#### Vaxil Bio Ltd.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF

#### FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## For the three-month period ended March 31, 2019

The following is a discussion and analysis of the activities, consolidated results of operations and financial condition of Vaxil Bio. Ltd. ("Vaxil", "we", "our", "us", or the "Company") for the three-month period ended March 31, 2019, which has been prepared on the basis of information available up until May 30, 2018. This Management's Discussion and Analysis ("MD&A") should be read in conjunction with the Company's interim consolidated financial statements for the three-month period ended March 31, 2019, as well as the annual consolidated financial statements for the year ended December 31, 2018, together with the notes thereto.

All monetary amounts are reported in Canadian dollars and in accordance with IFRS unless otherwise noted. This MD&A is dated May 22, 2019.

# **Forward-Looking Statements**

This MD&A (including, without limitation, the sections discussing Vaxil's Financial Conditions and Results of Operations) contains certain forward-looking statements. All statements other than statements of historical fact that address activities, events or developments that the Company believes, expects or anticipates will or may occur in the future are forward-looking statements. Forward-looking statements are often, but not always, identified by the use of words such as "seek", "anticipate", "contemplate", "target", "believe", "plan", "estimate", "expect" and "intend" and statements that an event or result "may", "will", "can", "should", "could" or "might" occur or be achieved and other similar expressions. These statements are based upon certain assumptions and analyses made by management in light of its experience and perception of historical trends, current conditions and expected future developments, as well as other factors management believes are appropriate in the circumstances. However, whether actual results and developments will conform with management's expectations is subject to a number of risks and uncertainties, including the considerations discussed herein and in other documents filed from time to time by the Company with Canadian security regulatory authorities, general economic, market or business conditions, the opportunities (or lack thereof) that may be presented to and pursued by management, competitive actions by other companies, changes in laws or regulations and other factors, many of which are beyond the Company's control. These factors may cause the actual results of the Company to differ materially from those discussed in the forward-looking statements and there can be no assurance that the actual results or developments anticipated by management will be realized or, even if substantially realized, that they will have the expected results on Vaxil. All of the forward-looking statements made herein are qualified by the foregoing cautionary statements. The Company expressly disclaims any obligation to update or revise any such forward-looking statements.

## Business overview and Significant Developments during the period

#### **Corporate Structure**

# Name and Incorporation

Vaxil Bio Ltd. ("Vaxil" or the "Company") was incorporated under the Business Corporations Act (BC) on July 26, 2006 and is listed on the TSX Venture Exchange under the symbol "VXL". The Company's head office is located at 6th Floor, 4576 Yonge Street, Toronto, Ontario, M2N 6N4, Canada. Vaxil's Israel office is within the Weizmann Science Park, an Israeli biotech hub and adjacent to the famed Weizmann Institute of Science, at Pinchas Sapir Street 3, P.O. Box 4058, Nes Ziona, 74140, Israel. This is also the principal place of business where Vaxil currently hosts its scientific laboratory.

#### **Business of Vaxil**

Vaxil is an Israeli immunotherapy biotech company focused on its novel approach to targeting prominent cancer markers and infectious diseases. Its lead product ImMucin<sup>TM</sup> successfully completed a Phase 1/2 clinical trial in multiple myeloma and received orphan drug status from the FDA and EMA. The company is also developing a tuberculosis vaccine / treatment that has demonstrated promising preliminary results with further preclinical evaluation underway at a top US academic and research institution. Additional indications and mAb candidates are under evaluation as immuno-oncology and infectious disease treatments alone and in combination with other treatments.

Vaxil exploits the unique properties of signal peptide domains on crucial proteins to develop targeted therapies against cancer targets and infectious disease pathogens. These signal peptide domains are identified by VaxHit<sup>TM</sup>, Vaxil's proprietary bioinformatic approach. These SPs induce a robust T- and B-cell response across wide and varied HLA subtypes, while acting as true, universal neoantigens. The peptide platform targets these cells by "educating" or specifically activating the immune system to recognize and attack the affected cells. In addition, Vaxil's mAb platform directly recognizes the target protein expressed on malignant cells and recruits other elements of the immune system to lyse those cells.

