SECURITIES & EXCHANGE COMMISSION EDGAR FILING

MYMETICS CORP

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

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018
OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____

COMMISSION FILE NUMBER 00025132

MYMETICS CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE	25-1741849
State or Other jurisdiction of Incorporation or Organization	I.R.S. Employer Identification No.
c/o Mymetics SA Route de la Corniche 4 Epalinges, Switzerland	CH-1066
Address of Principal Executive Offices	Zip Code

011 41 21 653 4535
Registrant's Telephone Number, Including Area Code

Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

COMMON STOCK, $0.01 PAR VALUE
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed be Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒.

The aggregate market value of the voting common stock held by non-affiliates of the registrant (assuming executive officers, directors and our largest shareholder whose representative serves on the Board of Directors are affiliates) was approximately U.S. $7,292,569 as of December 31, 2018, computed on the basis of the closing price on such date.
As of March 28, 2019, there were 303,757,622 shares of the registrant's Common Stock outstanding.

FORWARD LOOKING STATEMENTS

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements, which are identified by the words "believe," "expect," "anticipate," "intend," "plan" and similar expressions. The statements contained herein which are not based on historical facts are forward-looking statements that involve known and unknown risks and uncertainties that could significantly affect our actual results, performance or achievements in the future and, accordingly, such actual results, performance or achievements may materially differ from those expressed or implied in any forward-looking statements made by or on our behalf. These risks and uncertainties include, but are not limited to, risks associated with our ability to successfully develop and protect our intellectual property, our ability to raise additional capital to fund future operations and compliance with applicable laws and changes in such laws and the administration of such laws. These risks are described below and in "Item 1. Business," "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations," and "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" included in this Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements which speak only as of the date the statements were made.

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ITEM 1.BUSINESS

THE CORPORATION

OVERVIEW

We are a vaccine company and are focused on the research and development of next generation vaccines for infectious and life disabling diseases. Our core technology and expertise lays in the use of virosomes, lipid-based carriers containing functional fusion viral proteins and natural membrane proteins, in combination with rationally designed antigens and if required, adjuvants. We currently have several vaccine candidates in our pipeline: HIV-1/AIDS, intra-nasal influenza, malaria and Chikungunya, while our RSV and HSV vaccines candidate programs are on hold. We have started several discovery projects in immunotherapy, one in the allergy field and one the field of oncology, for which we collaborate with other biotech companies. Our vaccines for infectious diseases are designed to induce protection against early transmission and infection, focusing on the mucosal immune response as a first-line defense in combination with humoral and cellular immune responses as a second-line defense, which, for some pathogens, may be essential for the development of an effective prophylactic vaccine. Additionally, for certain immunotherapies, we are exploring the use of virosome platform to trigger specific immune responses. We believe that virosomes are the most promising vaccine delivery systems since they do not use live attenuated or killed pathogens and increase the immunogenicity and stability of the vaccine.

We currently do not make, market or sell any products, but we generate some revenue through collaboration projects, grant funding and R&D services. We believe that our research and development activities will result in valuable intellectual property and know-how that can generate significant revenues for us in the future such as by licensing. Vaccines and immunotherapy are one of the fastest growing markets in the pharmaceutical industry. Vaccines have evolved from being an exclusively low price sector to one where substantial prices may be paid for some vaccine products that address unmet medical needs.

HISTORY AND DEVELOPMENT OF THE COMPANY

We were incorporated in July 1994 pursuant to the laws of the Commonwealth of Pennsylvania under the name "PDG Remediation, Inc." In November 1996, we reincorporated under the laws of the State of Delaware and changed our name to "ICHOR Corporation." In July 2001, we changed our name to "Mymetics Corporation."

In March 2001, we acquired 99.9% of the outstanding shares of the French registered company Mymetics S.A. in consideration for shares of our common stock and shares of Class B Exchangeable Preferential Non-Voting Stock of 6543 Luxembourg S.A., which were convertible into shares of our common stock. In 2002, we acquired all but 0.01% of the remaining outstanding common stock of Mymetics S.A. pursuant to share exchanges with the remaining stockholders of Mymetics S.A. The terms of these share exchanges were substantially similar to the terms of the share exchange that occurred in March 2001. In 2004, all the remaining convertible shares of 6543 Luxembourg S.A. not already held by Mymetics Corporation were converted into shares of Mymetics Corporation. On February 7, 2006, the Tribunal de Commerce in Lyon, France placed the French subsidiary Mymetics S.A., under receivership ("Redressement Judiciaire") and this subsidiary was subsequently officially closed by the Tribunal de Commerce in Lyon on March 21, 2012.

We own all of the outstanding voting stock of: (i) Mymetics S.A., a company originally organized as Mymetics Management Sàrl in 2007 under the laws of Switzerland, (ii) Bestewil Holding B.V. and (iii) Bestewil Holding B.V's subsidiary Mymetics B.V. (formerly Virosome Biologicals B.V.) both of which are organized under the laws of The Netherlands and were acquired in 2009. In this document, unless the context otherwise requires, "Mymetics" and the "Corporation" refer to Mymetics Corporation and its subsidiaries.

MYMETICS S.A.

Our Swiss subsidiary Mymetics S.A. was founded in 2007 as Mymetics Management Sàrl to facilitate the conduct of our business in Switzerland. This includes managing our staff retirement and social security contributions, leasing our Swiss premises and other such local tasks which a U.S. registered company cannot easily conduct without significant legal and organizational costs. The change in name and bylaws affected in 2009, from "Société à Responsabilité Limitée » (SàRL) to "Société Anonyme" (SA) is indicative of the transition from a pure service company status of this unit to a development company in its own rights within Mymetics Corporation.

BESTEWIL HOLDING B.V. and its subsidiary MYMETICS B.V.

On April 1, 2009 we entered into an agreement with Norwood Immunology Limited ("NIL") for the acquisition of Bestewil Holding B.V. ("Bestewil") from its parent, NIL, under a Share Purchase Agreement pursuant to which we agreed to purchase all issued and outstanding shares of capital stock (the "Bestewil Shares") of Bestewil from its parent, NIL, and all issued and outstanding shares of capital stock of Virosome Biologicals B.V. which were held by Bestewil. Virosome Biologicals B.V., the name of which was subsequently changed to Mymetics B.V., continues to be engaged in research and development activities in its own facilities in Leiden (Netherlands) under the management of its founder, the original inventor of the virosome technology.

STRATEGY

With only 26 diseases addressed by vaccines in the world today, it is a well-known fact that the world needs many more vaccines and focus on prevention.

Our vision is to become the market leader in the research and development of new generation virosome and membrane protein based vaccines for life disabling and infectious diseases.

By using virosomes as a delivery platform, Mymetics vaccine candidates do not use live attenuated or killed pathogens, while increasing the immunogenicity and stability of the vaccine.

Moreover, the company's vaccines are designed to induce protection against early transmission and infection, focusing both on the mucosal immune response as a first-line defense and on the systemic humoral (blood) immune response, which, for some pathogens, may be essential for the development of an effective prophylactic vaccine.

Our strategy is to strengthen our virosome and membrane protein know how, expertise and intellectual property and extend the application of our key scientific approaches to new vaccines by:

- Leveraging the effective and safe virosome vaccine technology and know-how
- Building on our leading expertise in membrane proteins and lipid membranes
- Leveraging our expertise in incorporating adjuvants and antigens in the lipid membranes and on the same particle
- Advancing existing vaccine candidates through Phase II clinical trials with our partners
- Maintaining a comprehensive IP portfolio
- Adopting a flexible cost model based on a combination of in-house expertise and best-in-class outsourcing
- Entering into strategic partnerships with leading pharmaceutical companies and research organizations

This approach has resulted in the development of a rich pipeline of promising vaccine candidates in either the pre-clinical or Phase I stage of development and validations through world leading partnerships.

PRODUCTS UNDER DEVELOPMENT

Our current pipeline has proprietary vaccines in development: HIV-1, malaria, Chikungunya and intra-nasal influenza vaccines, while our HSV and RSV vaccine candidates are on hold. The vaccines in our portfolio are primarily prophylactic. The current stage of development of these vaccines is shown in the table below:

Vaccine	Pre-Clinical	Phase I
HIV-1		X
RSV	On hold	
Malaria		X
Influenza		X
Chikungunya	X	

Additionally to the above pipeline, we have several immunotherapy evaluation projects among which, one project with Anergis SA, for the use of Mymetics' virosomes in combination with Anergis' Continuous Overlapping Peptides against birch pollen allergy and some in the oncology field.

HIV-1 and AIDS

HIV-1 (human immunodeficiency virus type 1) is a retrovirus that gradually destroys the immune system and ultimately leads to AIDS. HIV-1 is among the pathogens harboring the highest genetic variation, leading to millions of variants, each rapidly mutating. Indeed, HIV-1 exists under many different versions (aka "clades"), like members of a large family; they are different from, but related to each other.

Our current prophylactic HIV-1 vaccine candidate is constituted of virosomes linked to conserved antigens (epitopes) derived from the HIV-1 gp41 proteins from the clade B, the dominant clade found in Europe and North America. The vaccine is designed to trigger blood and mucosal antibodies of both isotype IgG and IgA, for example in the vaginal and intestinal tracts. The rationale for the design of the vaccine was based on the observation that certain people who are repeatedly exposed to HIV-1 do not contract infection; they were shown to have mucosal antibodies in the semen or vaginal secretions against the HIV-1 gp41 that apparently protect them. We intend for our vaccine to imitate "Mother Nature".

Key scientific results with the HIV vaccine to date:

2005: "Proof of Concept" for inducing mucosal antibodies. Vaccination of rabbits with virosomes-P1 elicited mucosal antibodies in the vagina and intestinal mucosa. P1 is a synthetic peptide corresponding to the C-terminal end of the C-helix ectodomain of the gp41. In a laboratory test, these antibodies strongly inhibited HIV-1 passage through the mucosal tissues, also called transcytosis, confirming the potential of developing an HIV-1 vaccine that prevents infection at the mucosal layer.

2006/2007: Mucosal antibodies in monkeys. Macaque monkeys (*Macaca Mulatta),* of Chinese origin, showed after vaccination with virosomes-P1, specific mucosal antibodies, which were detected in more than 90% of the animals and harboring the potential to block *in-vitro* HIV-1 transcytosis, confirming the rabbit data.
2008: Full protection of monkeys against multiple vaginal challenges with live heterologous clade B virus . Macaque monkeys of Chinese origin were vaccinated with both virosomes-modified P1 and virosomes-rgp41 (vaccine MYM-V201). One month after the last vaccination, animals received multiple intra-vaginal challenges with the live SHIVSF162P3 virus. The vaccinated animals that developed mucosal antibodies with transcytosis inhibition activity were not infected with the virus, while the placebo vaccinated control group was fully infected. Results were published in "Immunity", February 25, 2011.

Dec 2008: Approval to start Phase I clinical trials. Phase I study proposal (IMPD, IB, clinical protocol, etc.) was submitted and approved by the Independent Ethics Committee (IEC) of the Ghent University Hospital. Mymetics received the approval and authorization from the Federal Agency for Medicines and Health Products (FAGG) in Belgium to conduct the clinical trial MYM-V101-CT08-101 (EudraCT number 2008-007306-10) for testing the drug product MYM-V101 (virosomes with the modified and lipidated P1).

Sep.- Oct. 2009: Production of the GMP-grade vaccine (MYMV101: virosomes-modified P1) for the Phase I clinical trial in Belgium. GMP-grade products are notoriously more difficult and costly to produce than GLP-grade ones. Succeeding in the GMP production is considered a major achievement.

Dec. 2009 - Sep. 2010: Phase I clinical trial –"proof of principle" with the final signed report in July 2011. The trial demonstrated that virosomes-modified P1 can induce mucosal antibodies in the genital tract of women, and confirmed the immunogenicity data previously obtained in monkeys. The drug product MYMV-101 was used as a vaccine in a double-blind, placebo-controlled Phase I study at CEVAC (Ghent, Belgium), involving 24 healthy women randomized in two panels to monitor safety and mucosal immunogenicity. In each panel, eight subjects received the vaccine and four subjects received the placebo through intra-muscular and intra-nasal administrations. The Phase I clinical trial achieved its primary objective and showed that the HIV vaccine MYMV101 was safe and well tolerated by healthy women. The secondary objective was also met as the presence of IgG and IgA antibodies in the serum of all vaccinated women was detected. Further, samples showed that mucosal antibodies in the vaginal and rectal secretions were present. Tested vaginal secretions could block *in vitro* the HIV-1 transcytosis, confirming the previous pre-clinical work. Mymetics could claim a shelf life of nine months for its MYM-V101 drug product. Results were published in "PlosOne", February 20, 2013.

Oct. 2014 – to Dec 2017: Non-human primate study in collaboration with Texas Biomedical Research Institute in San Antonio, Texas which was funded by the Bill & Melinda Gates Foundation. The objective of the study: to confirm the results obtained in previous pre-clinical studies and investigate the role of the two antigens. On April 11, 2016, the Company announced results that its HIV vaccine candidate was shown to generate significant protection in groups of 12 female monkeys against repeated AIDS virus exposures during part of the preclinical study. During the first part of the study the Mymetics' two-component virosome-based HIV vaccine was able to show significant efficacy of 87% in delaying the time to persistent infection versus the control group after seven intravaginal virus challenges. The study aimed to mimic the exposure of women to semen from HIV-infected men, although the viral dose of each of these seven animal challenges represented about 70,000 times the average human HIV dose passed during sexual intercourse from an HIV-infected male to an uninfected female. During the second part of the study the animal viral challenge dose was increased by 50% starting from the 8th challenge onward, reaching more than 100,000 times the average amount of virus passed from an infected man to a female partner. At this virus dose, the vaccine did not show significant protection in the animals as the immune system was overloaded. The Company continued its collaboration with the Texas Biomedical Research Institute and Gates Foundation funded laboratories to analyze the serum and mucosal samples to better understand the mechanisms of action of the vaccine and these analyses have not resulted in a significant correlation between presence and quantity of antibodies and level of protection.

Jan. 2018 – to Dec 2018: During this period we have advanced our HIV vaccine candidate mainly in the area of exploring thermostable formulations in powder and in tablet form and optimizing the analytical methods and GMP manufacturing capabilities, all part of the MACIVIVA project mentioned below.

Next steps:
Mymetics and the Texas Biomedical Research Institute are evaluating further collaboration opportunities, and we are starting to plan the clinical trial development for the Mymetics HIV vaccine candidate, building on the MACIVIVA project and the previous Phase I that already showed a good safety and tolerance profile and the induction of mucosal and humoral antibodies. Funding for the clinical trial development will be sought from partners and grant funding organizations. A combined Phase I/II on women and men might start by 2021.

HORIZON 2020-SERI

May 2015 to Nov. 2018: the MACIVIVA project (Manufacturing of Cold-chain Independent VIrosome Vaccines) as part of the EU Horizon 2020 research and innovation framework program started in May 2015 and finished in November 2018. Mymetics has lead this consortium project bringing together the consortium partners Catalent UK Swindon Zydis Ltd, Chimera Biotec GmbH (Germany), Upperton Ltd. (UK) and Bachem AG (Switzerland). A total of E8.4 million of grants was approved, of which E5.3 million is funded as part of Horizon 2020 and up to E3.1 million of funding was provided by the Swiss State "Secretariat for Education, Research and Innovation" (SERI) for the Swiss based consortium partners. The grant funds the evaluation, development and manufacturing scale-up of thermo-stable and cold-chain independent nano-pharmaceutical virosome-based vaccine candidates. Of the total amount, E3.8 million was directly attributable to Mymetics' activities, with the remaining balance going to the consortium partners. The project duration was 42 months and started on May 4, 2015.

In May 2015, the Company received a pre-payment from the two granting organizations for a total value of E1,554. A second pre-payment of E917 from the EU was received in December 2016, and E614 from "SERI" was received in April 2017, which was used to finance the next reporting covering the period of November 2016 to October 2017. In November 2017, the Company submitted the second report and a new request for payment, which resulted in another pre-payment from the EU of E77 received in February 2018. This brings the total cash received year to date to E3,162, which represents 82% of the agreed grant amount and the maximum funding available until the end of the project. The final report submitted in December 2018 to the EU has been approved on February 7, 2019 and the final payment has been received on February 22, 2019. The final report for Mymetics SA submitted to SERI has been approved on March 4, 2019 and the final payment received on March 19, 2019. This brings the total funding received to E3,693.

The project resulted in the development of analytical methods and GMP pilot lines to analyze and manufacture virosomes formulations into spray dried and freeze dried powder, sub-lingual and oral tablet formulations under GMP. Further studies showed that spray dried virosomes in a powder formulation stored at 4°C (40°F) or 40°C (104°F) maintained its structural integrity, while the liquid virosome formulation showed strong structural degradation at 40°C (104°F). Pre-clinical in vivo studies showed that Mymetics HIV-1 virosome vaccine candidate, after being down stream processed into different powder solid dosage forms, could trigger specific antibodies, which were variable depending on the formulation. In further pre-clinical in vivo studies, it was confirmed that the nasal delivery of spray dried virosomes was an effective, needle-free route for immunization, with levels of immune response comparative to that obtained by subcutaneous injection.

Next Steps:
The project has come to an end in November 2018. The know-how and expertise that has been created and the partnerships that have been built, will now be applied at first to the Mymetics HIV-1 vaccine candidate development and also applied to other virosome based vaccines.

Respiratory Syncytial Virus (RSV)

Respiratory syncytial virus (RSV) is a disease that causes infections of the lower respiratory tract, mainly in infants and young children. The virus, which belongs to the Paramyxoviridae family, can cause symptoms similar to the common cold, but can also lead to otitis media (middle ear infection), pneumonia, and bronchiolitis (inflammation of the small airways in the lung). Infection with RSV early in life can increase the chances of developing recurrent wheezing and asthma. Globally, RSV is responsible for over 30 million new acute lower respiratory infection episodes annually and up to 199,000 deaths in children under five years old, with 99 percent of these deaths occurring in low-resource countries. It is so widespread in the United States that nearly all children become infected with the virus before their second birthdays. The elderly population is also at risk of severe RSV disease.

Approach: The RSV vaccine consists of the reconstituted membrane of RSV containing the native viral proteins, which can be adjuvanted with a lipopeptide or other adjuvants. In mice, our RSV vaccine was shown to induce cellular and humoral immunity to the virus, with a balanced Th1/Th2 response, resulting in protection against a live virus challenge, and without inducing “enhanced disease” (a skewed Th1/Th2 response being the hallmark of enhanced disease). In cotton rats, a better model than mice for RSV, the vaccine protected against a live virus challenge, without inducing enhanced disease. In a direct comparison with the 1960’s vaccine of another pharmaceutical company that caused severe safety issues in infants, another group of cotton rats was immunized with formaldehyde-inactivated virus, and developed enhanced disease after vaccination and challenge. Mymetics focuses on developing an RSV vaccine for elderly followed by a vaccine for children.

Key Results to date:

2007: First pre-clinical research on our RSV vaccine.

2008 and 2009: MedImmune repeated key experiments in order to obtain their own validation of the results. Results were beyond their expectation, but MedImmune decided not to continue the program.

2010: Conducting additional pre-clinical research and improving the manufacturing procedure of the RSV virosomes and publication of Mymetics RSV results in scientific journal “Vaccine”.

2011: Improved the understanding of the adjuvant ratio in different formulations and continued further tests on cotton rats and mice at the University of Groningen, Netherlands, showing that a different adjuvant ratios still triggered protection and the absence of enhanced disease and the vaccine could trigger systemic and mucosal antibodies.

May 2012: Publication of Mymetics RSV vaccine results in scientific journal “PLOSONE”.

2013: Improved up-scale capabilities and up and down stream process of vaccine production and tested different formulations.
March 2013: Publication of Mymetics RSV vaccine results in scientific journal “Vaccine”.

