corporate Contracts and Instruments.* Except as otherwise provided by law, the certificate of incorporation or these bylaws, the board of directors may authorize any officer or officers, or agent or agents, to enter into any contract or execute any document or instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

9.2 Fiscal Year. The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

9.3 Seal. The corporation may adopt a corporate seal, which shall be adopted and which may be altered by the board of directors. The corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

9.4 Construction; Definitions. Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both an entity and a natural person.

## ARTICLE X – FORUM FOR ADJUDICATION OF DISPUTES

Unless the corporation consents in writing to the selection of an alternative forum, the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation; (ii) any action asserting a claim of breach of fiduciary duty owed by any director or officer or other employee of the corporation to the corporation or the corporation or any director or officer or other employee of the corporation arising pursuant to any provision of the DGCL, the Certificate of Incorporation or these Bylaws (in each case, as may be amended from time to time); (iv) any action asserting a claim against the corporation governed by the internal affairs doctrine; or (v) any other internal corporate claim as defined in Section 115 of the DGCL or any successor provision, shall be in the Court of Chancery of the State of Delaware, or, if the Superior Court of the State of Delaware, or, if the Superior Court of the State of Delaware, subject to the court's having personal jurisdiction over the indispensable parties named therein. Any person or entity purchasing or other subject matter of which is within the scope of this Article X is filed in a court other than a court located within the State of Delaware (a "Foreign Action") in the name of any stockholder, such stockholder shall be deemed to have consented to (i) the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the preceding sentence and (ii) having service of process made upon such stockholder in any such court of enforce the preceding sentence and (ii) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Failure to enforce the foregoing provisions would cause the corporation irreparable harm and the corporation shall be entitled to equitable relief, including injunctive relief and specific performance, to enforce the foregoing prov

## ARTICLE XI — AMENDMENTS

These bylaws may be adopted, amended or repealed by the stockholders entitled to vote; *provided, however*, that the affirmative vote of the holders of at least 66 2/3% of the total voting power of all outstanding shares of capital stock of the corporation entitled to vote thereon, voting together as a single class, shall be required for the stockholders of the corporation to alter, amend or repeal, or adopt any bylaw inconsistent with, the following provisions of these bylaws: Article II, Sections 3.1, 3.2, 3.4 and 3.11 of Article VIII and this Article XI (including, without limitation, any such Article or Section as renumbered as a result of any amendment, alteration, change, repeal, or adoption of any other Bylaw). The board of directors, acting by the affirmative vote of at least a majority of the Whole Board, shall also have the power to adopt, amend or repeal bylaws; *provided, however*, that a bylaw amendment adopted by stockholders which specifies the votes that shall be necessary for the election of directors shall not be further amended or repealed by the board of directors.

\* \* \* \* \*

# AQUAMED TECHNOLOGIES, INC.

# CERTIFICATE OF ADOPTION OF AMENDED AND RESTATED BYLAWS

The undersigned hereby certifies that he is the duly elected, qualified and acting Secretary of AquaMed Technologies, Inc., a Delaware corporation (the "*Company*"), and that the foregoing amended and restated bylaws, comprising twenty-four (24) pages, were adopted as the bylaws of the Company on [DATE], 2019.

(signature)

(print name)

(title)

Secretary

March 25, 2019

AquaMed Technologies, Inc. 2150 Cabot Boulevard, West, Suite B Langhorne, Pennsylvania 19067

Re: AquaMed Technologies, Inc. - Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to AquaMed Technologies, Inc., a Delaware corporation (the "<u>Company</u>"), in connection with the preparation and filing with the Securities and Exchange Commission (the "<u>Commission</u>") of, and the consummation of the transactions contemplated by, the Company's Registration Statement on Form S-1 (as it may be amended from time to time, the "<u>Registration Statement</u>"), initially filed by the Company with the Commission on January 9, 2019, under the Securities Act of 1933, as amended (the "<u>Act</u>"), relating to the registration and distribution by the Company of 1,750,000 shares of common stock, par value \$0.001 per share (the <u>Common Stock</u>"), of the Company specified in the Registration Statement (the "<u>Shares</u>"). The Shares are to be distributed by the Company pursuant to an Asset Contribution and Separation Agreement by and between the Company and Alliqua BioMedical, Inc., a Delaware corporation (the "<u>Agreement</u>"), the form of which has been filed as Exhibit 2.3 to the Registration Statement.

The opinions expressed herein are limited exclusively to the General Corporation Law of the State of Delaware (the <u>DGCL</u>") and applicable provisions of the Delaware Constitution and reported judicial decisions interpreting the DGCL and such provisions of the Delaware Constitution and we have not considered, and express no opinion on, any other laws of the laws of any other jurisdiction.

In rendering the opinions expressed herein, we have examined and relied upon the originals, or copies certified to our satisfaction, of (i) the Registration Statement, including the prospectus, and all exhibits thereto; (ii) the Company's Certificate of Incorporation of the Company which is filed as Exhibit 3.1 to the Registration Statement; (iii) the Amended and Restated Certificate of Incorporation of the Company, the form of which is filed as Exhibit 3.3 to the Registration Statement; (v) the Company's By-laws which are filed as Exhibit 3.4 to the Registration Statement; (v) the Amended and Restated Bylaws of the Company, the form of which is filed as Exhibit 3.5 to the Registration Statement; (vi) the minutes and records of the corporate proceedings of the Company with respect to the authorization of the issuance of the Shares covered by the Registration Statement and related matters thereto; (viii) a specimen of the Company's Common Stock certificate; and (ix) such other records, documents and instruments as we have deemed necessary for the expression of the opinions stated herein.

AquaMed Technologies, Inc. March 25, 2019 Page 2

In making the foregoing examinations, we have assumed the genuineness of all signatures (other than those of the Company), the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as certified or photostatic copies thereof and the authenticity of the originals of such latter documents. As to all questions of fact material to these opinions, where such facts have not been independently established, we have relied, to the extent we have deemed reasonably appropriate, upon representations or certificates of officers of the Company or governmental officials.

Based upon the foregoing and subject to the assumptions and qualifications stated herein, we are of the opinion that:

The Shares have been duly authorized for issuance by all necessary corporate action of the Company and, when issued and paid for in accordance with the terms and conditions of the Agreement, the Shares will be validly issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion with the Commission as Exhibit 5.1 to the Registration Statement and to the reference to our firm under the caption "Legal Matters" in the prospectus constituting part of such Registration Statement. In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act.

Very truly yours,

/s/ Haynes and Boone, LLP

Haynes and Boone, LLP

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of AquaMed Technologies, Inc. (a segment of Alliqua BioMedical, Inc.) (the "Company") on Amendment No. 2 to Form S-1 [File No. 333-229173] of our report dated March 11, 2019, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of AquaMed Technologies, Inc. as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum llp

Marcum llp New York, NY March 25, 2019

## INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the inclusion in this Registration Statement of AquaMed Technologies, Inc. on Amendment No. 2 to Form S-1 [File No. 333-229173] of our report dated March 11, 2019, which includes an explanatory paragraph as to TO Pharmaceuticals LLC's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of TO Pharmaceuticals LLC and Subsidiaries as of December 31, 2018 and 2017 and for each of the two years in the period ended December 31, 2018, which report appears in the Prospectus, which is part of this Registration Statement. We also consent to the reference to our Firm under the heading "Experts" in such Prospectus.

/s/ Marcum llp

Marcum llp New York, NY March 25, 2019