Advantages of the Vaxil platforms:

- Unique, universal neoantigens
- Circumvent HLA-I downregulation and initial antigen-loss-driven tumor escape
- Conserved, low mutation domain, allowing off-the-shelf treatment
- Dense and varied epitopes recognized by widespread HLA subclasses, allowing off-the-shelf treatment across diverse populations
- Target only malignant cells, with no observed off-target adverse effects

Preclinical studies and the clinical Phase 1/2 trial provide robust indications of an excellent safety profile coupled with promising efficacy for the selected candidates. Together, Vaxil has created effective, scientifically-validated, platforms to develop targeted immune-oncology and infectious disease treatments from discovery through clinical trials.

In addition to oncology, Vaxil's platform has great promise as a treatment for various infectious diseases. Over the past year, Vaxil advanced the signal peptide platform in infectious disease, focusing on tuberculosis with MTBuVax<sup>TM</sup>. Recently concluded preclinical studies have confirmed the high efficacy of Vaxil's signal peptides in reducing bacterial load in murine model lungs. Further studies may evaluate tuberculosis SPs as a boost to standard of care, in order to (1) increase treatment efficacy, (2) prolong the protective immunity effect and/or (3) expand the treated population. Vaxil has and is forming new collaborations with world-renowned tuberculosis researchers at top research universities.

Vaxil's strategy incorporates 3 key pillars"

- 1. SP / Oncology
- 2. SP / infectious disease
- 3. Incorporating unique and innovative Israeli technologies, especially from academia to bridge the challenging divide between world-renowned Israeli academia and commercialization leveraging Vaxil's 1<sup>st</sup> class global team with more than 75 years of pharma experience

Following the successful clinical trial of ImMucin<sup>TM</sup>, Vaxil plans to develop our MUC1-SP as an adjunct therapy and / or combination therapy to synergistically improve the standard of care for solid tumors with high risk of metastasis. Preclinical studies are ongoing to design and support these forthcoming clinical trials.

Vaxil's VaxHit<sup>TM</sup> has identified additional peptide candidates pertinent to a variety of cancers that can be developed as SPs and / or mAbs. VaxHit<sup>TM</sup> will continue to be employed to identify other relevant oncology and infectious diseases.

Vaxil is currently in advanced discussions to incorporate cutting-edge Israeli innovation from top academic institutions, which when matched with our first-class team, will be incorporated into our pipeline to develop safer and more powerful preventative and therapeutic combination treatments.

Moreover, during the past year and with continuous efforts, Vaxil enhanced its peptide production methodologies to increase yield and purity, improving and allowing future scale-up for prospective clinical trials as well as future commercial manufacturing.

## **Vaxil Intellectual Property**

Vaxil has three patent families including 28 granted patent and six patent applications with more work being done to expand the portfolio.

- The first patent family relates to the ImMucin<sup>TM</sup> product, a MUC1 signal peptide-based vaccine. This patent family includes patents in US, Europe, Australia, Canada, Israel and India, relating to the ImMucin<sup>TM</sup> vaccine and methods for using ImMucin<sup>TM</sup> such as for treating cancer and T-cell enrichment.
- The second patent family relates to immunogenic composition, specifically against a pathogen (e.g., Tuberculosis, Malaria, Toxoplasma, EBV, HIV, Herpes Virus, and Influenza). This patent family includes patents in US, Europe and South Africa.
- The third patent family relates to the antibodies produced by MUC1 signal peptides (note to self: check need for patenting anti-Her2-SP mAb), and diagnostic and therapeutic methods using these antibodies. This patent family includes a US granted patent and patent applications in Europe, Australia, Canada, Israel and India.

During the first quarter of 2019, U.S. Patent # 10,245,309 was granted to Vaxil, entitled "Antigen specific multi-epitope-based anti-infective vaccines." This patent provides broad protection for treating pathogenic infections using vaccines based on a pathogen's signal peptides, or T-cell populations enriched using these peptides.

This new patent provides further validation of the uniqueness of our innovative platform and encourages us to proceed with our research agenda, specifically in infectious disease. This new patent adds to and strengthens our already robust IP portfolio and we will continue to work to further broaden this portfolio."