April 2013: Publication of Mymetics RSV vaccine results in scientific journal “Influenza Journal”

Dec. 2013: Mymetics signed a License and Collaboration Agreement with RSV Corporation (RSVC), a dedicated entity specifically set-up for developing the Mymetics RSV vaccine. Under this agreement Astellas Pharma Inc. agreed to fund RSVC’s development of the virosome vaccine technology, licensed from Mymetics for the respiratory syncytial virus (RSV) through completion of a Phase 2b human proof-of-concept study. Based on the strategic partnership, Astellas received exclusive rights to acquire RSVC as well as further develop and commercialize the vaccine product. We provided research and development activities for the pre-clinical phases, prepared for the upscale production and assay developments and provided further scientific advice on the development of the RSV virosome vaccine.

Jan. 2016: Mymetics received notice from RSV Corporation (RSVC) that it would no longer pursue the development of a vaccine technology for RSV in order to focus on other infectious therapies. The LCA which was signed on December 27, 2013, between Bestewil Holding BV and RSVC, was formally terminated as of July 25, 2016. Mymetics regained all the rights, results and data related to the research, development and commercialization of this vaccine candidate.

Next steps:
Following the termination of the license and collaboration agreement with RSVC in 2016, Mymetics has currently put the further development of this vaccine candidate on hold.

Intranasal Influenza

Approach: The intranasal influenza vaccine consists of the reconstituted membrane of influenza virus, also containing a lipopeptide adjuvant. In mice, intranasal application of virosomes without adjuvant does not induce immunity to influenza; however, incorporation of the lipopeptide in the virosomes produces a candidate vaccine that does induce cellular immunity, as well as serum and mucosal antibodies to the virus. The vaccine was licensed to Solvay Pharmaceuticals, a major European pharmaceutical company, which was acquired by Abbott Laboratories. Since October 2011, Mymetics has been able to reclaim the intra-nasal influenza vaccine in its portfolio as Abbott decided not to continue the product due to strategic decisions.

Key results to date:

2005: The vaccine completed pre-clinical trials. A first milestone payment was received from Solvay in the same year.

2006: Successful completion of Phase I trial. The vaccine was shown to be safe and well tolerated and induced an immune response which met and exceeded CHMP (European regulatory) criteria for an off-the-shelf injected vaccine. Subsequent milestone payment was received.

Dec. 2016: Research project with Sanofi Pasteur. Mymetics B.V., the 100% subsidiary of Mymetics Corporation, agreed on a research project with Sanofi Pasteur, the vaccine division of Sanofi (SNY). The project will investigate the immunogenicity of influenza vaccines based on Mymetics’ proprietary virosome technology platform in pre-clinical settings.

Oct: 2017: The Company entered into an Amendment effective October 20, 2017, of the Research Agreement dated December 1, 2016 with Sanofi Pasteur Biologics, LLC, the vaccine division of Sanofi SA, (“Sanofi”), to extend the date of the Research Agreement for an additional year. The initial results of the recent study did not achieve the expected benefits of Mymetics’ influenza virosomes and were contrary to earlier results Mymetics obtained with Solvay in multiple studies. Mymetics agreed to pay for a redesigned study.

Jan. 2018 to date: Mymetics finished the study during Q4 2018 and presented the data to Sanofi. The blinded study incorporated 12 groups of 10 mice which received different virosome formulations, administered through different routes, and one control formulation. The results were positive for most of Mymetics virosome formulations, some virosomes generated significantly higher HA inhibition (HAI) titers and good antibody titers. Although this study was successful and the Company has discussed the results with Sanofi, Mymetics for the time being will not be continuing its collaboration with Sanofi due to other priorities of Sanofi. We are evaluating the possible publication of the results.

Malaria

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female mosquitoes.
About 3.2 billion people – almost half of the world's population – are at risk of malaria. Young children, pregnant women and non-immune travelers from malaria-free areas are particularly vulnerable to the disease when they become infected. Malaria is preventable and curable, and increased efforts are dramatically reducing the malaria burden in many places. Between 2000 and 2015, malaria incidence among populations at risk (the rate of new cases) fell by 37% globally. In that same period, malaria death rates among populations at risk fell by 60% globally among all age groups, and by 65% among children under 5. Sub-Saharan Africa carries a disproportionately high share of the global malaria burden. In 2015, the region was home to 88% of malaria cases and 90% of malaria deaths (Source: WHO).

Malaria is caused by a parasite called *Plasmodium*, which is transmitted via the bites of infected mosquitoes. In the human body, the parasites multiply in the liver, and then infect red blood cells.

Malaria being an extremely climate-sensitive disease, a potential risk exists that Global Warming leads Malaria towards areas in higher latitudes.

Approach: The malaria vaccine design is based on optimized mimicry of the native parasite protein structure and eliciting antibodies against two stages of the parasite life cycle, unlike 70% of vaccine candidates, which target only one or the other parasite. It is today among the rare malaria vaccine candidates able to also boost existing malaria immune responses (it has both prophylactic and therapeutic effects) in subjects that were previously exposed to malaria. A second malaria vaccine candidate is under development as Mymetics virosome technology and know-how had been selected to collaborate with PATH-MVI and the LMIV (NIAID) to develop a transmission blocking malaria vaccine candidate based on the virosome technology and two antigens provided by LMIV.

Key results to date:

2007: Mymetics acquired a Malaria vaccine project from Pevion Biotech (Ittigen, Switzerland). A human clinical trial Phase Ia for the vaccine with two antigens (AMA-1 and CSP-1) anchored to virosomes was successfully completed on adults in Switzerland. Results showed good safety and tolerability, and the induction of blood antibodies.

2008 - 2009: Phase Ib in Tanzania on children and young adults. The clinical trial Phase Ib in Tanzania evaluated the safety of the same antigens with virosomes on children and young adults under "native" (endemic) conditions. The final report showed that the vaccine induced specific AMA and CSP antibodies in the majority of children and the CSP antibodies have remained up 12 months. The overall malaria clinical episodes were reduced by 50% in vaccinated group compared to the placebo group.

Nov. 2014: Transmission blocking malaria vaccine preclinical study. Mymetics signed an agreement with PATH Malaria Vaccine Initiative (MVI) and the Laboratory of Malaria Immunology and Vaccinology (LMIV) of the National Institute of Allergy and Infectious Diseases (NIAID), where Mymetics developed and produced virosome based vaccine formulations for a malaria transmission-blocking vaccine candidate which was based on two antigens provided by LMIV. The vaccine formulations were tested in animal models. PATH MVI funded all activities under this project, which started in January 2015.

Apr. 2016: The Company announced that the preclinical study funded by PATH-MVI and in collaboration with LMIV where Mymetics' virosome based formulations for a malaria transmission-blocking vaccine candidate were tested and compared with other vaccine formulations, had been successful. The study showed that the virosome vaccine candidates, at the highest dose tested, generated high antibody titers against the required antigens and they were able to significantly reduce (97-100%) the transmission of the Plasmodium falciparum parasite. The Company is currently evaluating funding opportunities for the next steps of development.

Jan. 2018 to Nov. 2018: Mymetics has continued to collaborate with LMIV and produced different malaria transmission blocking virosome formulations that were tested in *in vivo* pre-clinical studies at LMIV and compared with clinical trial formulations. The results of this study were presented at the 67 th American Society of Tropical Medicine and Hygiene (ASTMH), held from October 28 – November 1, 2018 in New Orleans, Louisiana. The poster highlighted that virosomes containing the Pfs230D1M antigen and TLR7/8 agonist produced durable Pfs230D1M antibody titers over a period of 126 Days in CD-1 mice. The titers and functional activity of sera generated by the Pfs230D1M OEG-TLR7/8 virosomes were comparable to those generated by a liposomal formulation similar to the clinical benchmark. The combination of TLR4 + TLR7/8 in the virosome did not increase titer or function of the TLR4 only virosome.

Next steps:
Mymetics is currently evaluating possible the further development of a malaria vaccine in collaboration with PATH-MVI and LMIV. In parallel, Mymetics is in collaboration with the Swiss Tropical and Public Health Institute and researchers at Oxford University to add two important antigens for a possible malaria vaccine candidate, the RH5 and the CyRPA peptides and has received access to EU supported laboratories under the Transvac2 program to execute the development of the tetra-valent malaria vaccine candidate and test this in pre-clinical studies in 2019.

Chikungunya virus (CHIKV):

Chikungunya is a mosquito-borne, single-stranded, positive-sense RNA virus (family *Togaviridae*, genus *Alphavirus*) that has caused sporadic outbreaks every 2-50 years of predominantly rheumatic disease, primarily in Africa and Asia. CHIKV recently (2004-2016) produced the largest epidemic recorded for an alphavirus with an estimated 1.4 to 6 million patients, and imported cases reported in nearly 40 countries including Europe, Japan and the Americas (since 2013). The first autochthonous CHIKV infections in Europe (Italy in 2007 and France in 2010) were also seen during this epidemic. Although *Aedes aegypti* is the traditional vector for CHIKV, the recent outbreak was associated with the emergence of a new clade of CHIKV viruses, which were efficiently transmitted by *Aedes albopictus* mosquitoes, a vector that has seen a dramatic global expansion in its geographic distribution is a viral disease transmitted to humans by infected mosquitoes, of the type aug (same type as Zika and Dengue). It causes fever and severe joint pain. Other symptoms include muscle pain, headache, nausea, fatigue and rash. Joint pain is often debilitating and can vary in duration.

Approach: There are no vaccines available for Chikungunya although there are several in development, of which one is in a clinical trial Phase II. Mymetics' novel approach in CHIKV vaccine development is the generation of virosomal vaccines using the CHIKV envelope glycoproteins produced in insect cells. Virosomes are reconstituted viral envelopes, consisting of membrane lipids and viral spike glycoproteins. The external surface of the virosome resembles that of a virus particle, with spike (glyco) proteins protruding from the lipid membrane. Virosomes lack viral genetic material. The advantage is that highly purified CHIKV spikes (expressed in insect cells) will be used to constitute the virosomes. Thus, insect cell material (DNA, proteins) will be completely absent from the virosomal vaccine material. CHIKV spikes can be obtained from different sources: VLPs, from baculovirus virions or from the plasma membrane of insect cells.

Jan. 2016 to date: Mymetics has started the discovery phase of this project where we are assessing the overall CHIKV glycoprotein yields in scale up insect cell culture. In this project we have worked with the University of Wageningen in the Netherlands that has extensive expertise in this field. The project has been delayed due to other priorities and the aim is to start preclinical animal studies during 2019 if resources are available.

Immunotherapy evaluation projects:

Mymetics is exploring the application of the virosome vaccine technology for the use in immunotherapy in the fields of allergy and in oncology. This exploration and testing is done through collaboration and research projects with specialist biotech companies in the appropriate fields.

Allergy:
In April 2018 Mymetics engaged in a Research and Option to License Agreement with Anergis SA. Under the agreement, a mice proof-of-concept immunogenicity study evaluated the effects of the Bet v 1 COPs (Anergis' proprietary birch pollen allergy peptides) using the five subcutaneous injection schedule used in former AllerT clinical trials. The development of AllerT (Bet v 1 COPs plus aluminum hydroxide) was discontinued by Anergis in 2017 following completion of a Phase 2 clinical trial showing evidence of sensitization to the peptides and a 7% reduction in seasonal allergy symptoms vs placebo ($p=0.0047$). In the mice study, AllerT was compared to Bet v 1 COPs linked to Mymetics' virosomes (the "Bet v 1 COP-virosomes"). In December 2018 Anergis and Mymetics reported that the administration of AllerT led to the development of Bet v 1 specific IgEs ($p<0.001$) associated with a more pronounced TH2 than TH1 response. In contrast, in the mice receiving the Bet v 1 COP-virosomes, no development of Bet v 1 specific IgEs were observed ($p<0.001$ vs AllerT). With the same dose of Bet v 1 COPs, there was a strong boost of immunogenicity with a TH1 antibody response, which was a hundred times greater than with aluminum hydroxide ($p<0.001$). The Bet v 1 COP-virosomes were well tolerated. The success criteria were met and Anergis has now a time limited option to enter into an exclusive license agreement with Mymetics for the use of virosomes in the field of allergies.

Oncology:
Mymetics has strong data that shows that its virosomes have the capability to not only trigger good antibody responses, but also are able to trigger specific T-Cell responses as virosomes are able to be absorbed and processed by dendritic cells when specific antigens are incorporated into virosomes. This is of particular importance for developing a specific cancer immunotherapy. Since Q4 2018 Mymetics is exploring the possibilities to collaborate with biotech companies in the field of oncology. One of these projects was announced in October 2018 with eTheRNA immunotherapy NV, for an exploration project in the very challenging field of mRNA delivery for cancer immunotherapy.

MATERIAL THIRD PARTY AGREEMENTS

For the development of its vaccines the Company has entered into several agreements in the form of license agreements, exploitation agreements or co-ownership agreements with third parties. These third parties provide specific experience and capabilities or provide access to specific know how, which are not the core competence of Mymetics. The Company believes that the following third party agreements are material. The following summaries of their material terms are qualified in their entirety by reference to the agreements filed as exhibits to prior SEC filings by the Company as set forth under Item 15 (Exhibits and Financial Statement Schedules).

INSERM

The Co-Ownership Agreement dated January 8, 2008 for two patents PCT IB2005/001180 and PCT IB2005/001182, has been cancelled by Mymetics as it does not fit the strategic direction of the Company.

Exploitation Agreement dated January 8, 2008 that allows Mymetics to have global rights to develop, promote, produce, co-produce, sell and distribute HIV products based on any of the following three patents: PCT IB2005/001180, PCT IB2005/001182 and PCT IB 2006/000466 has been amended on August 4, 2011 and now only includes the PCT IB 2006/000466 patent. On October 9, 2013 this agreement was renegotiated and amended to link the progress of the related technology to milestones, which was reflected in the following financial considerations:

Milestone payments:

- By December 2013: E100 (paid in February 2014)
- Start of a second phase I: E50
- Positive results of second phase I: E100
- Positive results of phase II: E310
- Start of phase III: E1,000
- Positive results of phase III: E740
- Receipt of BLA Authorization: E1,000

Royalty payments in case of direct or indirect commercialization:

- For sales below E250,000: 1%
- For sales between E250,000 and E500,000: 2%
- For sales more than E500,000: 3%

The Exploitation Agreement terminates upon the later of: the expiration date of the longest-lived patent, or, 10 years after the first date of commercialization of the product, unless terminated by INSERM following market approval of the HIV products in the event (i)Mymetics does not develop the product for a period more than six months, (ii) the exploitation of the product is interrupted for a period of more than twelve months, or (iii) there is an absence of sales for twelve months starting from the date of market approval.

SANOFI PASTEUR BIOLOGICS

On December 1, 2016, Mymetics Corporation entered into a material definitive Research Agreement with Sanofi Pasteur Biologics, LLC, the vaccine division of Sanofi (SNY). The project was established to investigate the immunogenicity of influenza vaccines based on Mymetics' proprietary virosome technology platform in pre-clinical settings. If this project is successful it could result in a further and more extensive collaboration between the two companies. The project duration was 12 months and started in January 2017.

On October 20, 2017, the Company entered into an Amendment of the Research Agreement dated December 1, 2016 with Sanofi Pasteur Biologics, LLC, the vaccine division of Sanofi SA ("Sanofi"), to extend the date of the Research Agreement for an additional year. Under the terms of the Research Agreement Sanofi wanted to compare the immunogenicity of Mymetics' influenza virosomes compared to Sanofi Pasteur's egg-based split vaccine. The interest of Sanofi in a collaboration with Mymetics was based on the results of preclinical and clinical studies a few years ago with Solvay Pharmaceuticals that was acquired by Abbott in 2013. The initial results of the recent study did not achieve the expected benefits of Mymetics' influenza virosomes and were contrary to earlier results Mymetics obtained with Solvay in multiple studies. Mymetics believes that there was an issue with the influenza virosome formulations that were produced. Mymetics agreed to pay for a redesigned study. The executed blinded study in mice with an external service provider incorporated 12 groups of 10 mice, each group receiving a different virosome formulation, administered through different routes and one control formulation. The results were positive for most of Mymetics' virosome formulations. Some virosomes generated significantly higher HA inhibition titers (HAI) than the comparator group and good antibody titers. Although this study was successful and the Company has discussed the results with Sanofi at the end of the year, Mymetics, for the time being, is not continuing its collaboration with Sanofi due to other priorities of Sanofi. We are evaluating the possible publication of the results and exploring other opportunities to advance the findings.

ANERGIS SA

In April 2018, the Company entered into a Research and Option to License Agreement with Anergis SA ("Anergis"). Under the terms of the Research Agreement, a pre-clinical study program was triggered and evaluated the immunogenicity profile of the Anergis' peptides designed to treat birch allergy when presented on Mymetics' proprietary virosomes, with or without undisclosed TLR ligands or other adjuvants. The results were compared to Anergis' AllerT product combination.

In December 2018, Mymetics and Anergis announced that the pre-clinical study program was successful. The pre-defined success criteria were met and Anergis has now a time limited option to enter into an exclusive license agreement with Mymetics for the use of virosomes in the field of allergies. Should Anergis and Mymetics execute a License and Collaboration Agreement (LCA), Anergis would make an upfront payment to Mymetics in an amount that increases as the date of the LCA is executed. The LCA also includes milestone payments based on certain regulatory clearances and royalties for net sales. The contractual material had been delivered during the third quarter of the year 2018 and 100% of the agreed payments from the Research and Option to License Agreement has been received and fully recognized as revenue in Q3 2018. The LCA has not been executed as of the date this report has been filed.

INTELLECTUAL PROPERTY

WO/2004/071492	DCPC	Bestewil BV	Expiration date: February 11, 2024
Virosome-like particles			
WO/2004/045641	APRECS	Bestewil BV	Expiration date: November 19, 2023
Antigen-complexes			
WO/2004/078099	AMA49	Mymetics Corporation	Expiration date: March 2, 2024
Compositions and methods for the generation of immune response against Malaria			
WO/2004/106366	UK39	Mymetics Corporation	Expiration date: June 1, 2024
Methods for synthetizing conformationally constrained peptides, peptidomimetics and use of such peptidomimetics as synthetic vaccines			
WO/2004/110486	Lipopeptide	Bestewil BV	Expiration date: June 17, 2024
Functionally reconstituted viral membranes containing adjuvant			
WO/2007/099446	Virosome-P1	Mymetics Corp/Inserm/Pevion	Expiration date: March 2, 2027
Virosome-like vesicles comprising gp41 - derived antigens			
US/2009/0202215	GP41 4th gen	Mymetics Corporation	Expiration date: February 8, 2030
US/2009/0202219	Splitting GP41	Mymetics Corporation	Expiration date: February 8, 2030
WO/2016/039619	Virosome with adjuvants	Bestewil BV	Expiration date: September 12, 2034

COMPETITION

We have not yet developed an actual product. Our future competitive position depends on our ability to successfully develop our intellectual property, and to license or sell such intellectual property to third parties on financially favorable terms. Although we believe that the results of our research and development activities have been favorable, there are numerous entities and individuals conducting research and development activities in the area of human biology and medicine, all of which could be considered competitors.
The worldwide vaccine market is dominated by five large multinational companies: Sanofi Pasteur S.A., Merck & Co., GlaxoSmithKline Plc, Pfizer and Seqirus - CSL. Smaller and mid-size companies such as Crucell (acquired by Johnson & Johnson), Novavax and PaxVax are developing vaccines in the same area as Mymetics.

While many of these entities have greater financial and scientific capabilities, and greater experience in conducting pre-clinical and clinical trials, the Company believes that its innovative approach to vaccine development is very competitive.

GOVERNMENTAL REGULATION

Our strategy was crafted in part to minimize the risks usually associated with Phase III clinical trials, regulatory approvals and marketing, which are expected to be borne by one or more future partners.

We contract with third parties to perform research projects related to our business. These third parties are located in various countries and are subject to the applicable laws and regulations of their respective countries. Accordingly, regulation by government authorities in the United States, the European Union and other foreign countries is a significant factor in the development, manufacture and marketing of our proposed products by our future partners and therefore has a direct impact on our ongoing research and product development activities.

Any products that will be developed by our future partners based on our technology will require regulatory approval by government agencies prior to commercialization. In particular, like human therapeutic products, vaccines are subject to rigorous pre-clinical studies and clinical trials and other approval procedures of the FDA and similar regulatory authorities in foreign countries. In addition, various federal and state statutes and regulations will also govern, or influence testing, manufacturing, safety, labeling, storage and record keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent substantial compliance with appropriate federal and state statutes and regulations require the expenditure of substantial time and financial resources. Obtaining royalties in the future will depend on our future partners' ability to obtain and maintain the necessary regulatory approvals.

Pre-clinical studies are generally conducted on laboratory animals to evaluate the immunogenicity (induction of antibodies of the cellular response), first proof of potential efficacy and safety of a product. In light of our limited financial resources, clinical trials of our vaccines are conducted first in Europe under the European Union (“EU”) guidelines, a quicker and less expensive approach than seeking FDA approval, which we intend to do after EU approval is granted and we expect our financial resources to be greater. There is however no certainty that such EU approval will be granted. The Phase I, II and III EU clinical trials are similar to those required for FDA approval. The FDA requirements are addressed in this discussion.

The process which is described below is therefore to be considered as generic background information which is relevant to the industry as a whole. As such process applies to drugs as well as vaccines, the term “drugs” as used hereafter refers also to vaccines.

In the United States, any company developing new drugs must submit the results of pre-clinical studies to the FDA as a part of an investigational new drug application, or IND, which application must become effective before it can begin clinical trials in the United States. An IND becomes effective 30 days after receipt by the FDA unless the FDA objects to it and the IND must be annually updated. Typically, clinical evaluation involves a time-consuming and costly three-phase process.

Phase I refers typically to closely monitored clinical trials and includes the initial introduction of an investigational new drug into human patients or normal healthy volunteer subjects. Phase I clinical trials are designed to determine the safety (metabolic and pharmacologic actions of a drug in humans), the side effects associated with increasing drug doses and, if possible, to gain early evidence on effectiveness (inductions of antibodies in our case). Phase I trials also include the study of structure-activity relationships and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. During Phase I clinical trials, sufficient information about a drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase II studies. The total number of subjects and patients included in Phase I clinical trials varies but is generally in the range of 20 to 80 people. Bioanalyses on the clinical trial samples in different *in vitro* assays must be conducted under good laboratory practice (GLP). At this stage, all techniques must be qualified according to standard operating procedures (SOPs) but it is not required to have the assays validated. Validating an assay consists of analyzing or verifying the 8 or 9 assay parameters as described in the US pharmacopeia or the ICH guidelines: 1) accuracy; 2) precision; 3) limit of detection; 4) limit of qualification; 5) specificity; 6) linearity and range; 7) robustness; and 8) system suitability.

Phase II refers to controlled clinical trials conducted to evaluate the safety and effectiveness of a drug for a particular indication or indications in patients with a disease or condition under study and to determine the common short-term side effects and risks associated with the drug. These clinical trials are typically well-controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. For prophylactic vaccines, a fraction of the enrolled subjects for the Phase II trials should ideally correspond to people at higher risk to contract the infection due to their social and/or sexual behaviors. At this stage, all identified and relevant techniques must be qualified and validation should be initiated prior starting the phase II and full validation must be achieved at the end of the phase II, prior launching Phase III. Completion of Phase II trials generally corresponds to the “stage of development” where big Pharma have a high interest for the drug product.

Phase III refers to expanded controlled clinical trials, which many times are designated as "pivotal trials" designed to reach end points that the FDA has agreed in advance, if met, would allow approval for marketing. These clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained. Meanwhile, prophylactic vaccines are different because the true evidence of effectiveness is obtained during the Phase III trials involving an important fraction of the enrolled subjects with high risk of contracting the pathogen, providing more statistical power. Depending on the vaccine tested, vaccinated subjects are monitored over a period of few months to several years and the infection rate (protection) of this group is compared to the placebo treated group. Phase III trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III clinical trials can include from several hundred to tens of thousands of subjects depending on the specific indication being tested.

The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted in the United States and may, at its discretion, re-evaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. Once Phase III trials are completed, drug developers submit the results of pre-clinical studies and clinical trials to the FDA, in the form of a new drug application, or NDA, for approval to commence commercial sales. In response, the FDA may grant marketing approval, request additional information or deny the application if the FDA determines that the application does not meet the predetermined study goals and other regulatory approval criteria.

Furthermore, the FDA may prevent a drug developer from marketing a product under a label for its desired indications, which may impair commercialization of the product.

If the FDA approves the new drug application, the drug becomes available for physicians to prescribe in the United States. After approval, the drug developer must submit periodic reports to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional studies, known as Phase IV clinical trials to evaluate long-term effects. We will be required to comply with similar regulatory procedures in countries other than the United States.

In addition to studies requested by the FDA after approval, a drug developer may conduct other trials and studies to explore use of the approved compound for treatment of new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

At this time, neither we nor any of our partners have submitted any of its pre-clinical results to the FDA. Our partners and future partner(s) will have to complete an approval process, similar to the one required in the United States, in virtually every foreign target market in order to commercialize product candidates based on our technology in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. Approvals (both foreign and in the United States) may not be granted on a timely basis, or at all. In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the resulting prices would be insufficient to generate an acceptable return to our partner(s).

EMPLOYEES

Ronald Kempers is our President and Chief Executive Officer.

Our Swiss subsidiary, Mymetics S.A., has on its payroll, besides the CEO, three employees: the Company’s Chief Scientific Officer, the Director of Finance and the Head of Manufacturing and Quality.

Mymetics B.V. has one full time executive officer (CSO), one part-time administrative assistant and three technicians.

WWW.MYMETICS.COM

News and information about Mymetics Corporation are available on our web site, www.mymetics.com.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below together with all of the other information included in this report on Form 10-K. An investment in our common stock is risky. If any of the following risks materialize, our business, financial condition or results of operations could be adversely affected. In such an event, the trading price of our common stock could decline, and you may lose part or all of your investment. When used in these risk factors, the terms "we" or "our" refer to Mymetics Corporation and its subsidiaries.

We are a company engaged exclusively in research and development activities, focusing primarily on vaccine development. Our strategy was crafted in part to minimize the risks usually associated with clinical trials, regulatory approvals and marketing, which we would expect to be borne by our future partner(s).

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We historically have incurred net losses. In the years ended December 31, 2018, and December 31, 2017, we sustained net loss of approximately E4,172 and E4,112, respectively. At December 31, 2018, we had an accumulated deficit of approximately E84,675.

The amount of these losses may vary significantly from year-to-year and quarter-to-quarter and will depend on, among other factors:

- the timing and cost of product development;
- the progress and cost of preclinical and clinical development programs;
- the timing and cost of obtaining necessary regulatory approvals;
- the timing and cost of sales and marketing activities for future products; and
- the costs of pending and any future litigation of which we may be subject.

We currently are engaged in research and development activities and do not have any commercially marketable products. The research and development process requires significant capital expenditures.

The RSV vaccine activities were funded through incoming revenue from RSV Corporation and were formally terminated as of July 25, 2016. We also have attracted funding from PATH-MVI for our malaria vaccine development and from the Bill & Melinda Gates Foundation for the non-human primate study for our HIV vaccine candidate at Texas Biomedical Research Institute. In April 2015, Mymetics announced that it was leading a consortium of companies that have received a grant worth a total of E8.4 million. The grant will fund the evaluation, development and manufacturing scale-up of thermos-stable and cold-chain independent nano-pharmaceutical virosome-based vaccine candidates. These revenue streams and funds are not fully covering the costs of all our activities.

Accordingly, we expect to generate additional operating losses at least until such time as we are able to generate significant revenues.

To become profitable, we will need to generate revenues to offset our operating costs, including our general and administrative expenses. We may not achieve or, if achieved, sustain our revenue or profit objectives, and our losses may increase in the future, and, ultimately, we may have to cease operations.

In order to generate new and significant revenues, we must successfully develop and commercialize our proposed products or enter into collaborative agreements with others who can successfully develop and commercialize them. Our business plan is predicated on commercializing our products in collaboration with others. Even if our proposed products are commercially introduced, they may never achieve market acceptance and we may never generate significant revenues or achieve profitability.

We will require additional capital to fund our operations, and if we fail to obtain necessary financing, we will be unable to complete the development and potential commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to launch and commercialize our vaccine product candidates, if we receive regulatory approval. We will require additional capital for the further development and potential commercialization of our vaccine product candidates. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to the:

- initiation, progress, timing, costs and results of pre-clinical studies and clinical trials, including patient enrolment in such trials, for our product candidates or any other future product candidates;
- clinical development plans we establish for our current product candidates and any other future vaccine product candidates;
- number and characteristics of vaccine product candidates that we develop or in-license;
- outcome, timing and cost of regulatory review by the Food and Drug Administration, or FDA, and comparable foreign regulatory authorities, including the potential for the FDA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- costs of filing, prosecuting, defending and enforcing any patent claims and maintaining and enforcing other intellectual property rights;
- effects of competing technological and market developments;
- costs and timing of the implementation of commercial-scale manufacturing activities; and
- costs and timing of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.
- If we are unable to expand our operations or otherwise capitalize on our business opportunities due to a lack of capital, our ability to become profitable will be compromised.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates.

Until we can generate substantial revenue from product sales, if ever, we expect to seek additional capital through a combination of private and public equity offerings, debt financings, strategic collaborations, alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. Debt financing, if available, may involve agreements that include liens or other restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends, or issuing warrants that if exercised could be dilutive to our stockholders. If we raise additional funds through strategic collaborations and alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or any other future product candidates in particular countries, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant third parties rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We have not generated any revenues to date from vaccine product sales. We may never achieve or sustain profitability, which could depress the market price of our securities, and could cause you to lose all or a part of your investment.

To date, we have no vaccine products approved for commercial sale and have not generated any revenues from sales of any vaccine product candidate. We do not know when, or if, we will generate any revenues in the future. Our ability to generate revenue from product sales and achieve profitability will depend upon our ability to successfully gain regulatory approval and commercialize our current or future vaccine product candidates. Even if we are able to successfully achieve regulatory approval for any of our vaccine product candidates, we do not know when they will generate revenue from product sales for us, if at all. Our ability to generate revenue from product sales from our current or future product candidates also depends on a number of additional factors, including our ability to:

– successfully complete development activities, including enrolment of study participants and completion of the necessary clinical trials;

– complete and submit new drug applications, or NDAs, to the FDA, and obtain regulatory approval for indications for which there is a commercial market;

– complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities;

– make or have made commercial quantities of our products at acceptable cost levels;

– develop a commercial organization capable of manufacturing, selling, marketing and distributing any products we intend to sell ourselves;

– find suitable partners to help us market, sell and distribute our approved products in markets other than the markets in which we choose to commercialize on our own; and

– obtain adequate pricing, coverage and reimbursement from third parties, including government and private payers.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for our product candidates, we anticipate incurring significant costs associated with commercializing our product candidates.

If we fail to become profitable or are unable to sustain profitability on a continuing basis then we may be unable to continue our operations at planned levels, which would depress the market price of our securities.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

Two of our major shareholders, Round Enterprises and Eardley Holding, have issued secured convertible notes, short term convertible notes and short term promissory notes, which have a total carrying amount of E54,370, including currently due interest. Under the terms of the convertible notes both Round Enterprises and Eardley Holding have the right to demand repayment at the end of the quarter following the repayment request of those convertible notes and exercise their rights as secured creditors under the terms of these notes, and we are required to repay the other notes unless Round Enterprises and Eardley Holding elect to convert the notes. We could in the future incur additional indebtedness beyond our borrowings under the outstanding secured convertible notes.

Our outstanding indebtedness combined with our other financial obligations and contractual commitments, including any additional indebtedness beyond our borrowings under our secured convertible notes issued to Round Enterprises and Eardley Holding, could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, and prepayment and repayment fees and penalties, thereby reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our existing debt. Failure to make payments or comply with other covenants under our existing debt instruments could result in an event of default and acceleration of amounts due. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets, including our intellectual property.

We might not be able to utilize a significant portion of our net operating loss carryforwards and foreign tax credit carryforwards.

As of December 31, 2018, we had federal net operating loss carryforwards in the U.S. of E76 million. Of this amount, E73 million will expire in years 2019-2037. Tax credit carryforwards of E224 which if not utilized will expire in 2023. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including this offering, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

We might not be able to continue as a going concern.

Our cash balances, recurring losses, negative cash flows from operations, and debt outstanding as of December 31, 2018 and our projected spending in 2019, raise substantial doubt about our ability to continue as a going concern, and our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2018 regarding this uncertainty. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, the inclusion of a going concern statement by our auditors, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect the price of our securities and our ability to raise new capital or to enter into critical contractual relations with third parties.

Risks Related to Our Business and Development of Our Products

Our future success is dependent on the successful clinical development, regulatory approval and commercialization of our vaccine product candidates, which will require significant capital resources and years of additional clinical development effort.

We do not have any products that have regulatory approval. Currently, our vaccine product candidates are in varying stages of development. As a result, our business is dependent on our ability to successfully complete clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize our product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates for a target indication, we must demonstrate with substantial evidence gathered in pre-clinical studies and well-controlled clinical trials, generally including well-controlled Phase III studies to the satisfaction of applicable regulators, that our product candidates are safe and effective for use for the target indication and that the manufacturing facilities, processes and controls are adequate. Even if our product candidates were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of any of our product candidates. Furthermore, even if we obtain regulatory approval for our product candidates, we will still need to develop a commercial organization, establish commercially viable pricing and obtain approval for adequate reimbursement from third party and government payers. If we are unable to successfully commercialize our product candidates, we may not be able to earn sufficient revenues to continue our business.

Because the results of pre-clinical studies or earlier clinical trials are not necessarily predictive of future results, our product candidates may not have favorable results in later clinical trials or receive regulatory approval.

Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of our product candidates. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier pre-clinical studies and clinical trials for our HIV vaccine, we do not know whether the clinical trials we may conduct in the future will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for our product candidates may be adversely impacted.

The therapeutic efficacy of our HIV and our other product candidates is unproven and we may not be able to successfully develop and commercialize our product candidates.

Our ability to generate revenues from our HIV and our other vaccine product candidates, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our successful development and commercialization after regulatory approval, if achieved, which is subject to many potential risks. For example, our HIV vaccine may not demonstrate in study subjects any or all of the results that may have been demonstrated in pre-clinical studies and earlier clinical trials. Our product candidates may interact with human biological systems in unforeseen, ineffective or harmful ways. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early stage testing for treating certain diseases that our product candidates are intended to address have later been found to cause side effects that prevented further development of the products. As a result of these and other risks described herein that are inherent in the development of novel therapeutic agents, we may never successfully develop, enter into or maintain third party licensing or collaboration transactions with respect to, or successfully commercialize, our product candidates, in which case we will not achieve profitability and the value of our stock may decline.

Clinical development of product candidates involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Study subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the subject population, the proximity of subjects to clinical sites, seasonality, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain subject consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and subjects' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new vaccines that may be approved or product candidates that may be studied in competing clinical trials for the diseases we are investigating.

Clinical trials may be delayed, suspended or prematurely terminated for a variety of other reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay or failure in reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delay or failure in obtaining institutional review board, or IRB, approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable study subjects to participate in a trial;
- delay or failure in study subjects completing a trial or returning for post-treatment follow-up;
- clinical sites and investigators deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for competing product candidates with the same or similar indication;
- failure of our third party clinical trial managers to satisfy their contractual duties or meet expected deadlines;
- delay or failure in adding new clinical trial sites;
- ambiguous or negative interim results or results that are inconsistent with earlier results;
- feedback from the FDA, the IRB, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent pre-clinical studies and clinical trials, that might require modification to the protocol for the trial;
- decision by the FDA, the IRB, a comparable foreign regulatory authority, or us, or recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects or adverse events;

- failure of a product candidate to demonstrate any benefit;
- difficulties in manufacturing sufficient quantities of a product candidate for use in clinical trials;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrolment delays, requirements to conduct additional clinical trials or increased expenses associated with the services of our CROs, clinical trial sites and other third parties; or
- changes in governmental regulations or administrative actions.

If we experience delays in the completion of any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from our product candidates, if approved, will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our development and approval process for our product candidates and jeopardize our ability to commence product sales and generate revenues. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any marketing approval.

Undesirable side effects caused by our vaccine product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority or restrictive label requirements. If such side effects or other safety or toxicity issues are reported in our future clinical trials, we may not receive approval to market those products which could prevent us from ever generating revenues or achieving profitability. Results of our clinical trials could reveal an unacceptably high prevalence and severity of side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development, or deny approval, of our product candidates for any or all targeted indications. Drug-related side effects could affect study subject recruitment, affect the ability of enrolled subjects to complete our future clinical trials and may result in potential product liability claims.

Additionally, if any of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- we may be forced to suspend marketing of the product;
- regulatory authorities may withdraw their approvals of the product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of the product;
- we may be required to conduct post-market studies;
- we could be sued, could incur substantial litigation expenses and may be held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of our product candidates, if approved, and materially adversely impact the market price of our securities.

Even if one or more of our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for one or more of our product candidates, they would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The safety profile of our product candidates will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If new safety information becomes available after approval of our product candidates, the FDA or comparable foreign regulatory authorities may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or similar strategy, impose significant restrictions on our product candidates, indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or GMP, and other regulations. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our products or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, a regulatory authority may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall .

The occurrence of any event or penalty described above may inhibit or preclude our ability to commercialize our product candidates and generate revenue.

Changes in regulatory requirements and guidance may also occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Additionally, if we are required to conduct additional clinical trials or other studies with respect to any of our product candidates beyond those that we currently contemplate or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval for our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval for indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals and we may not have sufficient funding to complete the testing and approval process for any of our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business will be materially harmed.

Even if we obtain regulatory approval for a product candidate, our products will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates also may be subject to a Risk Evaluation and Mitigation Strategy, or REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and efficacy of the product. For example, the holder of an approved Biologics License Application (“BLA”) is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;

- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing, manufacturing or distribution of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of products; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and adversely affect our business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of equivalent foreign regulatory agencies, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would materially and adversely affect our business, financial condition, results of operations and prospects.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, including China, Japan and South Korea, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of our product candidates by regulatory authorities in the European Union, China, Japan, South Korea or another country or jurisdiction, the commercial prospects of our product candidates may be significantly diminished and our business prospects could decline.

Risks Related to the Commercialization of Our Products

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, government and private payers and others in the medical community.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, government and private payers, or others in the medical community. Market acceptance of our product candidates, if we receive approval, depends on a number of factors, including the:

- efficacy and safety of our product candidates, or our product candidates administered with other drugs, each as demonstrated in clinical trials and post-marketing experience;
- clinical indications for which our product candidates are approved;
- recommendation of physicians and patients of our product candidates as safe and effective treatments;

- potential and perceived advantages of our product candidates over alternative treatments;
- prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of our product candidates as well as competitive products;
- cost of treatment in relation to any alternative treatments available;
- availability of coverage and adequate reimbursement and pricing by government and private payers;
- relative convenience and ease of administration; and
- effectiveness of our sales and marketing efforts.

Moreover, if our product candidates are approved but fail to achieve market acceptance in the medical community, or our products are restricted, withdrawn or recalled, or fail to be approved, as the case may be, we may not be able to generate significant revenues, which would compromise our ability to become profitable.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sale, marketing and distribution of any approved products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any approved products, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable. By the time that any of our product candidates are available for sale, we may be competing with other companies that have more extensive sales and marketing operations. Without an internal commercial organization or the support of third party sales and marketing functions, we may be unable to compete successfully against these more established companies. To the extent we rely on third parties to commercialize our product candidates, if approved, our revenues from product sales may be lower than if we had commercialized our product candidates ourselves, impacting how quickly we may reach profitability, if at all.

A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.

We plan to seek regulatory approval for our product candidates outside of the United States, and accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including but not limited to:

- differing regulatory requirements in foreign countries;
- the potential local sellers importing goods from a foreign market with low or lower prices rather than buying them locally from us;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

– economic weakness, including inflation, or political instability in particular foreign economies and markets;

– costs of compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

– foreign taxes, including withholding of payroll taxes;

– foreign currency fluctuations, which could result in increased operating expenses and reduced revenues;

– difficulties staffing and managing foreign operations;

– workforce uncertainty in countries where labor unrest is more common than in the United States;

– challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

– production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

– business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our future international operations may materially adversely affect our ability to attain or maintain profitable operations.