## Additional Disclosure for Venture Issuers without Significant Revenues (in Thousands of Canadian Dollars):

	Three Months ended March 31			
	20	)19	2(	)18
Research and development costs, net	\$	163	\$	100
General and administration costs		39		136
	\$	202	\$	236

#### **Discussion of Operations**

The following is a discussion of the results of operations which have been derived from the condensed consolidated interim financial statements of the Company for the three-month period ended March 31, 2019 (in Thousands of Canadian Dollars):

Three Months ended March 31			
			2
\$	163	\$	100
	39		136
	49		-
	251		236
	(251)		(236)
	1		3
	1		3
	(252)		(239)
	(7)		(43)
\$	(259)	\$	(282)
	\$	\$ 163 39 49 251 (251) 1 (252)	March 31  2019  \$ 163  \$ 39 49 251 (251)  1 (252)

# Three-month period ended March 31, 2019, compared to the three-month period ended March 31, 2018

# Research and Development costs, net

For the three-month period ended March 31, 2019, research and development costs expenses amounted to \$163 thousand as compared to \$100 thousand for the three-month period ended March 31, 2018. The increase in research and development costs is as a result of increased focus on research and development reflected in higher salary expenses, and additional personnel and higher costs of materials expenses during the quarter.

# General and Administrative Expenses

For the three-month period ended March 31, 2019, general and administrative expenses amounted to \$39 thousand as compared to \$136 thousand for the three-month period ended March 31, 2018. The decrease in general and administrative expenses in 2019 resulted from sharp management focus on science with a decrease in consulting, professional, management and directors' fees.

## Share based compensation

For the three-month period ended March 31, 2019, share-based compensation is \$49 thousand as compared to \$nil for the three-month period ended March 31, 2018. The amount in 2019 relates to the fair value of options granted to the CEO during the third quarter of 2018. During the first quarter of 2019 there were no new option grants and the fair value of previously issued option grants were all fully vested, and therefore there was no charge to the statement of compressive loss during this period.

#### Net Losses

The Company reported a net loss for the three-month period ended March 31, 2019 of \$252 thousand as compared to a net loss of \$239 for the three-month period ended March 31, 2018. The increase in the loss in 2019 is due to increased research and development costs, partially offset by reduced, general and administration costs.

#### Inflation

During the three-month period ended March 31, 2019 and 2018, inflation has not had a material impact on our operations.

### **Summary of Quarterly Results**

	 31-Mar-19	31-Dec-18	30-Sep-18	30-Jun-18
	Canadians dollars in thousands, except per share data			
Revenues	\$ -	-	-	-
Net loss	\$ (252)	(398)	(230)	(180)
Net loss and comprehensive loss	\$ (259)	(386)	(236)	(141)
Net loss per share	\$ (0.00)	(0.01)	(0.01)	(0.01)
	Quarter ended			
	31-Mar-18	31-Dec-17	30-Sep-17	30-Jun-17
	Canadians do	llars in thousands	, except per sha	re data
Revenues	\$ -	-	-	-
Net loss	\$ (239)	(538)	(336)	(319)
Net loss and comprehensive loss	\$ (282)	(568)	(288)	(367)
Net loss per share	\$ (0.00)	(0.01)	(0.01)	(0.01)

Net loss per quarter is a function of the exploration and operational activity during that quarter. The loss per quarter and related loss net loss per share is a function of the level of research and development activity that took place during that quarter. In 2017 and 2018 and during the first quarter of 2019, the losses per quarter relates to work completed in respect of the submission of an application to commence a Phase II clinical trial.

## Liquidity

Liquidity is a measure of a company's ability to meet potential cash requirements. The Company has historically met its capital requirements through the issuance of common shares.

The Company has an accumulated deficit of \$15,360 thousand as of March 31, 2019 (\$15,108 thousand as of December 31, 2018), and the Company had negative cash flows from operations of \$216 thousand for the three-month period ended March 31, 2019 (negative cash flows of \$520 thousand during the three-month period ended March 31, 2018). The ability of the Company to continue as a going concern depends upon the ability of the Company to obtain financing to complete development, and upon future profitable operations from the properties or proceeds from their disposition. The Company is an exploration stage company and has not earned any revenues to date.

There can be no assurance that the Company will be able to continue to raise funds, in which case the Company may be unable to meet its obligations. The Company is considering various alternatives with respect to raising additional capital to remedy any future shortfall in capital, but to date has made no specific plans or arrangements. Because of the early stage of the Company's operations, there can be no assurance this capital will be available and if it is not, the Company may be forced to substantially curtail or cease research and development expenditures.

#### Three-month period ended March 31, 2019 compared to the three-month period ended March 31, 2018

During the three-month period ended March 31, 2019, the Company's overall position of cash and cash equivalents decreased by \$225 thousand. This decrease in cash and cash equivalents can be attributed to the following activities:

The Company's net cash used in operating activities during the three-month period ended March 31, 2019 was \$216 thousand as compared to \$520 thousand for the three-month period ended March 31, 2018. The decrease was due primarily to the increase in share-based compensation and decrease in accounts payable and other accounts payable and accrued liabilities.

Cash used in financing activities for the three-month period ended March 31, 2019 was \$9 as compared to cash flows from financing activities of \$1,736 thousand during the three-month period ended March 31, 2018. The amount in 2019 related to the repaid a loan on our FACS machine and in 2018, the amount relates to the completion of a private placement.

## **Capital Resources**

As of March 31, 2019, the Company's cash and cash equivalents were \$521 thousand (December 31, 2018 - \$753 thousand). The majority of this balance is being held in Canadian Dollars. Our working capital at March 31, 2019 was positive \$173 as compared to \$373 at December 31, 2018.

#### Commitments

The Company has an agreement for the lease of the offices in Israel for a period ending in February 2020. The total future minimum lease payments under the operating lease is \$65 thousand.

## **Disclosure of Outstanding Share Data**

As of the date of this report, the Company has 88,929,447 ordinary shares outstanding, 37,102,278 warrants outstanding and 5,647,684 options granted. Each warrant and option entitles the right of the holder thereof to acquire one ordinary share.

## **Management of Capital**

The Company is an early-stage biotechnology research and development company and currently does not generate significant cash flows from operations. The Company's primary source of funds comes from the issuance of share capital. The Company does not use other sources of financing that require fixed payments of interest and principal and is not subject to any externally imposed capital requirements.

The Company defines its capital as share capital plus warrants. To effectively manage the Company's capital requirements, the Company has a planning and budgeting process in place to ensure that adequate funds are available to meet its strategic goals. The Company monitors actual expenses to budget to manage its costs and commitments.

The Company's capital management objective is to maximize investment returns to its equity-linked stakeholders within the context of relevant opportunities and risks associated with the Company's operations. Achieving this objective requires management to consider the underlying nature of research and development activities, the availability of capital, the cost of various capital alternatives and other factors. Establishing and adjusting capital requirements is a continuous management process.

Although the Company has been successful at raising funds in the past through the issuance of share capital, there can be no assurance that future financings will be successful.

#### **Off-Balance Sheet arrangements**

See "Commitments" above.

#### **Transactions with Related Parties**

No director or senior officer of the Company, and no associate or affiliate of the foregoing persons, and no insider has or has had any material interest, direct or indirect, in any transactions, or in any proposed transactions, which in either such case has materially affected or will materially affect the Company or the Company's predecessors since the beginning of the Company's last completed fiscal year except as follows:

During the three-month period ended March 31, 2019, the Company incurred \$41 thousand, in consulting fees and Research and Development expense from two officers of the Company, as compared to \$44 thousand during the three-month period ended March 31, 2018.

These transactions are in the normal course of operations and are measured at the exchange amount, which is the amount of consideration established and agreed to by the related parties.

# **Critical Accounting Policies and Estimates**

Our results of operation and financial condition are based on our consolidated financial statements, which are presented in accordance with IFRS. Certain accounting principles require us to make certain estimates, judgments and assumptions. We believe that the estimates, judgments and assumptions upon which we rely are reasonable based upon information available to us at that time. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities as of the date of the financial statements, as well as the reported amounts of revenues and expenses during the periods presented. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. The significant accounting policies and estimates that we believe are the most critical to aid in fully understanding and evaluating our reported financial results include the following:

The critical judgments and significant estimates in applying accounting policies that have the most significant effect on the amounts recognized in the consolidated financial statements are:

The series of loans made to the subsidiary company are considered part of the parent Company's net investment in a foreign operation as the Company does not plan to settle these balances in the foreseeable future. As a result of this assessment, the unrealized foreign exchange gains and losses on the intercompany loans are recorded through other comprehensive loss. If the Company determined that settlement of these amounts was planned or likely in the foreseeable future, the resultant foreign exchange gains and losses would be recorded through the statement of comprehensive profit and loss.