Our vaccine product candidates may not receive coverage and adequate reimbursement from third party payers, which could harm our financial performance.

Our ability to commercialize our vaccine product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for our product candidates and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third party payers, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry worldwide is cost containment through limited coverage and reimbursement. Reimbursement rates may vary according to the use of the vaccine and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost vaccines and may be incorporated into existing payments for other services. Net prices for vaccines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third party payers often rely upon government healthcare program coverage policy and payment limitations in setting their own reimbursement policies. Increasingly, third party payers are requiring that vaccine companies provide them with predetermined discounts from list prices and are challenging the prices charged for vaccines. Third party payers may also seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations before covering our product candidates for those patients.

We cannot be sure that coverage and adequate reimbursement will be available for our product candidates and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, and the price of, any approved products. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any approved products. There also may be significant delays in obtaining coverage and reimbursement for newly approved vaccines, and coverage may be more limited than the purposes for which the drug is approved by the relevant regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any vaccine will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new vaccines, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement policies may change and new policies may be adopted, and we cannot predict the likelihood, nature or extent of such changes or new policies, either in the United States or abroad. Our inability to obtain coverage and profitable reimbursement rates from both government-funded and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new vaccine products is highly competitive. We face competition with respect to our product candidates from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are other pharmaceutical and biotechnology companies that currently are pursuing the development of products for the treatment of HIV, RSV, and other indications for which we are developing product candidates. Some of these products and therapies are based on scientific approaches that are similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, foreign government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Compared to us, many of our potential competitors may have significantly greater financial, technical and human resources providing a comparative advantage. As a result of these factors, our competitors may obtain regulatory approval of their products before we are able to, which may limit our ability to gain a share of the market for our product candidates, if approved. Our competitors may also develop vaccines that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or non-competitive before we can recover the expenses of our product candidates' development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors and fewer potential acquirers or collaboration partners, especially if potential acquirers or collaborators acquire companies with competitive products. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us 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, or necessary for, our programs.

Product liability lawsuits against us could cause us to incur substantial liabilities and materially adversely impact our operations.

We face an inherent risk of product liability exposure related to the testing of our vaccine product candidates by us or our investigators in human clinical trials. We will face an even greater risk if one or more of our product candidates receives regulatory approval and we commercially sell our products. Product liability claims may be brought against us by study subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our product candidates or approved products. If we cannot successfully defend ourselves against claims that our product candidates or approved products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, for example:

- decreased demand for our product candidates and/or approved products;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize our product candidates; and
- increased scrutiny and potential investigation by, among others, the FDA, the DOJ, the Office of Inspector General of the HHS, state attorneys general, members of Congress and the public.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of product candidates. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our product liability insurance coverage may not be adequate to cover any and all liabilities that we may incur.

Product liability insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our product liability insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates, but we may be unable to obtain commercially reasonable product liability insurance for our product candidates, if approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Additionally, if any claims are brought against us, even if we are fully covered by insurance, we may suffer harm such as adverse publicity. We also could suffer diversion of attention of technical and management personnel and incur substantial costs in resolving disputes, including litigation, with our insurance provider regarding coverage.

Risks Related to Our Dependence on Third Parties

We rely, and will rely in the future, on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not appropriately carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We rely on third parties to monitor, manage data for, and execute our pre-clinical and clinical programs, and we control only some aspects of their activities. Because we have relied on third parties, our internal capacity to perform these functions is limited. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third party providers. Nevertheless, we are responsible for ensuring that each of our pre-clinical studies and clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific requirements and standards, including, for example, Good Laboratory Practices, or GLP, the Animal Welfare Act and Good Clinical Practices, or GCP. Our reliance on third parties does not relieve us of our regulatory responsibilities. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the relevant regulatory authorities may require us to perform additional clinical trials in support of our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. Failure to comply with these regulations may require us to repeat pre-clinical studies and clinical trials, which would delay the regulatory approval process.

The third parties conducting our pre-clinical studies and clinical trials are not our employees, and, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, nonclinical and pre-clinical programs. To the extent we are unable to identify and successfully manage the performance of third party service providers in the future, our business may be adversely affected. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our pre-clinical studies and clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

If we lose our relationships with the third parties conducting our pre-clinical studies and clinical trials or providing other services to us, our vaccine development efforts could be delayed.

We rely on third parties for pre-clinical studies and clinical trials related to our vaccine development efforts. Our third party service providers conducting our pre-clinical studies and clinical trials generally have the right to terminate their agreements with us upon 90 days' notice for any reason and other service providers may terminate their agreement with us upon shorter notice. Generally, these agreements may also be terminated if we breach the agreement and such breach remains uncured, make a general assignment for the benefit of our creditors or if we are liquidated. Switching or adding additional third party service providers would involve additional cost and requires management time and focus. In addition, there is a natural transition period when a new service provider commences work and the new service provider may not provide the same type or level of services as the original provider. If any of our relationships with our third party service providers terminate, we may not be able to enter into arrangements with alternative service providers or to do so on commercially reasonable terms. Such transactions, if possible, may adversely impact our operations and financial performance.

We have no experience manufacturing our product candidates and have no manufacturing facility. We are dependent on third party manufacturers for the manufacture of our product candidates as well as on third parties for our supply chain, and if we experience problems with any such third parties, the manufacturing of our product candidates could be delayed.

We do not own or operate facilities for the manufacture of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on contract manufacturing organizations, or CMOs, for the manufacture and supply of our product candidates. To meet our projected needs for pre-clinical and clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we may work may need to increase the scale of production. If such CMOs are unable to satisfy our production needs, we will need to identify additional CMOs for continued production of supply for our product candidates. Although alternative third party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers. If we are unable to arrange for alternative third party manufacturing sources on commercially reasonable terms, in a timely manner or at all, we may not be able to complete development of our product candidates, or market or distribute our product candidates.

We are also reliant on the third party manufacturers for regulatory compliance, quality assurance and know-how. Certain components or know-how obtained from partners such as PX Therapeutics, supplier of GMP grade engineered mutated gp41 protein, are key components of our vaccines currently under development. Accordingly, the loss of any of these components or know-how might prevent us from achieving our business plan, despite the fact that contractual safeguards are in place. In addition a failure to synthesize and manufacture our product candidates or products eventually approved, if any, in accordance with our specifications, or the possibility of termination or nonrenewal of the agreement by the third party would be costly or damaging to us. Further, the FDA and other regulatory authorities would require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of our product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for our product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of our product candidates, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction, or imposing civil and criminal penalties.

Disruptions or delays in the supply of our vaccine product candidates would delay development of our product candidates and impair our ability to generate revenues from the sale of our products, if approved.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of our vaccine product candidates or its key materials for an ongoing pre-clinical study or clinical trial could considerably delay completion of our pre-clinical study or clinical trial, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We may elect to enter into licensing or collaboration agreements with respect to some or all of our vaccine product candidates in certain territories. Our dependence on such relationships may adversely affect our business.

Because we have limited resources, we may seek to enter into collaboration agreements with other pharmaceutical or biotechnology companies such as we have done with Astellas Pharma Inc. and our RSV vaccine and that we may do with Anergis SA, who has a time limited exclusive option to enter into a license and collaboration agreement with the Company for virosomes in the field of allergies, pending if Anergis is successful with their fundraising efforts. Our commercialization strategy for our product candidates may depend on our ability to enter into agreements with other collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates in the territories in which we seek to partner. Despite our efforts, we may be unable to secure other collaborative licensing or other arrangements that are necessary for us to further develop and commercialize our product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs.

Any failure by our partners to perform their obligations or any decision by our partners to terminate these agreements could negatively impact our ability to successfully develop, obtain regulatory approvals for and commercialize our product candidates. In the event we grant exclusive rights to such partners, we could be precluded from potential commercialization of our product candidates within the territories in which we have a partner. In addition, any termination of our collaboration agreements will terminate any funding we may receive under the relevant collaboration agreement and may impair our ability to fund further development efforts and our progress in our development programs.

Further, our other potential future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our product candidates receives less attention or resources than we would like, or they may be terminated altogether. Any such actions by our potential future collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our potential future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of our product candidates or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

If our third party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials by our third party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing medical, radioactive and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from such materials. As a result of any such contamination or injury we may incur liability or local, city, state or federal authorities may curtail the use of these materials, interrupting our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Risks Related to Our Industry

Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, marketing approvals, coverage, pricing and reimbursement for new vaccine and drug products vary widely from country to country. In the United States and some foreign jurisdictions, 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 our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell our product candidates, if we obtain marketing approval.

Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the legislation and Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, or the Affordable Care Act. These new laws and subsequent legislation may result in additional reductions in Medicare and other healthcare funding.

In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Some countries require approval of the sale price of a vaccine or drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for our product candidates in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in our product candidates even if our product candidates obtain marketing approval. Lower pricing in one territory may cause other territories to lower their prices, and so negatively impact our revenue and our ability to recoup our investments in product candidates.

In addition, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products and may increase our regulatory burdens and operating costs. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates may be.

Laws and regulations governing conduct of international operations may preclude us from developing, manufacturing and selling products outside of the United States and require us to develop and implement costly compliance programs.

As we seek to expand our operations outside of the United States, we must comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where we must rely on third parties.

The Foreign Corrupt Practices Act, or FCPA, prohibits any United States individual or business from paying, offering, 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 certain 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. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain foreign nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Our expanding presence outside of the United States will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling our product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the United States government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. Additionally, the SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions.

Our relationships with customers and third party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third party payers, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our operations and expose us to areas of risk including the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and will fully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, which impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and will fully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the Affordable Care Act, which requires manufacturers of vaccines, drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to HHS information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payers, including private insurers; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require vaccine and drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties are compliant with applicable healthcare laws and regulations will involve the expenditure of appropriate, and possibly significant, resources. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Risks Related to Our Intellectual Property

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology and vaccine product candidates, our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and vaccine products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. Our strategy is to obtain patent protection for chemical structures, pharmacokinetic profiles, timing of administration, dose strengths and drug combinations and secondarily seek to protect specific formulations, uses and administration regimens relating to our product candidates**.**

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us to narrow the claims of our pending patent application, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

With respect to patent rights, we do not know whether any of our patent applications will result in patents that effectively prevent others from commercializing competitive technologies and products. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore we cannot be certain that we were the first to make the inventions claimed in our pending patent applications or that we were the first to file for patent protection of such inventions.

Our intellectual property portfolio has certain pending patent applications. If our pending patent applications fail to issue or fail to issue with a scope that is meaningful to our product candidates, or if issued, if our patents are found to be invalid, not enforceable or not infringed by competitor products, our business will be adversely affected.

Our pending patent applications may not result in issued patents in the United States or foreign jurisdictions in which such applications are pending. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Even if a patent issues, it still may be challenged as to its inventorship, scope, validity or enforceability in the courts or patent offices in the United States 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 our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Protecting against the unauthorized use of our technology and other intellectual property rights is expensive, difficult and may in some cases not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

While certain of our vaccine product candidates are in pre-clinical studies, we believe that the use of our product candidates in these pre-clinical studies falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There can be no assurance that our product candidates do not infringe other parties' patents or other proprietary rights, however, and competitors or other parties may assert that we infringe their proprietary rights in any event. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the United States Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Under certain circumstances, we could be forced, including by court order, to cease commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our current product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, novel formulations of existing drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may in certain countries, particularly developing countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our patents are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents, by means including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in patent laws, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity, and obtaining and enforcing pharmaceutical patents is costly, time-consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents we may obtain in the future. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our patents once issued.

The Leahy-Smith America Invents Act, or the Leahy-Smith Act, as adopted in September 2011, includes provisions that affect the way patent applications will be prosecuted and that may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 from a "first to invent" system to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate patent rights, which could adversely affect our competitive position.

The USPTO recently has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are some situations in which noncompliance cannot be cured and result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction, including, but are not limited to, any failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patent applications and patents, if issued, covering our product candidates, our competitive position would be adversely affected.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe our patents, once issued, or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own or control. These proceedings can be expensive and time consuming. Many of our potential competitors have the ability to dedicate substantially greater resources to defend their intellectual property rights than we can. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned or controlled by us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our securities.

We may be subject to claims by third parties asserting that we have misappropriated their intellectual property through our employees and advisory board members.

Some of our employees and advisory board members are or were previously employed or affiliated with universities or at other biotechnology or pharmaceutical companies, including our potential competitors. Some of these employees and advisory board members executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or affiliation. Although we try to ensure that our employees and advisory board members do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or advisory board members have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds or formulations of our product candidates that are similar to our product candidates' formulations but that are not covered by the claims of the patents that we own or control;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our 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 we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- we may not develop additional proprietary technologies that are patentable.

Risks Related to Employee Matters, Managing Growth

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have a code of conduct and ethics for our directors, officers and employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

As of December 31, 2018, we had eight full-time employees, including those in our two subsidiaries. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, sales, marketing, financial and other resources. In addition, it may become more cost effective to bring in house certain resources currently outsourced to consultants and other third parties. Our management, personnel and systems currently in place may not be adequate to support our future growth. Future growth would impose significant added responsibilities on members of management, including:

– managing our clinical trials effectively;

– identifying, recruiting, maintaining, motivating and integrating additional employees;

– managing our internal development efforts effectively while complying with our contractual obligations to any licensors, licensees, contractors and other third parties;

– improving our managerial, development, operational and finance systems; and

– expanding our facilities.

As our operations expand, we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon. Ronald Kempers, our President, CEO and CFO, and our two CSOs. The employment agreements we have with the persons named above do not prevent such persons from terminating their employment with us at any time. Although we currently do not maintain "key person" insurance for any of our executives or other employees, we intend to obtain this insurance following this offering. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

If we are unable to attract and retain highly qualified employees, and other personnel, advisors and consultants with scientific, technical and managerial expertise, we may not be able to grow effectively.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees, consultants and other third parties. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results.

Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel, advisors and consultants. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including pre-clinical, clinical or commercial stage products or product candidates, or businesses, or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a detrimental effect on our financial condition, results of operations and cash flows. We have limited experience with acquiring other companies, products or product candidates, and limited experience with forming strategic alliances and collaborations. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. We may not be able to find suitable strategic alliance or collaboration partners or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or equity securities as consideration. Any such issuance of securities would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our business and operations would suffer in the event of computer system failures.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. In addition, our systems safeguard important confidential personal data regarding subjects enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, as we do not carry insurance to cover such risks.

Risks Related to Ownership of Our Securities

We do not know whether an active, liquid and orderly trading market will develop for our securities or what the market price of our securities will be and as a result it may be difficult for you to sell your shares of common stock.

There is currently an illiquid market for our securities. The lack of an active market may impair your ability to sell those securities at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your securities. Further, an inactive market may also impair our ability to raise capital by selling securities and may impair our ability to enter into collaborations or acquire companies or products by using our securities as consideration.

Insiders have substantial influence over us and could delay or prevent a change in corporate control.

Our executive officers, directors and our largest shareholder whose representative serves on the Board of Directors collectively owned approximately 54% of our outstanding voting stock. This concentration of ownership could harm the market price of our securities by:

– limiting the volume of active trading;

– delaying, deferring or preventing a change in control of our company;

– impeding a merger, consolidation, takeover or other business combination involving our company; or

– discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their securities, and might negatively affect the prevailing market price for our securities.

If we do not meet the listing standards of a national securities exchange our investors' ability to make transactions in our securities will be limited and we will be subject us to additional trading restrictions.

Our securities currently are traded over-the-counter on the OTCQB market and are not qualified to be listed on a national securities exchange, such as NASDAQ. Accordingly, we face significant material adverse consequences, including:

– a limited availability of market quotations for our securities;

– reduced liquidity with respect to our securities;

– our shares of common stock are currently classified as "penny stock" which requires brokers trading in our shares of common stock to adhere to more stringent rules, resulting in a reduced level of trading activity in the secondary trading market for our shares of common stock;

– a limited amount of news and analyst coverage for our company; and

– a decreased ability to issue additional securities or obtain additional financing in the future.

The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as "covered securities." Since our common stock is traded on the OTCQB, our common stock is a covered security. Although the states are preempted from regulating the sale of our securities, the federal statute allows the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were no longer traded over-the-counter, our common stock would not be a covered security and we would be subject to regulation in each state in which we offer our securities.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our securities.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In our annual reports on Form 10-K, we are required, under Section 404(a) of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needed to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis. Section 404(b) of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

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

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, will result in additional dilution of the percentage ownership of our stockholders and could cause our trading price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of equity or equity-linked securities, together with the exercise of stock options and warrants granted in the future and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Our Board of Directors and stockholders also has adopted a 2013 Stock Incentive Plan reserving for issuance 30 million shares of our common stock. Future equity incentive grants and issuances of common stock under our equity incentive plans may have an adverse effect on the market price of our securities.

If there is significant downward pressure on the price of our common stock, it may encourage shareholders to sell shares by means of short sales or otherwise. Short sales involve the sale, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller's right to acquire common stock, such as upon exercise of warrants. A holder of warrants may close out any covered short position by exercising all, or a portion, of its warrants, or by purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of warrants will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the exercise price of the warrants. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and bylaws that will become effective in connection with consummation of this offering, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that:

- permit our Board of Directors to issue up to ten million shares of preferred stock, with any rights, preferences and privileges as it may designate;
- provide that all vacancies on our Board of Directors, including as a result of 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;
- establish a classified Board of Directors such that only one of three classes of directors is elected each year;
- not provide for cumulative voting rights, thereby 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;
- provide that special meetings of our stockholders may be called by a majority of the Board of Directors;
- provide that our board of directors is expressly authorized to make, alter or repeal the bylaws.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the Board of Directors has approved the transaction. Any provision of our certificate of incorporation or bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our management and Board of Directors control a substantial percentage of our stock and therefore have the ability to exercise substantial control over our affairs.

As of the date of this Annual Report on Form 10-K, our directors, executive officers and our largest shareholder whose representative serves on our Board of Directors owned approximately 54% of our outstanding common stock in the aggregate. Because of the large percentage of stock held by our directors, executive officers and our largest shareholder whose representative serves on our Board of Directors, these persons could influence the outcome of any matter submitted to a vote of our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Since March 1, 2009, we have leased office space in a life science campus near Lausanne (40 miles from Geneva). We lease 100 square meters of office space that houses our executive and scientific management and administrative operations.

Bestewil Holding B.V. and its subsidiary Mymetics B.V operate from a similar biotechnology campus near Leiden in the Netherlands, where they occupy approximately 204 square meters for office and laboratory use.

We also conduct research operations at the properties of various third parties, worldwide.

ITEM 3. LEGAL PROCEEDINGS

Neither we, nor our wholly owned subsidiaries Mymetics S.A. and Bestewil Holding B.V., nor its subsidiary, Mymetics B.V., are presently involved in any litigation incident to our business.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

(a) Market Information. The Corporation's common stock is quoted on the OTC Bulletin Board under the trading symbol "MYMX".

The following table sets forth the quarterly high and low sales price per share of our common stock for the periods indicated. The prices represent inter-dealer quotations, which do not include retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

FISCAL QUARTER ENDED	HIGH	LOW
2018		
March 31	$ 0.0350	$ 0.0188
June 30	0.0642	0.0250
September 30	0.0630	0.0380
December 31	0.0770	0.0390
2017		
March 31	$ 0.0230	$ 0.0206
June 30	0.0295	0.0258
September 30	0.0458	0.0375
December 31	0.0472	0.0403

(b) Stockholders. At March 28, 2019, we had approximately 650 holders of record of our common stock, some of which are securities clearing agencies and intermediaries.

(c) Dividends. We have not paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future.

(d) Securities Authorized for Issuance under Equity Compensation Plans.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information about the common stock that may be issued upon the exercise of options, warrants and rights under all of the Company's existing equity compensation plans as of December 31, 2018.

Plan Category	Number of Securities to be issued upon exercise of vested Options, Warrants and Rights (a)		Weighted Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans (1)				
Approved by Security Holders				
2001 Plan	--(2)	$	--	
2009 Plan	3,350,000(3)	$	U.S. 0.15	--
2013 Plan	24,140,000(4)	$	U.S. 0.02	1,150,000
Total	**27,490,000**	**$**	**U.S. 0.04**	**1,150,000**

(1) Equity compensation plans approved by security holders include (i) our 1994 Amended and Restated Stock Option Plan, (ii) our 1995 Qualified Incentive Stock Option Plan, (iii) our 2001 Stock Option Plan, and (iv) our 2013 Stock Option Plan.

(2) (i) All of the 442,500 shares of common stock underlying options granted under the registrant's 2001 Stock Option Plan have expired as of December 31, 2017.

(3) In June 2010 our Board of Directors and a majority of our shareholders approved a 2009 Stock Incentive Plan .

(4) On October 4, 2013 our Board of Directors and a majority of our shareholders approved a 2013 Stock Incentive Plan and allowed the issuance of 30,000,000 shares for this plan.

ISSUANCES OF UNREGISTERED SECURITIES

During the period commencing on January 1, 2018 and ending on December 31, 2018, no issuance of unregistered securities were made.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

GENERAL

The following discussion and analysis of the results of operations and financial condition of the Company for the years ended December 31, 2018 and 2017 should be read in conjunction with our audited consolidated financial statements and related notes and the description of our business and properties included elsewhere herein.

RESULTS OF OPERATIONS - YEAR ENDED DECEMBER 31, 2018 COMPARED TO YEAR ENDED DECEMBER 31, 2017:

We reached E967 and E1,515 in revenue for the years ending December 31, 2018 and 2017, respectively. For 2018 the revenue was related to the recognition of E892 of grant revenue from the Horizon 2020 and E75 related to the fees from R&D services. For 2017 the revenue was related to the recognition of E1,313 of grant revenue from the Horizon 2020 and E202 related to fees from R&D Services.

Research and development expenses decreased to E1,217 in the current period from E2,130 in the comparative period of 2017, a decrease of 42.9%, which was mainly due to high subcontracting services related to the Horizon 2020 project with acronym “Maciviva” incurred during the year 2017.

General and administrative expenses decreased by -5.2% to E1,095 in the year ended December 31, 2018 from E1,155 in the comparable period of 2017.

REVENUE RECOGNITION AND RECEIVABLES

We have not generated any material revenues since we commenced our current line of business in 2001 other than the cumulative E15 million resulting from the collaboration agreements with Pharma companies and grants received from the Horizon 2020 program, PATH-MVI, the Bill & Melinda Gates Foundation and the Swiss Education Research and Innovation organization.

In April 2015, the Company was selected to receive project grants with a total of E8.4 million. A total of E5.3 million is funded as part of Horizon 2020, the European Union research and innovation framework program and up to E3.1 million of funding will be provided by the Swiss State “Secretariat for Education, Research and Innovation” (SERI) for the Swiss based consortium partners. The grant funds the evaluation, development and manufacturing scale-up of thermo-stable and cold-chain independent nano-pharmaceutical virosome-based vaccine candidates. Of the total amount, E3.8 million is directly attributable to Mymetics’ activities, with the remaining balance going to the consortium partners and is not part of Mymetics financial statements. The project started on May 4, 2015 and officially ended on November 2, 2018, after which a final report has been prepared, presented and submitted to the EU for a total costs declared of E8,262 for the total project and E3,673 for Mymetics.

The amounts mentioned in the following statements are purely related to Mymetics and not to the other partners in the project: The Company received a pre-payment from the two granting organizations for a total value of E1,554 in May 2015, a second tranche of E917 from the EU was received in December 2016, and E614 from “SERI” was received in April 2017, which was used to finance the next reporting covering the period of November 2016 to October 2017. In November 2017, the Company submitted the second report and a new funding request, which resulted in another tranche of funding from the EU of E77 received in February 2018. This brings the total funding received year to date to E3,162, which represents 82% of the awarded grant contribution. On December 21, 2018, the final report has been officially submitted to the EU. The total cost incurred by the Company of E3,673 represents 96% of the maximum grant. As a result, the Company funded the project for a total of E511 as of December 31, 2018. This amount is accounted as receivable by the EU and SERI and will be paid to the Company no later than March 24, 2019 upon validation of the final report by the EU and SERI.

On December 1, 2016, Mymetics Corporation entered into a material definitive Research Agreement with Sanofi Pasteur Biologics, LLC, the vaccine division of Sanofi (SNY). The project investigated the immunogenicity of influenza vaccines based on Mymetics' proprietary virosome technology platform in pre-clinical settings. If this project is successful it could result in a further and more extensive collaboration between the two companies. The project duration was 6 to 12 months and started in January 2017. The first payment was received and recognized in March 2017 and the second payment was received and recognized in June 2017. The Company entered into an Amendment of the Research Agreement effective October 20, 2017 to extend the date of the Research Agreement for an additional year. The initial results of the recent study did not achieve the expected benefits of Mymetics' influenza virosomes and were contrary to earlier results Mymetics obtained with Solvay in multiple studies. In the amendment Mymetics agreed to pay for a redesigned study. This study started in Q1 2018 and ended in Q4 2018.

In April 2018, the Company entered into a Research and Option to License Agreement with Anergis SA ("Anergis"). Under the terms of the Research Agreement, a pre-clinical study program was triggered and evaluated the immunogenicity profile of the Anergis' peptides designed to treat birch allergy when presented on Mymetics' proprietary virosomes, with or without undisclosed TLR ligands or other adjuvants. The results were compared to Anergis' AllerT product combination.

In December 2018, Mymetics and Anergis announced that the pre-clinical study program was successful. The pre-defined success criteria were met and Anergis has now a time limited option to enter into an exclusive license agreement with Mymetics for the use of virosomes in the field of allergies. Should Anergis and Mymetics execute a License and Collaboration Agreement (LCA), Anergis would make an upfront payment to Mymetics in an amount that increases as the date of the LCA is executed. The LCA also includes milestone payments based on certain regulatory clearances and royalties for net sales. The contractual material had been delivered during the third quarter of the year 2018 and 100% of the agreed payments from the Research and Option to License Agreement has been received and fully recognized as revenue in Q3 2018. The LCA has not been executed as of the date this report has been filed.

RESEARCH AND DEVELOPMENT

Research and development costs are expensed as incurred.

CURRENCY TRANSLATION

Our reporting currency is the Euro because substantially all of our activities are conducted in Europe. Non-Euro assets and liabilities of our subsidiaries are translated at the rate of exchange at the balance sheet date. Revenues and expenses are translated at the average rate of exchange throughout the year. Unrealized gains or losses from these translations are reported as a separate component of comprehensive income. Transaction gains or losses are included in general and administrative expenses in the consolidated statements of operations. The translation adjustments do not recognize the effect of income tax because we expect to reinvest the amounts indefinitely in operations.

GOODWILL

Goodwill represents the excess of purchase price over the value assigned to the net tangible and identifiable intangible assets of a business acquired. The Company typically performs its annual goodwill impairment test effective as of April 1 of each year, unless events or circumstances indicate impairment may have occurred before that time. The Company assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. After assessing qualitative factors, the Company determined that no further testing was necessary. If further testing was necessary, the Company would determine the fair value of each reporting unit, and compare the fair value to the reporting unit's carrying amount. As of December 31, 2018, management believes there are no indications of impairment.

STOCK BASED COMPENSATION POLICY

Compensation cost for all share-based payments is based on the estimated grant-date fair value. The Company amortizes stock compensation cost ratably over the requisite service period.

BUSINESS PLAN

We aim to be a lean and effective research and development company, focused on virosome based vaccines and immunotherapies. Our core value lies in the know-how and intellectual property related to virosome based vaccines, membrane proteins, integration of antigens and adjuvants into lipid membranes and the mucosal immune response. We have in-house laboratory facilities and expertise and we subcontract some of our research project modules to best of class research teams. We pay for and coordinate the work, consolidate the results and retain all associated intellectual property. If required, we execute partnership agreements with companies offering technologies that can enhance our products or we collaborate with specific biotech partners in order to enhance their therapies.

We will continue in the foreseeable future to outsource to specialized third parties all human clinical trials of our vaccines, such process being complex and highly regulated. Further, we will continue to seek partnerships with leading vaccine development groups, pharma companies and grant providing organizations for the vaccines we are developing.

Our business plan is predicated by the size and availability of our resources. The short term focus of our research team is aimed on the execution of further development of our virosome platform in certain immunotherapy fields and the development of our Chikungunya vaccine candidate. In parallel, we are eager to advance our promising Malaria and HIV-1 vaccine candidates by working closely with non-for-profit funding organizations and academic institutions.

Depending on the situation, we would not pursue human clinical trials for our vaccine beyond phase II, which normally involves no more than 250-300 volunteers and a cost in the range of $5-10 million per phase I and II trial cycle. In contrast, phase III trials for a prophylactic vaccine can involve up to 30,000 patients and several testing centers spread over two or more continents. The high number of volunteers, as well as the logistical complexity of such an undertaking, implies a cost-per-volunteer in the $10,000 to $12,000 range, or up to $360 million per phase III trial. Similarly, the cost and complexity of the vaccine registration procedure with the relevant European agencies can be very expensive. The cost of registration with the U.S. Food and Drug Administration (FDA) is generally significantly higher due to a variety of factors, including, potential product liability claims.

We will enter into negotiations with potential pharmaceutical partners as soon as positive intermediary results will be observed in view of a partnership agreement as described above.

LIQUIDITY AND CAPITAL RESOURCES

We had E479 cash at December 31, 2018, compared to E1,180 at December 31, 2017.

Most of our revenue in 2018 was generated through the Horizon 2020, the European Union research and innovation framework program. New significant revenues are not expected, unless and until a second major licensing agreement or other commercial arrangement is entered into with respect to our technology.

As of December 31, 2018, we had an accumulated deficit of approximately E85 million and generated net loss of E4,172 in the year ended December 31, 2018. The net loss in 2018 was mainly associated with interest expenses on shareholder loans (E2,634) and expenses that are not covered by revenues. We expect to continue to incur expenses in the future for research, development and activities related to the future licensing of our technologies.

Net cash used in operating activities is (E2,313) for the year ended December 31, 2018, compared to (E2,451) for the year ended December 31, 2017.

Investing activities used cash of NIL for the year ended December 31, 2018 and E37 for the year ended December 31, 2017, related to the purchase of equipment in the Netherlands.

Financing activities provided E1,600 cash for the year ended December 31, 2018 from short term promissory notes from our two main investors and E2,300 for the year ended December 31, 2017 from our two main investors.

Our major shareholder, a member of our Board of Directors and another previous investor have made available an aggregate E54,370 in the form of notes payable including accumulated interest, the details of which are described in Note 2 of our financial statements.

The Company's budgeted operational cash outflow, or cash burn rate, for 2019 is approximately E1,647 for research, fixed and normal recurring expenses, assuming the ability to obtain the necessary financing and without taking into account any grants that may be obtained.

2019 budget	12 Months
Revenue from R&D services	E --
Grant revenue for Horizon 2020	511
Total revenue:	511
R&D costs	922
G&A costs	1,236
Total cost:	2,158
Total cash burn rate	**E 1,647**

Management expects the cash outflow on R&D will focus on the Chikungunya, Influenza and virosome immunotherapy vaccine development which will be partially offset by the expected incoming cash related to the HIV/Horizon 2020 final payments.

Additional funding requirements during the next 12 months will be needed to further develop our Chikungunya, Influenza, HIV and Malaria vaccines, which we will try to seek through collaborations with not-for-profit organizations and through additional financing from our investors.

In the past, we have financed our research and development activities primarily through debt and equity financings from various parties, complemented by the recent grant agreements for our HIV and malaria vaccine candidates.

We anticipate that our normal operations will require approximately E1,200 additional funding in the year ending December 31, 2019. We will seek to raise the additional capital from equity or debt financings, and grants through donors and potential partnerships with major international pharmaceutical and biotechnology firms. However, there can be no assurance that it will be able to raise additional capital on satisfactory terms, or at all, to finance its operations on the longer term. In the event that we are not able to obtain such additional capital, we will be required to further restrict or even cease our operations.

RECENT FINANCING ACTIVITIES

During 2018, our principal source of funds has been revenues related to the Horizon 2020 Maciviva project, the Research and Option to License Agreement with Anergis and additionally promissory notes from our two main investors.
We have filed or are in the process of filing several new grant applications with U.S. and European institutions in relation to our virosome based vaccines.

We anticipate using our current funds and those we receive in the future both to meet our working capital needs and for funding the ongoing vaccines pre-clinical research costs for new virosome vaccine.

Management anticipates that our existing capital resources will be sufficient to fund our cash requirements through the next five months. We have cash presently on hand in conjunction with the collection of receivables, based upon our current levels of expenditures and anticipated needs during this period. For 2019, we will need additional funding through future collaborative arrangements, licensing arrangements, and debt and equity financings under Regulation D and Regulation S under the Securities Act of 1933. We do not know whether additional financing will be available on commercially acceptable terms when needed.

If management cannot raise funds on acceptable terms when needed, we may not be able to successfully commercialize our technologies, take advantage of future opportunities, or respond to unanticipated requirements. If unable to secure such additional financing when needed, we will have to curtail or suspend all or a portion of our business activities and could be required to cease operations entirely. Further, if new equity securities are issued, our shareholders may experience severe dilution of their ownership percentage.

The extent and timing of our future capital requirements will depend primarily upon the rate of our progress in the research and development of our technologies, our ability to enter into a partnership agreement with a major pharmaceutical company, and the results of our present projects and future clinical trials.

OFF-BALANCE SHEET ARRANGMENTS
None

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and supplementary data required with respect to this Item 8, and as identified in Item 14 of this annual report, are included in this annual report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer the Company conducted an evaluation of the effectiveness of the Company's disclosure controls and procedures, as defined in Rule 13a–15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), as of the end of the period covered by this annual report. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded as of December 31, 2018 that the Company's disclosure controls and procedures were effective such that the information required to be disclosed in the Company's United States Securities and Exchange Commission (the "SEC") reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, currently the same person to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Based on its evaluation under the framework in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission as of December 31, 2018, the Company's management, with the participation of its Chief Executive Officer and Chief Financial Officer, concluded that its internal control over financial reporting were effective as of December 31, 2018.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, which permanently exempts non-accelerated filers from complying with Section 404(b) of the Sarbanes-Oxley Act of 2002.
Attached as exhibits to this Form 10-K are certifications of Mymetics' Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This "Controls and Procedures" section includes information concerning the controls and controls evaluation referred to in the certifications.

Material Weakness Identified

None.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including the CEO/CFO, does not expect that the Disclosure Controls or our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our Company have been detected.
These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions of deterioration in the degree of compliance with policies or procedures.

ITEM 9B. OTHER INFORMATION

None

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Our number of directors is established at three, divided into three classes, designated as Class I, Class II and Class III. The term of the Class II directors will expire at the 2019 annual meeting of stockholders, and the term of the Class III directors will expire at the 2019 annual meeting of stockholders. A plurality of the votes of the shares of the registrant's common stock present in person or represented by proxy at the annual meeting and entitled to vote on the election of directors are required to elect the directors. The Board members have three year terms and in the absence of a vote at an annual meeting of stockholders, they continue for successive three year terms until they are replaced or resign.

The following table sets forth information regarding each of our current directors and executive officers:

NAME	CURRENT POSITION WITH THE COMPANY	AGE	EXPIRATION OF TERM AS A DIRECTOR
Ronald Kempers	Chief Financial Officer (appointed August 1, 2010), Chief Executive Officer (appointed November 19, 2012)	51	n/a
Thomas Staehelin (Class II)	Director	71	2019
Ernest M. Stern (Class II)	Director	68	2019
Ulrich Burkhard (Class III)	Director	58	2019

RONALD KEMPERS

Ronald Kempers is the President and CEO. He started as Chief Operating Officer in July 1, 2009, and was appointed Chief Financial Officer on August 1, 2010. Effective November 19, 2012, Ronald Kempers was appointed President and Chief Executive Officer. Mr. Kempers is a senior business leader and entrepreneur, having over 20 years of international business management, business development and finance experience with leading global corporations (Hewlett Packard, Oracle) and medical and IT start-ups. Mr. Kempers has a M.Sc. in Business Administration from the Erasmus University, Rotterdam School of Management and has continued further education with various executive courses, including IMD, Lausanne.

DR. THOMAS STAEHELIN

Dr. Staehelin is Senior Managing Partner of Fromer, Schultheiss and Staehelin, a law firm located in Basel, Switzerland. Dr. Staehelin focuses primarily on corporate and tax law. Dr. Staehelin has served as a member of this law firm since 1975. Dr. Staehelin also serves on the boards of various Swiss companies and is Chairman of the Chamber of Commerce of the Basel region. In addition, Dr. Staehelin is Managing Director of the "Swiss Association of privately held Swiss Companies" and is a member of the Board of "economie suisse," The Swiss Business Federation. Dr. Staehelin received his Ph.D. degree in Law from the University of Basel. He formerly served as a member of the cantonal parliament of Basel.

We benefit from Dr. Staehelin's significant international business experience, financial expertise through his role as a lawyer and board member of many companies conducting business on a global basis and knowledge of the Swiss legal system to assist the Company with its Swiss subsidiaries.

ERNEST M. STERN

Ernest M. Stern was appointed as a Director in January 2008. Mr. Stern is a partner in the law firm of Culhane Meadows PLLC, which serves as outside U.S. counsel of Mymetics, where he specializes in securities and corporate law, representing public companies, investment banks and venture funds, and is the engagement partner for Mymetics. Mr. Stern received his undergraduate degree from Bowdoin College (Phi Beta Kappa, *summa cum laude*), and his J.D and LL.M (Taxation) degrees from Georgetown University Law Center (Case and Note Editor, *Law and Policy in International Business*).

Mr. Stern assists us through his extensive international business experience and contacts through his representation as a U.S. lawyer of many companies engaged in international business, knowledge of state and federal laws applicable to the Company and finance knowledge.

ULRICH BURKHARD

Ulrich Burkhard is Co-Founder, Managing Partner and Director of Marcuard Family Office, a multi-client family office founded in 1998 and located in Zurich, Switzerland, providing asset management advice. From 1994 to 1998, Mr. Burkhard held overall responsibility for Latin American marketing and relationship management at Bank J. Vontobel & Co. Ltd., Zurich, and was appointed First Vice President in 1995. From 1989 to 1994, Mr. Burkhard was Head of Private Banking Latin America at Vontobel USA Inc., New York, and was appointed Vice President in 1990. From 1987 to 1989, he worked at Bank J. Vontobel & Co. Ltd. as Head of Staff of the CEO's office. Mr. Burkhard began his career at Bank J. Vontobel & Co. Ltd., Zurich in 1978, focusing on global investment management and private banking. Mr. Burkhard holds a Bachelor of Science and Business Administration degree from the University of Applied Sciences, Zurich. Mymetics believes that it benefits from the significant financial expertise of Mr. Burkhard as it seeks to attract capital for its future growth.

SCIENTIFIC ADVISORY BOARD

We have established a Scientific Advisory Board (SAB) which we consult on an ad-hoc basis and are eminent intellectuals with expertise related to the Company's products:

- Dr. Stanley Plotkin, Emeritus Professor Wistar Institute, University of Pennsylvania, consultant to Sanofi Pasteur, developed the rubella vaccine in 1960s; worked extensively on the development and application of other vaccines including polio, rabies, varicella, rotavirus and cytomegalovirus as well as senior roles at the Epidemic Intelligence Service, U.S. Public Health Service; Aventis Pasteur (medical and scientific director); and Sanofi Pasteur (executive advisor).
- Dr. Ruth Ruprecht, Scientist at Texas Biomedical Research Institute Department of Virology & Immunology and Director, Texas Biomed AIDS Research Program.

AUDIT COMMITTEE

The Company's board of directors has appointed Ernest M. Stern and Dr. Thomas Staehelin to serve as members of its Audit Committee. The board of directors has determined that Dr. Staehelin qualifies as our "audit committee financial expert" and is independent as that term is defined under NASDAQ Rule 4200(a)(15).

CODE OF ETHICS

The registrant has adopted a Code of Ethics that applies to its executive officers, including its chief executive officer, as well as to the entire staff of the Company. A copy of the Code of Ethics is filed as an exhibit to Form 10-K annual report for the year ended December 31, 2018, hereby incorporated by reference.