# Disclosure Controls and Procedures and Internal Controls over Financial Reporting

There were no changes to the Company's internal controls over financial reporting during the three-month period ended March 31, 2019, which have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

As of March 31, 2019, the Company evaluated its disclosure controls and procedures and internal control over financial reporting, as defined by the Canadian Securities Administrators. These evaluations were carried out under the supervision of and with the participation of management, including the Company's chief financial officer. Based on these evaluations, the chief financial officer concluded that the design of these disclosure controls and procedures and internal control over financial reporting were effective.

## **Financial Instruments and Other Instruments**

The Company's financial instruments have been designated as follows:

Financial assets and liabilities	Classification
Cash and cash equivalents	Loans and receivables
Other receivables	Loans and receivables
Account payable	Other financial liabilities
Other payables and accrued liabilities	Other financial liabilities

The carrying values of cash and cash equivalents, restricted deposits, other receivables, trade payables and accounts payable and accrued liabilities approximate their fair values due to the short-term maturity of these financial instruments.

#### **Risks and Uncertainties**

#### Credit risk

The Company manages credit risk, in respect of cash and cash equivalents and restricted deposits, by holding them at major Canadian and Israeli financial institutions in accordance with the Company's investment policy. The Company places its cash and cash equivalents with high credit quality Israeli and Canadian financial institutions. Concentration of credit risk exists with respect to the Company's cash and cash equivalents and other receivables. The Company's exposure as at March 31, 2019 and December 31, 2018 was \$595 thousand and \$828 thousand respectively, which consisted of \$521 thousand (December 31, 2018 - \$753 thousand) in cash held in bank accounts, and \$74 thousand (December 31, 2018 - \$75 thousand) in amounts receivable and prepaid expenses. None of the Company's amounts receivable are overdue as at March 31, 2019.

## Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulty in obtaining funds to meet current obligations and future commitments. The Company's approach to managing liquidity risk is to forecast cash requirements to provide reasonable assurance that it will have sufficient funds to meet its liabilities when due. As of March 31, 2019, the Company had cash and cash equivalents of \$521 thousand and accounts receivable and prepaid expenses of \$74 thousand to settle other payables in the amount of \$424 thousand.

## Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk is comprised of two types of risk: interest rate risk, and foreign currency risk.

# (i) Interest rate risk

The Company is not exposed to significant interest rate risk due to the short-term maturity of its cash equivalents.

# (ii) Foreign currency risk

The Company is exposed to financial risk related to the fluctuation of foreign exchange rates. The Company operates in Israel and most of the Company's expenditures are currently incurred in NIS. However, the Company also has expenditures in US Dollars and Canadian Dollars. The Company has not hedged its exposure to currency fluctuations. An increase or decrease of 5% of the NIS or the US Dollar relative to the Canadian dollar would not have a significant effect on the Company.

### **Development Stage Company**

Vaxil has only a limited history upon which one can evaluate its business and prospects as its technologies are still at an early stage of development and thus Vaxil has limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Vaxil has not begun to market or generate revenues from the commercialization of any products related to human health. The likelihood of the success of the Company must be considered in light of the risks inherent in, and the difficulties, costs and complications associated with the early growth stages of a business enterprise, as well as with the development and marketing of new products.

#### **Future Capital Needs**

The Company may not be able to fully implement and execute its business strategy without additional financing. There can be no assurance that such additional financing will be available, and if available, there can be no assurance that the cost of obtaining such financing will be on favourable or reasonable commercial terms or that it will not result in substantial dilution to its shareholders. If additional funds are raised through the issuance of equity or equity-linked debt securities, the percentage ownership in Vaxil of the shareholders will be reduced, and such securities may have rights, preferences, or privileges senior to or equal to those of the Company's shares held by the current shareholders, or any other securities outstanding on the date hereof.