MEETINGS OF THE BOARD OF DIRECTORS

In 2018, our Board of Directors held eight meetings, which were all conducted by telephone conference call. All directors attended each of the Board meetings. The Board of Directors has determined that Mr. Stern is independent within the meaning of Section 10A and Rule 10A-3 of the Exchange Act. The Company does not have a formal policy regarding attendance by members of the board of directors at our annual meetings of stockholders since we did not hold an annual meeting in 2018.

Shareholders may contact our Board of Directors by mail addressed to the entire board of directors, or to one or more individual directors, at c/o Mymetics S.A., Biopole, Route de la Corniche 4, CH-1066 Epalinges, Switzerland, Attn: Secretary. All communications directed to our board of directors or individual directors in this manner will be relayed to the intended recipients.

We do not have a separate nominating committee and do not believe that such a committee is required at this time given our emphasis on research and development rather than active revenue generating business and our limited shareholder base.

DIRECTORS' FEES

Our non-executive directors became eligible for compensation of E10,000 each for their services as directors in 2018.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities and Exchange Act of 1934, as amended, requires that executive officers, directors and persons who own more than 10% of a registered class of the Company's equity securities to file reports of ownership and changes of ownership with the SEC within specified due dates. These persons are required by SEC regulations to furnish the Company with copies of all such reports they file. Based solely on the review of the copies of such reports furnished, we believe that, with respect to our fiscal year ended December 31, 2018, all of our executive officers, directors and 10% stockholders filed all required reports under Section 16(a) in a timely manner.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Committee Report

The Compensation Committee of the Board of Directors (the "Committee") is composed of three non-Executive directors, Ulrich Burkhard, Ernst M. Stern and Thomas Staehelin. The Compensation Committee does not have a charter. The Compensation Committee did not hold any telephone conference in 2018.

Compensation Discussion and Analysis
The Committee is responsible for reviewing and approving the compensation paid to executive officers of the Company, including salaries, bonuses, stock grants and stock options. Following review and approval by the Committee, action pertaining to executive compensation is reported to the full Board of Directors for further consideration.

Compensation Philosophy
The Company's compensation of executive officers and its philosophy regarding executive compensation is comprised of the following characteristics:

(i) Competitive base salary;
(ii) Granting stock awards as a portion of the total compensation, which vest over a certain number of years; and
(iii) Granting performance-based bonuses either in cash or common stock.

We believe our executive compensation should be designed to allow us to attract, motivate and retain executives of a high caliber to permit us to remain competitive in our industry. We desire to maintain for now a uniformity of base salary compensation in light of the contributions each of the two principal executives has either made, or is expected to make, to our ability to remain in business and achieve the level of success that we have reached in meeting scientific results, primarily to date the vaccines in our portfolio. We take into account the compensation paid at similarly situated companies, both within and outside of our industry, when determining executive compensation. We believe that by granting shares of our Common Stock to our executives, which vest over a certain number of years, we will be able to encourage executives to remain with us.

Additionally, individual performance of the executive is considered as a factor in determining executive compensation, as well as the overall performance of the Company, which, since we are primarily involved in research and development, includes, but is not limited to, fund raising and meeting our business plan milestones on time and within budget, including successful conclusion of strategic partner agreements and achieving the regulatory approvals to commercialize our vaccines, rather than earnings, revenue growth, cash flow and earnings per share which would be more typical for a company generating revenues and earnings. The Committee also uses subjective criteria it deems relevant in its reasonable discretion.

Compensation of Chief Executive Officer and Chief Financial Officer

As Chief Executive Officer and Chief Financial Officer, Mr. Kempers was paid a salary of CHF300 for the twelve months ending December 31, 2018.

Compensation of Chief Scientific Officer

Dr. Fleury was the Company's Scientific Consultant from July 31, 2003 until November 3, 2003 when he was appointed Chief Scientific Officer. Dr. Fleury was paid a base salary of E96 in calendar year 2004, the first full year of his employment by the Company. The Company had very little cash and Mr. Fleury deferred a significant portion of his salary in 2004, 2005, and 2006. As a result of Mr. Fleury's efforts, the Company achieved important scientific goals for its HIV-AIDS vaccine that encouraged investment in the Company. Dr. Fleury's salary was first increased to E120 in 2005, then E180 in 2006 and E216 in 2007 based upon his success in the animal studies leading to the Company's ability to commence Phase I clinical trials for its HIV-AIDS vaccine in addition to his role in the negotiations in concluding an agreement with Pevion Biotech Ltd. to acquire the malaria vaccine. As of January 1, 2010, Dr. Fleury's based salary has been converted into CHF300, which is approximately equal to his previous salary of E216 at the exchange rate at that time. A contractual clause allowing for a 3% success fee upon sale of the Company to, or licensing of technology to, a major partner was deleted in favor of stock options.

SUMMARY COMPENSATION TABLE

The following table sets forth for the last three fiscal years information on the annual compensation earned by our directors and officers.

Name and Principal Position		Year	Salary (E)	Bonus (E)	Awards (E)	Stock Awards (E)	Option Plan (E)	Non-Equity Incentive Earnings (E)	Change in Pension Value and Nonqualified Deferred Compensation (E)	Total Annual Compensation
Ronald Kempers	(6)	2018	282,000	-	-	-	-	-	-	E282,000(1)
(CEO)		2017	282,000	-	-	-	-	-	-	E282,000(1)
		2016	282,000	-	-	-	-	-	-	E282,000(1)
Sylvain Fleury, Ph. D.	(6)	2018	282,000	-	-	-	-	-	-	E282,000(2)
(CSO)		2017	282,000	-	-	-	-	-	-	E282,000(2)
		2016	282,000	-	-	-	-	-	-	E282,000(2)
Thomas Staehelin, Dr.		2018	10,000	-	-	-	-	-	-	E10,000(3)
		2017	10,000	-	-	-	-	-	-	E10,000(3)
		2016	10,000	-	-	-	-	-	-	E10,000(3)
Ernest Stern		2018	10,000	-	-	-	-	-	-	E10,000(4)
		2017	10,000	-	-	-	-	-	-	E10,000(4)
		2016	10,000	-	-	-	-	-	-	E10,000(4)
Ulrich Burkhard		2018	-	-	-	-	-	-	-	E-(5)
		2017	-	-	-	-	-	-	-	E-(5)
		2016	-	-	-	-	-	-	-	E-(5)

(1) Mr. Kempers has been Mymetics' Chief Operating Officer since July 1st, 2009, Chief Financial Officer since August 1, 2010, and was appointed Chief Executive Officer on November 19, 2012.

(2) Dr. Fleury has been appointed as Mymetics' Chief Scientific Officer on November 3, 2003.

(3) Dr. Staehelin is a member of the Board of Directors and of the Audit Committee of the Company. He was elected on July 2, 2007 as non-executive director and eligible for annual compensation of E10 for attendance at the Board meetings, whether in person or by telephone.

(4) Ernest Stern is a member of the Board of Directors and of the Audit Committee of the Company. He was elected on January 21, 2008 as non-executive director and eligible for annual compensation of E10 for attendance at the Board meetings, whether in person or by telephone.

(5) Ulrich Burkhard is a member of the Board of Directors of the Company. He was elected on March 23 rd, 2012 as non-executive director for attendance at the Board meetings, whether in person or by telephone.

(6) See below “Employment Agreements”.

The tables entitled," "PENSION BENEFITS," "NONQUALIFIED DEFERRED COMPENSATION" and "DIRECTOR COMPENSATION" and the respective discussions related to those tables have been omitted because no compensation required to be reported in those tables was awarded to, earned by or paid to any of the named executive officers or directors in any of the covered fiscal years.

Employment Agreements

Under the Executive Employment Agreement for Sylvain Fleury Ph.D., he is employed as CSO since November 3, 2003 with a contract renewed June 30, 2013 for an indefinite period with three months’ notice. Dr. Fleury receives an annual salary of CHF 300. During the employment period, at the discretion of the Board and the Compensation Committee and based on the company’s performance and individual achievements, the executive shall be eligible for an annual bonus to be paid in cash, stock or stock options. If Dr. Fleury is terminated without cause or he terminates for good reason, he is entitled six months of his salary. Retroactive to January 1, 2010, Dr. Fleury’s salary has been converted into CHF300, which is approximately equal to his previous salary of E216.

Under the Executive Employment Agreement for Ronald Kempers, he is employed as President and CEO for five years commencing July 1, 2009, which was amended to an indefinite contract on July 1, 2014. Mr. Kempers receives an annual salary of CHF300, which is approximately equal to E216 and is entitled to participate in the stock incentive plan. If Mr. Kempers is terminated without cause or he terminates for good reason, he is entitled to a lump-sum payment equal to 12 months of his salary.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth information about the beneficial ownership of our common stock as of December 31, 2018, by: (a) each of our named executive officers; (b) each of our directors; (c) each person known to the management to be the beneficial owner of more than 5% of our outstanding voting securities; and (d) all of our current executive officers and directors as a group. The following is based solely on statements and reports filed with the Securities and Exchange Commission or other information we believe to be reliable.

There were 303,757,622 shares of our common stock outstanding on March 28, 2019. Beneficial ownership has been determined in accordance with the rules of the Securities and Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished, that the persons and entities named in the tables below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options or warrants held by that person that are currently exercisable or exercisable within 60 days of March 28, 2019, are deemed outstanding. These shares of common stock, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person.

NAME AND ADDRESS OF BENEFICIAL OWNER	TITLE OF CLASS	AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP	PERCENT OF CLASS
Ulrich Burkhard (1) Director	Common	--	0%
Dr. Thomas Staehelin (1) Director	Common	112,777,638(2)	11.70%
Dr. Sylvain Fleury (1) Chief Scientific Officer	Common	8,150,000(3)	0.85%
Ernest M. Stern (1) Director	Common	1,500,000(4)	0.16%
Ronald Kempers (1) CEO, CFO and President	Common	21,400,000(6)	2.22%
Round Enterprises Ltd. (1)	Common	670,693,371(5)	69.61%
All current executive officers and directors as a group (5 persons)	Common	814,521,008(7)	84.53%

(1) Address is Mymetics Corporation, Biopole, Route de la Corniche 4, CH-1066 Epalinges (Switzerland).

(2) Which includes 100,297,731 potentially issuable shares from conversion of convertible loans from Eardley.

(3) Of which 500,000 were issued for services, 1,000,000 were acquired through conversion of unpaid salary and expenses and 5,000,000 were acquired as a bonus and 1,650,000 potentially issuable shares related to stock options which have vested or vest within 60 days of this filing.

(4) 500,000 were issued for services rendered.

(5) As stated in the Form 13-D filed by Round Enterprises Ltd. all its shares are held through Anglo Irish Bank, SA, as nominee which, as a fiduciary, cannot take any action without the prior consent of Round Enterprises Ltd. This includes 529,686,819 potentially issuable shares from conversion of convertible notes in addition to 141,006,552 shares of common stock held of record by Round Enterprises Ltd.

(6) Of which 3,000,000 were issued through exercise of stock options and 18,300,000 potentially issuable shares related to stock options that have vested or will vest within 60 days of this filing.

(7) Includes 649,934,549 shares of common stock issuable upon conversion of convertible notes and vested options.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The Company received loans from Round Enterprises and Eardley Holding totaling E1,280 and E320, respectively, in two equal tranches for which the Company issued to each lender promissory notes on June 1, 2018 and November 10, 2018, bearing interest of 2.5% per annum. The maturity dates of the promissory notes are the later of (i) June 30, 2019, or (ii) the end of a subsequent calendar quarter in which the Company receives a written request from the lender for repayment of the unpaid principal and accrued interest due under the Notes.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table provides information about the fees billed to us for professional services rendered by Peterson Sullivan LLP during fiscal years 2018 and 2017:

	2018	2017
Audit Fees	$ 57	$ 54
Audit-Related Fees	--	--
Tax Fees	10	9
All Other Fees	-	-
Total	$ 67	$ 63

Audit Fees. Audit fees consist of fees for the audit of our annual financial statements or services that are normally provided in connection with statutory and regulatory annual and quarterly filings or engagements.

Audit-Related Fees. Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and are not reported as Audit Fees. During fiscal years 2018 and 2017, no services were provided in this category.
Tax Fees. Tax fees consist of fees for tax compliance services, tax advice and tax planning. During fiscal 2018 and 2017, the services provided in this category included assistance and advice in relation to the preparation of corporate income tax returns.

All Other Fees. Any other fees not included in Audit Fees, Audit-Related Fees or Tax Fees.

Pre-Approval Policies and Procedures.

Our audit Committee pre-approved all services to be provided by Peterson Sullivan LLP.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)	(1)	*Index to Financial Statements*
		Report of Independent Registered Public Accounting Firm
		Consolidated Balance Sheets
		Consolidated Statements of Comprehensive Loss
		Consolidated Statements of Changes in Shareholders' Equity (Deficit)
		Consolidated Statements of Cash Flows
		Notes to Consolidated Financial Statements
(a)	(2)	*ALL OTHER SCHEDULES HAVE BEEN OMITTED BECAUSE THEY ARE NOT APPLICABLE OR THE REQUIRED INFORMATION IS SHOWN IN THE FINANCIAL STATEMENTS OR NOTES THERETO.*
	(3)	*List of Exhibits*
2.1		Share Exchange Agreement dated December 13, 2001 between the Company and the stockholders of Mymetics S.A. listed on the signature page thereto (1)
2.2		Share Exchange Agreement dated December 13, 2001 between the Company and the stockholders of Mymetics S.A. listed on the signature page thereto (1)
2.3		Purchase Agreement dated October 17, 1998 between the Company and the majority stockholders of Nazca Holdings Ltd. (2)
2.4		Amendment to the Purchase Agreement dated October 17, 1998 between the Company and the majority stockholders of Nazca Holdings Ltd. (3)
2.5		Revised Purchase Agreement dated July 28, 1999 between the Company and the majority stockholders of Nazca Holdings Ltd. (4)
2.6		Share Exchange Agreement dated July 30, 2002 between the Company and the stockholders of Mymetics S.A. listed on the signature page thereto (5)
3 (i)		Articles of Incorporation of the Company (as amended through May 10, 2002) (6)
3 (ii)		Bylaws (7)
4.1		Form of Specimen Stock Certificate (8)
4.2		Form of letter regarding Warrant (8)
4.3		Form of Share Exchange Agreement (8)
9.1		Voting and Exchange Trust Agreement dated March 19, 2001, among the Company, 6543 Luxembourg S.A. and MFC Merchant Bank S.A. (8)
10.1		Services Agreement dated May 31, 2001, between the Company and MFC Merchant Bank, S.A.(7)
10.2		Employment Agreement dated May 3, 2001, between Pierre-Francois Serres and the Company (7)
10.3		Indemnification Agreement dated March 19, 2001, between the Company and MFC Bancorp Ltd. (7)
10.4		Agreement dated for reference May 15, 2000, between the Company and Maarten Reidel (7)
10.5		Preferred Stock Redemption and Conversion Agreement dated for reference December 21, 2000, between the Company and Sutton Park International Ltd. (10)
10.6		Preferred Stock Conversion Agreement dated for reference December 21, 2000, between the Company and Med Net International Ltd. (11)
10.7		Preferred Stock Conversion Agreement dated December 21, 2000, between the Company and Dresden Papier GmbH (11)
10.8		Assignment Agreement dated December 29, 2000, among the Company, Mymetics S.A. and MFC Merchant Bank S.A. (1)
10.9		Credit Facility Agreement dated July 27, 2000, between MFC Merchant Bank, S.A. and the Company (1)
10.10		Amended Credit Facility Agreement dated for reference August 13, 2001, between MFC Merchant Bank, S.A. and the Company (16)
10.11		Second Amended Credit Facility Agreement dated for reference February 27, 2002, between MFC Merchant Bank, S.A. and the Company (16)
10.12		Amended and Restated Credit Facility Agreement dated for reference February 28, 2003, among MFC Merchant Bank, S.A., MFC Bancorp Ltd., and the Company (16)
10.13		Guarantee dated for reference February 28, 2003, by MFC Bancorp Ltd. to MFC Merchant Bank S.A. (16)
10.14		Shareholder Agreement dated March 19, 2001, among the Company, the Holders of Class B Exchangeable Preferential Non-Voting Shares of 6543 Luxembourg S.A. signatory thereto and6543 Luxembourg S.A.(8)

10.15	Support Agreement dated March 19, 2001, between the Company and 6543 Luxembourg S.A. (8)
10.16	1995 Qualified Incentive Stock Option Plan (12)
10.17	Amended 1994 Stock Option Plan (13)
10.18	2001 ICHOR Company Stock Option Plan (7)
10.19	Employment Agreement dated March 18, 2002, between the Company and Peter P. McCann (14)
10.20	Consulting Agreement dated August 31, 2001, between the Company and Michael K. Allio (8)
10.21	Amendment to Consulting Agreement dated August 21, 2002, between the Company and Michael K. Allio (16)
10.22	Employment Agreement dated March 18, 2002, between the Company and Dr. Joseph D. Mosca (15)
10.23	Separation Agreement and Release dated January 31, 2003,between the Company and Peter P. McCann (16)
10.24	Director and Non-Employee Stock Option Agreement dated July 19, 2001, between the Company and Robert Demers (8)
10.25	Director and Non-Employee Stock Option Agreement dated July 19, 2001, between the Company and Michael K. Allio (8)
10.26	Director and Non-Employee Stock Option Agreement dated July 19, 2001, between the Company and John M. Musacchio (8)
10.27	Director and Non-Employee Stock Option Agreement dated July 19, 2001, between the Company and Patrice Pactol (8)
10.28	Director and Non-Employee Stock Option Agreement dated July 19, 2001, between the Company and Pierre-Francois Serres (8)
10.29	Director and Non-Employee Stock Option Agreement dated July 23, 2002, between the Company and Pierre-Francois Serres (16)
10.30	Director and Non-Employee Stock Option Agreement dated July 23 2002, between the Company and Patrice Pactol (16)
10.31	Director and Non-Employee Stock Option Agreement dated July 23,2002, between the Company and Robert Demers (16)
10.32	Director and Non-Employee Stock Option Agreement dated July 23, 2002, between the Company and John M. Musacchio (16)
10.33	Director and Non-Employee Stock Option Agreement dated July 23, 2002, between the Company and Michael K. Allio (16)
10.34	Director and Non-Employee Stock Option Agreement dated August 21, 2002, between the Company and Michael K. Allio (16)
10.35	Director and Non-Employee Stock Option Agreement dated June 20, 2002, between the Company and Peter P. McCann (16)
10.36	Director and Non-Employee Stock Option Agreement dated July 23, 2002, between the Company and Peter P. McCann (16)
10.37	Director and Non-Employee Stock Option Agreement dated February 6, 2003, between the Company and Peter P. McCann (16)
10.38	Patent Pledge Agreement dated November __, 2002 among Mymetics S.A., Mymetics Deutschland GmbH, the Company and MFC Merchant Bank S.A. (16)
10.39	Third Amendment to the Credit Facility Agreement dated for Reference December 31, 2006, between MFC Merchant Bank, S.A. and the Company (17)
10.40	Fourth Amendment to the Credit Facility Agreement dated for Reference February 16, 2005, between MFC Merchant Bank, S.A. and the Company (17)
10.41	Consulting Agreement dated for reference January 1, 2004, between the Centre Hospitalier Universitaire Vaudois (CHUV), the Company and Dr. Sylvain Fleury, Ph.D. (18)
10.42	Consulting Agreement dated for reference January 1, 2004, between the Company and Professor Marc Girard, DVM, D.Sc. (18)
10.43	Cooperation and Option Agreement dated March 10, 2005, between the Company and Pevion A.G. (18)
10.44	Consulting Agreement dated March 23, 2005, between the Company and Northern Light International. (18)
10.45	Sixth Amended Credit Facility Agreement dated for reference December 31, 2005, between MFC Merchant Bank, S.A. and the Company (19)
10.46	Employment Agreement dated July 1, 2006, between the Company and Dr. Sylvain Fleury (20)
10.47	Employment Agreement dated July 1, 2006, between the Company and Christian Rochet (20)
10.48	Employment Agreement dated July 1, 2006, between the Company and Ernst Luebke (20)
10.49	License Agreement dated March 1, 2007, between the Company and Pevion Biotech Ltd. (21)
10.50	Settlement Agreement dated March 19, 2007 between the Company and MFC Merchant Bank S.A. (22)
10.51	Co-ownership Agreement dated January 8, 2008 between the Company, INSERM and Pevion Biotech Ltd. (23)
10.52	Co-ownership Agreement dated January 8, 2008 between the Company and INSERM (23)
10.53	Exploitation Agreement dated January 8, 2008 between the Company and INSERM (23)
10.54	Non-Executive Director Agreement dated 21 January between the Company and Mr. Ernest M Stern.(24)
10.55	NGIN Material Transfer Agreement dated 11 February 2008 between the Company, Institute Cochin, Universite Paris Descartes and Pevion Biotech.(25)
10.56	Acquisition & License Agreement dated 19 May 2008 between the Company and Pevion Biotech Ltd. (26)

10.57	Extension of Convertible Note Maturity Date Agreement dated 22 August 2008 between the Company, Anglo Irish Bank and Round Enterprises Ltd. (27)
10.58	Gp41 Manufacturing Technology Agreement dated 26 January 2009 between the Company and PX Therapeutics (28)
10.59	Share Purchase Agreement pursuant to which the Company purchased all issued and outstanding shares of capital stock of Bestewil Holding B.V. ("Bestewil") from its parent, Norwood Immunology Limited ("NIL"), and all issued and outstanding shares of capital stock of Virosome Biologicals B.V. now held by Bestewil. (29)
10.60	Resignation of Prof Marc Girard as Head of vaccine development for reasons of personal health. (30)
10.61	Completion of Share Purchase Agreement pursuant to which Mymetics purchased all issued and outstanding shares of capital stock of Bestewil Holding B.V. and Virosome Biologicals B.V. including Unregistered Sales of Equity Securities, Financial Statements and Exhibits. (31)
10.62	Completion of Share Purchase Agreement pursuant to which Mymetics purchased all issued and outstanding shares of capital stock of Bestewil Holding B.V. and Virosome Biologicals B.V. including Statements and Exhibits. (32)
10.63	Election of Jacques-Francois Martin as a member of the Board of Directors and Chairman of the Board, resignation of Christian Rochet as President and CEO and agreement of Jacques-Francois Martin to serve as President and CEO. (33)
10.64	Consulting Agreement dated September 1, 2009, between the Company and Mr. Christian Rochet.
10.65	Resignation of Ernest Luebke as Chief Finance Officer and Board member. (37)
10.66	Press release on partial funding by the National Institutes of Health of a new preclinical trial to test the effectiveness of a candidate HIV vaccine in a nonhuman primate model. (38)
10.67	Amendment of Exploitation Agreement dated January 8, 2008 with INSERM-TRANSFERT. (43)
10.67	Amendment of License and Cooperation Agreements for Intranasal Delivery of APRECS based Vaccines and Virosomes between Mymetics B.V. and Abbott Biologicals B.V (44)
10.68	Election of Martine Reindle to the Board of Directors. (45)
10.68	Resignation of Jacques-François Martin as President and CEO. (46)
10.69	Election of Dr. Christopher S. Henney, Ulrich Burkhard and Grant Pickering to the Board of Directors. Resignation of Jacques-François Martin, Martine Reindle, Christian Rochet and Sylvain Fleury from the Board of Directors. (47)
10.70	Second Amended and Restated Executive Employment Agreement of Dr. Sylvain Fleury. (49)
10.71	Amendment of convertible secured notes issued to Round Enterprises Ltd., Eardley Holding A.G. and Anglo Irish Bank. (50)
10.72	Election of Ronald Kempers as President and Chief Executive Officer. , Departure of Dr. Christopher S. Henney and Grant Pickering from the Board of Directors. (51)
11.1	Statement Regarding Calculation of Per Share Earnings.
14.1	Code of Ethics.
21.1	List of Subsidiaries
24.1	Powers of Attorney (included on the signature page hereto)
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14 of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14 of the Securities Exchange Act of 1934
32.1	Section 1350 Certification of Chief Executive Officer and Chief Financial Officer
101.INS	Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Company's Schedule 14C filed with the Securities and Exchange Commission on April 26, 2001.
(2) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on October 22, 1998.
(3) Incorporated by reference to the Company's report on Form 8-K/A filed with the Securities and Exchange Commission on April 15, 1999.
(4) Incorporated by reference to the Company's report on Form 8-K/A filed with the Securities and Exchange Commission on August 13, 1999.
(5) Incorporated by reference to the Company's Amendment No. 1 to Form S-1 filed with the Securities and Exchange Commission on August 8, 2002.
(6) Incorporated by reference to the Company's report on Form 10-Q for the quarter ended March 31, 2002, filed with the Securities and Exchange Commission on May 15, 2002.
(7) Incorporated by reference to the Company's report on Form 10-Q for the quarter ended June 30, 2001, filed with the Securities and Exchange Commission on August 14, 2001.
(8) Incorporated by reference to the Company's Registration Statement on Form S-1, File No. 333-88782, filed with the Securities and Exchange Commission on May 22, 2002.
(9) Incorporated by reference to the Company's report on Form 8-K/A filed with the Securities and Exchange Commission on August 9, 2000.
(10) Incorporated by reference to Schedule 13D/A filed by MFC Bancorp Ltd. With the Securities and Exchange Commission on dated January 2, 2001.
(11) Incorporated by reference to the Company's report on Form 10-K for the fiscal year ended December 31, 2000, filed with the Securities and Exchange Commission on March 14, 2001.
(12) Incorporate by reference to the Company's Registration Statement on Form S-8, File No. 333-15831, filed with the Securities and Exchange Commission on November 8, 1996.
(13) Incorporated by reference to the Company's Registration Statement on Form S-8, File No. 333-15829, filed with the Securities and Exchange Commission on November 8, 1996.
(14) Incorporated by reference to the Company's report on Form 10-K for the fiscal year ended December 31, 2004, and filed with the Securities and Exchange Commission on March 29, 2002.
(15) Incorporated by reference to the Company's report on Form 10-Q for the quarter ended March 31, 2002, filed with the Securities and Exchange Commission on May 15, 2002.
(16) Incorporated by reference to the Company's report on Form 10-K for the fiscal year ended December 31, 2005, and filed with the Securities and Exchange Commission on March 27, 2003.

(17) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on February 18, 2005.
(18) Incorporated by reference to the Company's report on Form 10-K for the fiscal year ended December 31, 2004, filed with the Securities and Exchange Commission on March 30, 2005.
(19) Incorporated by reference to the Company's report on Form 10-K for the fiscal year ended December 31, 2005, filed with the Securities and Exchange Commission on April 17, 2006.
(20) Incorporated by reference to the Company's report on Form 10-Q for the period ended June 30, 2006, and filed with the Securities and Exchange Commission on August 21, 2006.
(21) Incorporated by reference to the Company's report on Form 10-K for the fiscal year ended December 31, 2006, filed with the Securities and Exchange Commission on April 17, 2007.
(22) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on March 21, 2007.
(23) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on January 14, 2008.
(24) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on January 25, 2008.
(25) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on February 19, 2008.
(26) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on May 19, 2008.
(27) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on June 30, 2008.
(28) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on January 30, 2009.
(29) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on March 5, 2009.
(30) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2009.
(31) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on June 16, 2009.
(32) Incorporated by reference to the Company's report on Form 8-K/A filed with the Securities and Exchange Commission on June 22, 2009.
(33) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2009.
(34) Incorporated by reference to the Company's Statement on Form 4, filed with the Securities and Exchange Commission on July 28, 2009.
(35) Incorporated by reference to the Company's Statement on Form 3 filed with the Securities and Exchange Commission on July 14, 2010.
(36) Incorporated by reference to the Company's Statement on Form 3 filed with the Securities and Exchange Commission on August 9, 2010.
(37) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on August 10, 2010.
(38) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on September 13, 2010.
(39) Incorporated by reference to the Company's Statement on Form 4 filed with the Securities and Exchange Commission on December 2, 2010.
(40) Incorporated by reference to the Company's Statement on Form 3 filed with the Securities and Exchange Commission on December 20, 2010.
(41) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on March 7, 2011.
(42) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on March 16, 2011.
(43) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on August 12, 2011.
(44) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on October 4, 2011.
(45) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on October 26, 2011.
(46) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on February 03, 2012.
(47) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on March 23, 2012.
(48) Incorporated by reference to the Company's Statement on Form 13D filed with the Securities and Exchange Commission on April 05, 2012.
(49) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on July 02, 2012.

(50) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on September 21, 2012.
(51) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on November 26, 2012.
(52) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on April 15, 2013.
(53) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on January 03, 2014.
(54) Incorporated by reference to the Company's report on Form 8-K/A filed with the Securities and Exchange Commission on February 28, 2014.
(55) Incorporated by reference to the Company's report on Form S-8 filed with the Securities and Exchange Commission on April 11, 2014.
(56) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on July 16, 2014.
(57) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on September 30, 2014.
(58) Incorporated by reference to the Company's statement on Form SC 13D/A filed with the Securities and Exchange Commission on March 17, 2015.
(59) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on June 24, 2015.
(60) Incorporated by reference to the Company's Schedule PRE 14C filed with the Securities and Exchange Commission on October 26, 2015.
(61) Incorporated by reference to the Company's Schedule DEF 14C filed with the Securities and Exchange Commission on November 9, 2015.
(62) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on January 29, 2016.
(63) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on December 1, 2016.
(64) Incorporated by reference to the Company's report on Form 8-K/A filed with the Securities and Exchange Commission on January 26, 2017.
(65) Incorporated by reference to the Company's report on Form 8-K filed with the Securities and Exchange Commission on April 23, 2018.

(c) Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors
Mymetics Corporation

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Mymetics Corporation and Subsidiaries ("the Company") as of December 31, 2018 and 2017, the related consolidated statements of comprehensive loss, changes in shareholders' equity (deficit), 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 "consolidated financial statements"). In our opinion, the consolidated 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 their operations and their 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.

Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has experienced recurring losses from operations and negative cash flows from operating activities. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/S/ PETERSON SULLIVAN LLP

We have served as the Company's auditor since 1996.

Seattle, Washington
March 28, 2019

MYMETICS CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2018 and 2017
(In Thousands of Euros, Except Share and Per Share Amounts)

	2018	2017
ASSETS		
Current Assets		
Cash	E 479	E 1,180
Receivables	585	90
Prepaid expenses	37	36
Total current assets	1,101	1,306
Property and equipment, net of accumulated depreciation of E391 and E406 at December 31, 2017 and 2016, respectively	36	65
Goodwill	6,671	6,671
	E 7,808	E 8,042
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current Liabilities		
Accounts payable	E 75	E 237
Deferred revenue from grants	--	274
Non-convertible notes payable and related accrued interest to related parties	4,002	2,330
Convertible notes payable and related accrued interest to related parties	50,756	48,079
Total liabilities	54,833	50,920
Shareholders' Equity (Deficit)		
Common stock, U.S. $.01 par value; 1,000,000,000 shares authorized at December 31, 2017 and 2016; issued and outstanding 303,757,622 at December 31, 2017 and 2016	2,530	2,530
Preferred stock, U.S. $.01 par value; 5,000,000 shares authorized; none issued or outstanding	--	--
Additional paid-in capital	34,441	34,428
Accumulated deficit	(84,675)	(80,503)
Accumulated other comprehensive income	679	667
	(47,025)	(42,878)
	E 7,808	E 8,042

The accompanying notes are an integral part of these consolidated financial statements.

MYMETICS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the Years Ended December 31, 2018 and 2017
(In Thousands of Euros, Except Per Share Data)

	2017	2016
Revenues		
Research and Development services	E 75	E 202
Grants	892	1,313
	967	1,515
Expenses		
Research and development	1,217	2,130
General and administrative	1,095	1,155
Bank fee	2	2
Depreciation	29	39
Directors' fees	20	20
Foreign exchange gain (loss)	123	(319)
	2,486	3,027
Operating Loss	(1,519)	(1,512)
Interest expense	2,634	2,595
Loss before income tax (provision) benefit	(4,153)	(4,107)
Income tax (provision) benefit	(19)	(5)
Net loss	(4,172)	(4,112)
Other comprehensive income (loss)		
Foreign currency translation adjustment	12	23
Comprehensive loss	E (4,160)	E (4,135)
Basic and diluted loss per share	E (0.01)	E (0.01)

The accompanying notes are an integral part of these consolidated financial statements.

MYMETICS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT)
For the Years Ended December 31, 2018 and 2017
(In Thousands of Euros, Except Share Amounts)

	Common Stock					
	Number of Shares	Par Value	APIC	Accumulated deficit	Accumulated Other Comprehensive Income	Total
Balance at December 31, 2016	**303,757,622**	**E 2,530**	**E 34,392**	**E (76,391)**	**E 690**	**E (32,892)**
Stock compensation expense – options	-	-	77	-	-	77
Net loss for the year	-	-	-	(4,112)	-	(5,964)
Translation adjustment	-	-	-	-	(23)	--
Balance at December 31, 2017	**303,757,622**	**E 2,530**	**E 34,428**	**E (80,503)**	**E 667**	**E (42,878)**
Stock compensation expense – options	-	-	13	-	-	13
Net loss for the year	-	-	-	(4,172)	-	(4,172)
Translation adjustment	-	-	-	-	12	(12)
Balance at December 31, 2018	**303,757,622**	**E 2,530**	**E 34,441**	**E (84,675)**	**E 679**	**E (47,025)**

The accompanying notes are an integral part of these consolidated financial statements.

MYMETICS CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2018 and 2017
(In Thousands of Euros)

	2018	2017
Cash Flows from Operating Activities		
Net loss	E (4,172)	E (5,964)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	29	42
Stock compensation expense-options	13	77
Changes in operating assets and liabilities,		
Receivables	(495)	48
Accrued interests on notes payable	2,749	2,664
Deferred revenue from grants	(274)	67
Accounts payable	(162)	(212)
Other	(1)	25
Net cash used in operating activities	(2,313)	(987)
Cash Flows from Investing Activities		
Purchase of property and equipment	--	(3)
Net cash used in investing activities	--	(3)
Cash Flows from Financing Activities		
Increase in notes payable	1,600	--
Net cash provided by Financing activities	1,600	--
Effect of foreign exchange rate on cash	12	--
Net decrease in cash	(701)	(990)
Cash, beginning of period	1,180	2,381
Cash, end of period	E 479	E 1,391
Supplemental Disclosure of Cash Flow Information:		
Cash paid for interest	E -	E -

The accompanying notes are an integral part of these consolidated financial statements.

Note 1. The Company and Summary of Significant Accounting Policies

Basis of Presentation and Going Concern

The amounts in the notes are stated in Euros, unless otherwise noted, and rounded to the nearest thousand except for share and per share amounts.

Mymetics Corporation (the "Company" or "Mymetics") was created for the purpose of engaging in vaccine research and development. Its main research efforts in the beginning have been concentrated in the prevention and treatment of the AIDS virus and malaria. The Company has established a network which enables it to work with education centers, research centers, pharmaceutical laboratories and biotechnology companies. Besides the HIV and malaria vaccine candidates under development, the Company additionally has the following vaccines in its pipeline; (i) Herpes Simplex which is at the pre-clinical stage and currently on hold, (ii) influenza for elderly which has finished a clinical trial Phase I, (iii) Respiratory Syncytial Virus (RSV) which is at the pre-clinical stage and currently on hold and (iv) Chikungunya virus at the discovery stage.

As of December 31, 2018, the Company is in the pre-clinical testing of some of its vaccine candidates and a commercially viable product is not expected for several more years. However, the Company generated some revenue through its license, collaboration and grant agreements. The Company is working on several research projects with commercial partners for immunotherapy in the fields of allergy and oncology. The allergy project is in collaboration with Anergis SA, for which the Company prepared virosome based vaccines which include Anergis peptides for treating birch pollen allergy. These formulations were tested in preclinical studies and compared to the Anergis earlier formulations. The success criteria were met and Anergis has now a time limited exclusive option to enter into a License and Collaboration Agreement with Mymetics for the use of virosomes in the field of allergies. The Company also finished the grant funded project in the field of HIV from the EU Horizon 2020 and Switzerland SERI which focused on developing thermostable and cold chain independent virosome based vaccines (MACIVIVA project). This project ended on November 3, 2018. Management believes that the Company’s research and development activities will result in valuable intellectual property that can generate significant revenues in the future through licensing. Vaccines are one of the fastest growing markets in the pharmaceutical industry.

These consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has experienced negative cash flows from operations and significant losses since inception resulting in an accumulated deficit of E84,675 at December 31, 2018. Further, the Company’s current liabilities exceed its current assets by E53,732 as of December 31, 2018, and there is no assurance that cash will become available to pay current liabilities in the near term. Management is seeking additional financing but there can be no assurance that management will be successful in any of those efforts. These conditions raise substantial doubt about our ability to continue as a going concern within one year from the issuance of the financial statements.

Critical Accounting Policies and Management Estimates

The preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America requires management to use judgment in making estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. Certain of the estimates and assumptions required to be made relate to matters that are inherently uncertain as they pertain to future events. While management believes that the estimates and assumptions used were the most appropriate, actual results could differ significantly from those estimates under different assumptions and conditions. The following is a description of those accounting policies believed by management to require subjective and complex judgments which could potentially affect reported results.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. Significant intercompany accounts and transactions have been eliminated.

Foreign Currency Translation

The Company translates assets and liabilities of its subsidiaries at the rate of exchange at the balance sheet date. Revenues and expenses of its subsidiaries are translated at the average rate of exchange throughout the period. Unrealized gains or losses from these translations are reported as a separate component of comprehensive income. Transaction gains or losses are included in expenses in the consolidated statements of comprehensive loss. The translation adjustments do not recognize the effect of income tax because the Company expects to reinvest the amounts indefinitely in operations. The Company's reporting currency is the Euro because substantially all of the Company's activities are conducted in Europe.

Cash

We consider all highly liquid investments purchased with maturities of three months or less to be cash equivalents. Cash deposits are occasionally in excess of insured amounts.

Revenue Recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification (ASC) Topic 606, Revenue from Contracts with Customers, using the modified retrospective method and there was no impact to financial position and results of operations as a result of the adoption. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Overall, adoption of the new standard did not result in an adjustment to amounts previously reported in our consolidated financial statements and there were no other significant changes impacting the timing or measurement of our revenue or our business processes and controls.

The Company has concluded that government grants are not within the scope of Topic 606, as they do not meet the definition of a contract with a “customer”. The Company concluded the definition of a contract with a “customer” was not met as the counterparty to the government grants has not contracted to obtain goods or services and thus the contracts are not considered to have commercial substance. Government grants provide the Company with payments for certain types of expenditures related to research and development activities over a contractually defined period. Revenue from government grants is recognized in the period during which the related costs are incurred, provided that the applicable conditions under the government contracts have been met.

Grant Revenue - HORIZON 2020

In April 2015, the Company was selected to receive project grants with a total of E8.4 million. A total of E5.3 million is funded as part of Horizon 2020, the European Union research and innovation framework program and up to E3.1 million of funding will be provided by the Swiss State “Secretariat for Education, Research and Innovation” (SERI) for the Swiss based consortium partners. The grant funds the evaluation, development and manufacturing scale-up of thermo-stable and cold-chain independent nano-pharmaceutical virosome-based vaccine candidates. Of the total amount, E3.8 million is directly attributable to Mymetics’ activities, with the remaining balance going to the consortium partners and is not recorded in Mymetics financial statements. The project started on May 4, 2015 and officially ended on November 2, 2018, after which a final report has been prepared, and submitted to the EU for a total costs declared of E8,262 for the total project and E3,673 for Mymetics.

The amounts mentioned in the following statements are purely related to Mymetics and not to the other partners in the projects: The Company received a pre-payment from the two granting organizations for a total value of E1,554 in May 2015, a second tranche of E917 from the EU was received in December 2016, and E614 from “SERI” was received in April 2017, which was used to finance the next reporting covering the period of November 2016 to October 2017. In November 2017, the Company submitted the second report and a new funding request, which resulted in another tranche of funding from the EU of E77 received in February 2018. This brings the total funding received to date to E3,162, which represents 82% of the awarded grant contribution. On December 21, 2018, the final report has been officially submitted to the EU. The total cost incurred by the Company of E3,673 represents 96% of the maximum grant. As a result, the Company funded the project for a total of E511 as of December 31, 2018. The final report has been validated by the EU and SERI and the final payments have been received during the first quarter of 2019.