If adequate funds are not available to satisfy ongoing capital requirements, the Company may be required to curtail its operations significantly or to obtain funds, if available, through arrangements with strategic partners or others that may require the Company to relinquish material rights to certain technologies or potential markets. There is no certainty that financing will be available in amounts or on acceptable terms, if at all.

Any failure to raise additional funds on favorable terms is likely to have a material adverse effect on the Company's liquidity and financial condition.

# **Dependence on Key Personnel**

The Company's future success depends on its ability to retain key employees and attract, train, retain and successfully integrate new talent into its management team. Vaxil is dependent on the services of its senior management team. The loss of any of the members of the Company's senior management team could have a material adverse effect on the Company's results of operations, business and prospects. The Company's future success also depends, to a significant extent, on its ability to attract and retain talented personnel. Recruiting and retaining talented personnel, particularly those with the expertise required for the Company's business is vital to the Company's success and may prove difficult.

## **Changes in Technology and Industry Standards**

The pharmaceutical and biotechnology drug development industry is susceptible to technological advances and the introduction of new technologies. Further, this industry is also subject to changing industry standards, market trends and customer preferences and to competitive pressures, which can, among other things, necessitate revisions in pricing strategies, price reductions and reduced profit margins. The success of the Company will depend, in part, on its ability to secure technological superiority in its products and operations and maintain such superiority in the face of new technologies. No assurance can be given that further modification of product offerings of Vaxil will not be required in order to meet demands or to make changes necessitated by developments made by competitors that might render services and operations of the Company less competitive. The future success of the Company will be influenced by its ability to continue to adapt its products. Although Vaxil has committed resources to research and develop its products, there can be no assurance that these efforts will be successful.

## **Applicability of Patents and Proprietary Technology**

Competitors may have filed patent applications, or hold issued patents, relating to products or processes competitive with those Vaxil has developed or will in future develop. The Company's patent applications for a product may not be approved or approved as desired. The patents of the Company's competitors may impair its ability to do business in a particular area. Others may independently develop similar products or duplicate any of the Company's unpatented products or technologies. The Company's success will depend, in part, on its ability in the future to obtain patents, protect trade secrets and other proprietary information and operate without infringing the proprietary rights of others. Patent protection is uncertain and involves many complex legal, scientific and technical questions. The degree of legal protection afforded under patents is unclear. As a result, the scope of patents issued to Vaxil or their partners may not successfully prevent third parties from developing similar or competitive products.

Vaxil has and will continue to enter into confidentiality agreements with its employees, suppliers and vendors. However, these confidentiality agreements may be breached, and the Company may not have adequate remedies for such breaches. Others may independently develop substantially equivalent proprietary information without infringing upon any proprietary technology belonging to the Company. Third parties may otherwise gain access to the Company's proprietary information and adopt it in a competitive manner.

In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued. Also, Vaxil faces the following intellectual property risks: (i) some or all patent applications may not result in the issuance of a patent; (ii) patents issued may not provide the holder with any competitive advantages; (iii) patents could be challenged by third parties; (iv) the patents of others could impede our ability to do business; (v) competitors may find ways to design around our patented products; and (vi) competitors could independently develop products which duplicate our products.

## **Patent Litigation**

A number of industry competitors and institutions have developed technologies, filed patent applications or received patents on various technologies that may be related to or affect our business. Claims by these companies that Vaxil infringes their proprietary technology may result in liability for damages or may delay the development and commercialization efforts for the Company's products. Such conflict could limit the scope of the patents, if any, that the Company may be able to obtain or result in the denial of its patent applications. In addition, if patents that cover the Company's activities are issued to other companies, there can be no assurance that Vaxil would be able to obtain licenses to these patents at a reasonable cost or be able to develop or obtain alternative technology. If the Company does not obtain such licenses, it could encounter delays in the introduction of products, or could find that the development, manufacture or sale of products requiring such licenses could be prohibited. In the pharmaceutical industry, it is not uncommon for competitors to advance such claims for strategic purposes. Furthermore, there can be no assurance that patent or other litigation will not arise in connection with any of the Company's or future products or product candidates. Patent litigation, with or without merit, is time-consuming and costly and may significantly impact the Company's financial condition and results of operations, even if the Company prevails. In addition, the Company could incur substantial costs in defending suits brought against it on patents it might infringe or in filing suits against others to have such patents declared invalid.

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