ANERGIS SA

In December 2018, the Company announced that the success criteria of the Research and Option to License Agreement with Anergis SA (“Anergis”) had been met. Under the terms of the Research Agreement, a pre-clinical study program evaluated the immunogenicity profile of the Anergis’ peptides designed to treat birch allergy when presented on Mymetics’ proprietary virosomes, with or without undisclosed TLR ligands or other adjuvants, and these results were compared to Anergis’ AllerT product combination.

The pre-defined success criteria were met and Anergis has now a time limited option to enter into an exclusive license agreement with Mymetics for the use of virosomes in the field of allergies. Should Anergis and Mymetics execute a License and Collaboration Agreement (LCA), Anergis would make an upfront payment to Mymetics in an amount that increases as the date of the LCA is executed. The LCA also includes milestone payments based on certain regulatory clearances and royalties for net sales. The contractual material had been delivered during the third quarter of the year 2018 and 100% of the agreed payments from the Research and Option to License Agreement has been received and fully recognized as revenue in Q3 2018. The LCA has not been executed as of the date this report has been filed.

Receivables

Receivables are stated at their outstanding principal balances. Management reviews the collectability of receivables on a periodic basis and determines the appropriate amount of any allowance. There was no allowance necessary at December 31, 2018 or 2017. The Company charges off receivables to the allowance when management determines that a receivable is not collectible. The Company may retain a security interest in the products sold.

Property and Equipment

Property and equipment is recorded at cost and is depreciated over its estimated useful life on straight-line basis from the date placed in service. Estimated useful lives are usually taken as three years.

Impairment of Long Lived Assets

Long-lived assets, which include property and equipment, are assessed for impairment whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount to the forecasted undiscounted future cash flows generated by that asset. In the event the carrying value of the assets exceeds the undiscounted future cash flows generated by that asset and the carrying value is not considered recoverable, impairment exists. An impairment loss is measured as the excess of the asset’s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would be recognized in net income (loss) in the period that the impairment occurs.

Goodwill

Goodwill represents the excess of purchase price over the value assigned to the net tangible and identifiable intangible assets of a business acquired. The Company typically performs its annual goodwill impairment test effective as of April 1 of each year, unless events or circumstances indicate impairment may have occurred before that time. The Company assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. After assessing qualitative factors, the Company determined that no further testing was necessary. If further testing was necessary, the Company would determine the fair value of each reporting unit, and compare the fair value to the reporting unit’s carrying amount. As of December 31, 2018, management believes there are no indications of impairment. The Company has one reporting unit.

Research and Development

Research and development costs are expensed as incurred.

Taxes on Income

The Company accounts for income taxes under an asset and liability approach that requires the recognition of deferred tax assets and liabilities for expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. In estimating future tax consequences, the Company generally considers all expected future events other than enactments of changes in the tax laws or rates.

The Company reports a liability, if any, for unrecognized tax benefits resulting from uncertain income tax positions taken or expected to be taken in an income tax return. Estimated interest and penalties, if any, are recorded as a component of interest expense and other expense, respectively.

The Company has not recorded any liabilities for uncertain tax positions or any related interest and penalties at December 31, 2018 or 2017. The Company's United States tax returns are open to audit for the years ended December 31, 2015 to 2018. The returns for the Swiss subsidiary, Mymetics S.A., are open to audit for the year ended December 31, 2018. The returns for the Netherlands subsidiaries, Bestewil B.V. and Mymetics B.V., are open to audit for the year ended December 31, 2018.

Earnings per Share

Basic earnings per share is computed by dividing net income or loss attributable to common shareholders by the weighted average number of common shares outstanding in the common period. Diluted earnings per share takes into consideration common shares outstanding (computed under basic earnings per share) and potentially dilutive securities. For the years ended December 31, 2018 and 2017, options and convertible debt were not included in the computation of diluted earnings per share under the treasury stock method because their effect would be anti-dilutive due to the net loss.

For the year ended December 31, 2018, the weighted average number of shares was 303,757,622. For the same period, the total potential number of shares issuable of 659,783,442 includes 630,683,442 potential issuable shares related to convertible loans and 29,100,000 potential issuable shares related to outstanding not expired options granted to employees.

For the year ended December 31, 2017, the weighted average number of shares was 303,757,622. For the same period, the total potential number of shares issuable of 623,183,765 includes 594,083,765 potential issuable shares related to convertible loans and 29,100,000 potential issuable shares related to outstanding not expired options granted to employees.

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock. No shares are issued or outstanding at December 31, 2018 or 2017. The preferred stock is issuable in several series with varying dividend, conversion and voting rights. The specific series and rights will be determined upon any issuance of preferred stock.

Stock-Based Compensation

Compensation cost for all share-based payments is based on the estimated grant-date fair value. The Company amortizes stock compensation cost ratably over the requisite service period.

The issuance of common shares for services is recorded at the quoted price of the shares on the date the services are rendered.

Estimates

The preparation of financial statements in conformity with United States generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Fair Value Measurements

Fair value guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include:

Level 1-	Quoted prices in active markets for identical assets or liabilities.
Level 2-	Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3-	Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Fair Values of Financial Instruments

The Company generally has the following financial instruments: cash, receivables, accounts payable, and notes payable. The carrying value of cash, receivables and accounts payable, approximates their fair value based on the short-term nature of these financial instruments. Management believes that it is not practicable to estimate the fair value of the notes payable due to the conversion features and unique nature of these instruments.

Concentrations

In 2018 and 2017, the Company derived 92% and 87% of revenue from the Horizon 2020 project respectively.

Recently Issued Accounting Standards

In February 2016, FASB issued Accounting Standards Update No. 2016-02, Leases: Topic 842 (ASU 2016-02), that replaces existing lease guidance. The new standard is intended to provide enhanced transparency and comparability by requiring lessees to record right-of-use (ROU) assets and corresponding lease liabilities on the balance sheet. Under the new guidance, leases will continue to be classified as either finance or operating, with classification affecting the pattern of expense recognition in the Consolidated Statements of Comprehensive Loss. Lessor accounting is largely unchanged under ASU 2016-02. Adoption of ASU 2016-02 is required for fiscal reporting periods beginning after December 15, 2018, including interim reporting periods within those fiscal years with early adoption being permitted. The new standard initially required application with a modified retrospective approach to each prior reporting period presented with various optional practical expedients. In July 2018, this requirement was amended with the issuance of Accounting Standards Update No. 2018-11, Leases: Topic 842: Targeted Improvements (ASU 2018-11), which permits an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, 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. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases). An entity that elects this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments do not change the existing disclosure requirements in Topic 840. The Company adopted the standard on January 1, 2019 and based on leases in place at that date, the Company doesn't expect a material impact.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments: Credit Losses ("ASU 2016-13"), which changes the impairment model for most financial instruments, including trade receivables from an incurred loss method to a new forward-looking approach, based on expected losses. The estimate of expected credit losses will require entities to incorporate considerations of historical information, current information and reasonable and supportable forecasts. This ASU is effective for us in the first quarter of 2020 and must be adopted using a modified retrospective transition approach. The Company is currently evaluating the potential impact that the adoption of ASU 2016-13 will have on our consolidated financial statements.

Note 2. Transactions with Affiliates

Mr. Ernest M. Stern, the Company's outside U.S. counsel, is both a director of the Company and was a partner in Akerman LLP, the firm retained in 2016 as legal counsel by the Company. Mr. Stern resigned from the firm Akerman LLP and became a partner in the law firm of Culhane Meadows PLLC as of March 1, 2017. Culhane Meadows PLLC is the Company's legal counsel effective March 1, 2017. Fees paid to the law firms in the years ended December 31, 2018 and 2017, amounted to E22 and E63, respectively.

Two of the Company's major shareholders have granted secured convertible notes, short term convertible notes and short term promissory notes, which have a total carrying amount of E54,370, including interest due to date. Conversion prices on the Euro-denominated convertible debt have been fixed to a fixed Euro/US dollar exchange rate.

The details of these notes and other loans are as follows at December 31, 2018:

Lender	1st-Issue Date		Principal Amount	Duration (Note)	Interest Rate	Conversion Price (US$ stated)	Fixed Rate EUR/USD Conversion Price
Eardley Holding A.G. (1)	06/23/2006	E	166	(2)	10% pa	$ 0.10	N/A
Anglo Irish Bank S.A.(3)	10/01/2007	E	500	(2)	10% pa	$ 0.50	1.4090
Round Enterprises Ltd.	12/10/2007	E	1,500	(2)	10% pa	$ 0.50	1.4429
Round Enterprises Ltd.	01/22/2008	E	1,500	(2)	10% pa	$ 0.50	1.4629
Round Enterprises Ltd.	04/25/2008	E	2,000	(2)	10% pa	$ 0.50	1.5889
Round Enterprises Ltd.	06/30/2008	E	1,500	(2)	10% pa	$ 0.50	1.5380
Round Enterprises Ltd.	11/17/2008	E	1,200	(2)	10% pa	$ 0.50	1.2650
Round Enterprises Ltd.	02/06/2009	E	1,500	(2)	10% pa	$ 0.50	1.2940
Round Enterprises Ltd.	06/15/2009	E	5,500	(2,4)	10% pa	$ 0.80	1.4045
Eardley Holding A.G.	06/15/2009	E	100	(2,4)	10% pa	$ 0.80	1.4300
Von Meyenburg	08/03/2009	E	200	(2)	10% pa	$ 0.80	1.4400
Round Enterprises Ltd.	10/13/2009	E	2,000	(2)	5% pa	$ 0.25	1.4854
Round Enterprises Ltd.	12/18/2009	E	2,200	(2)	5% pa	$ 0.25	1.4338
Round Enterprises Ltd.	08/04/2011	E	1,049	(5,6)	10% pa	$ 0.034	N/A
Eardley Holding A.G.	08/04/2011	E	262	(5,6)	10% pa	$ 0.034	N/A
Round Enterprises Ltd.	11/08/2011	E	400	(6)	10% pa	$ 0.034	1.3787
Eardley Holding A.G.	11/08/2011	E	100	(6)	10% pa	$ 0.034	1.3787
Round Enterprises Ltd.	02/10/2012	E	1,000	(6)	10% pa	$ 0.034	1.3260
Eardley Holding A.G.	02/14/2012	E	200	(6)	10% pa	$ 0.034	1.3260
Round Enterprises Ltd.	04/19/2012	E	321	(6)	10% pa	$ 0.034	1.3100
Eardley Holding A.G.	04/19/2012	E	81	(6)	10% pa	$ 0.034	1.3100
Round Enterprises Ltd.	05/04/2012	E	480	(6)	10% pa	$ 0.034	1.3152
Eardley Holding A.G.	05/04/2012	E	120	(6)	10% pa	$ 0.034	1.3152
Round Enterprises Ltd.	09/03/2012	E	200	(6)	10% pa	$ 0.034	1.2576
Eardley Holding A.G.	09/03/2012	E	50	(6)	10% pa	$ 0.034	1.2576
Round Enterprises Ltd.	11/04/2012	E	500	(6)	10% pa	$ 0.034	1.2718
Eardley Holding A.G.	12/06/2012	E	125	(6)	10% pa	$ 0.034	1.3070
Round Enterprises Ltd.	01/16/2013	E	240	(6)	10% pa	$ 0.034	1.3318
Eardley Holding A.G.	01/16/2013	E	60	(6)	10% pa	$ 0.034	1.3318
Round Enterprises Ltd.	03/25/2013	E	400	(6)	10% pa	$ 0.037	1.2915
Eardley Holding A.G.	04/14/2013	E	150	(6)	10% pa	$ 0.034	1.3056
Round Enterprises Ltd.	04/14/2013	E	600	(6)	10% pa	$ 0.034	1.3056
Eardley Holding A.G.	05/15/2013	E	170	(6)	10% pa	$ 0.037	1.2938
Round Enterprises Ltd.	05/15/2013	E	680	(6)	10% pa	$ 0.037	1.2938
Eardley Holding A.G.	06/24/2013	E	60	(6)	10% pa	$ 0.025	1.3340
Round Enterprises Ltd.	06/24/2013	E	240	(6)	10% pa	$ 0.025	1.3340
Eardley Holding A.G.	08/05/2013	E	80	(6)	10% pa	$ 0.018	1.3283
Round Enterprises Ltd.	08/05/2013	E	320	(6)	10% pa	$ 0.018	1.3283
Eardley Holding A.G.	03/01/2017	E	230	(7)	2.5% pa		
Round Enterprises Ltd.	03/01/2017	E	920	(7)	2.5% pa		
Eardley Holding A.G.	10/18/2017	E	230	(7)	2.5% pa		
Round Enterprises Ltd.	10/18/2017	E	920	(7)	2.5% pa		
Eardley Holding A.G.	06/01/2018	E	160	(8)	2.5% pa		
Round Enterprises Ltd.	06/01/2018	E	640	(8)	2.5% pa		
Eardley Holding A.G.	11/10/2018	E	160	(8)	2.5% pa		
Round Enterprises Ltd.	11/10/2018	E	640	(8)	2.5% pa		
Total Short Term Principal Amounts		E	31,654				
Accrued Interest		E	23,104				
TOTAL LOANS AND NOTES		E	54,758				

(1) Private investment company of Dr. Thomas Staehelin, member of the Board of Directors and of the Audit Committee of the Company. Face value is stated in U.S. dollars at $190.

(2) This maturity date is automatically prolonged for periods of three months, unless called for repayment.

(3) Renamed Hyposwiss Private Bank Genève S.A. and acting on behalf of Round Enterprises Ltd. which is a major shareholder.

(4) The loan is secured against 2/3rds of the IP assets of Bestewil Holding BV and against all property of the Company.

(5) The face values of the loans are stated in U.S. dollars at $1,200 and $300, respectively.

(6) This maturity date is automatically prolonged for periods of three months, unless called for repayment. The conversion price per share is determined by the lower of (i) reducing by 10% the price per share of the Company's common stock paid by the investors in connection with an investment in the Company of not less than US$20,000, or (ii) at the stated conversion price using a fixed exchange rate which are noted in the table above.

(7) On March 1, 2017, Round Enterprises Ltd. and Eardley Holding AG each provided two promissory Notes for a total of E1,840 and E460, respectively, with a 2.5% interest per annum and a maturity date of March 1, 2018. The first 50% of the promissory Notes of E920 and E230, respectively, were provided immediately. The second 50% of the promissory notes of E920 and E230, respectively, were provided on October 18, 2017 with a 2.5% interest per annum and a maturity date of October 18, 2018. Both Round Enterprises Ltd. And Eardley Holding AG have agreed to amend the maturity date of these promissory notes to follow the same terms of the other convertible loans. Therefore the maturity date of the promissory notes is amended to be the later of (i) June 30, 2018, or (ii) the end of a subsequent calendar quarter in which the Company receives a written request from the lender for repayment of the unpaid principal and accrued interest due under the Notes.

(8) On June 1, 2018, Round Enterprises Ltd. and Eardley Holding AG each provided two promissory Notes for a total of E1,280 and E320 in two tranches, respectively, with a 2.5% interest per annum. The first tranche of the promissory Notes of E640 and E160, respectively, were provided immediately. The second tranche of the promissory notes of E640 and E160, respectively, were provided on November 10, 2018 with a 2.5% interest per annum. The maturity date of these promissory notes to follow the same principle of other convertible loans and is the later of (i) June 30, 2019, or (ii) the end of a subsequent calendar quarter in which the Company receives a written request from the lender for repayment of the unpaid principal and accrued interest due under the Notes.

Note 3. Income Taxes

The reconciliation of income tax on loss computed at the federal statutory rates to income tax expense is as follows:

	2018	2017
U.S. Federal statutory rates on net loss before income taxes	E (876)	E (1,396)
Effect of foreign statutory rate differences	(43)	(36)
Effect of exchange rate changes	(952)	3,516
Expiration of net operating loss carry forwards	299	580
Permanent differences	(24)	(12)
Deferred tax impact from tax rate change	--	9,422
Change in valuation allowance	1,615	(12,069)
Income tax provision (benefit)	E 19	E 5

Deferred tax asset is composed of the following:

	2018	2017
Licenses capitalized for United States tax purposes	E 295	E 357
Stock options	160	157
Foreign tax credit carry over	224	214
Net operating loss carry forwards		
United States	16,017	14,687
Switzerland	160	299
The Netherlands	907	434
	17,763	16,148
Less valuation allowance for deferred tax asset	(17,763)	(16,148)
Net deferred tax asset	E --	E --

On December 22, 2017, “H.R.1”, formerly known as the “Tax Cuts and Jobs Act”, was signed into law. Among other items, H.R.1 reduces the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company revalued its net deferred tax asset at December 31, 2017 at the new lower tax rate resulting in a reduction to the value of the deferred tax asset.

The Company's provision for income taxes was derived from U.S., Swiss, and Netherlands operations. At December 31, 2018, the Company had estimated net operating loss carry forwards which expire as follows:

	United States	Switzerland	The Netherlands
2019	334	466	--
2020	493	114	251
2021	1,015	--	629
2022	1,901	--	
2023	1,266		43
2024-2037	67,687	30	2,703
Perpetual	3,575	--	
	E 76,271	E 611	E 3,626

Note 4. Stock Options

2001 Qualified Incentive Stock Option Plan:
The Company's board of directors approved a Stock Option Plan on June 15, 2001, which provides for the issuance of up to 5,000,000 shares of the Company's common stock to employees and non-employee directors.

2009 Qualified Incentive Stock Option Plan:
During 2010, the Board of Directors of Mymetics awarded 4,350,000 incentive stock options to the employees and officers of the Company.

2013 Qualified Incentive Stock Option Plan:
For the year ended December 31 2013, the Board of Directors of Mymetics approved 30,000,000 incentive stock options to the employees and officers of the Company.

The Company recognized compensation expense related to the issued option grants of E13 and E36 for the years ended December 31, 2018 and 2017, respectively. These amounts were recognized as research and development expense and general and administrative expense based on the specific recipient of the award for the years ended December 31, 2018 and 2017. As of December 31, 2018, a total of 442,500 shares of common stock with unrecognized compensation cost of E1 are unvested. The cost is expected to be recognized ratably through March 2019.

A summary of activity related to stock options under the 2001, 2009 and 2013 Stock Option Plans is represented below:

	Number of Shares	Exercise Price Range	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding, December 31, 2016	29,100,000	$ 0.02 to $0.19	$ 0.0364		
Granted	--	--	--		
Exercised	--	--	--		
Expired/forfeited	--	--	--		
Outstanding, December 31, 2017	29,100,000	$ 0.02 to $0.19	$ 0.0364		
Granted	--	--	--		
Exercised	--	--	--		
Expired/forfeited	--	--	--		
Outstanding, December 31, 2018	29,100,000	$ 0.02 to $0.19	$ 0.0364	4.81	$ 809,400
Exercisable, December 31, 2018	27,490,000	$ 0.02 to $0.19	$ 0.0372	4.72	$ 762,066

The aggregate intrinsic value of the stock options fluctuates in relation to the market price of the Company’s common stock.

Outstanding and exercisable options by price range as of December 31, 2018, were as follows:

	Outstanding options			Exercisable Options	
Range of Exercise Prices per Share	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 0.14	2,350,000	1.0	$ 0.140	2,350,000	$ 0.140
$ 0.19	1,000,000	1.5	$ 0.190	1,000,000	$ 0.190
$ 0.02	17,450,000	4.8	$ 0.020	17,450,000	$ 0.020
$ 0.023	8,300,000	6.3	$ 0.023	6,690,000	$ 0.023
$ 0.02 - $ 0.19	29,100,000		$ 0.0364	27,490,000	$ 0.0372

During the year 2018 and 2017, no stock options were issued.

As of December 31, 2018, the 2013 Stock Option Plan has 1,150,000 shares available for future grants of stock options.

The Company will issue new shares upon the exercise of any options.

Note 5. Commitments

Total rent expense per year was E150 for 2018 and E150 for 2017. The lease of the Company's Lausanne, Switzerland facilities and the lease of the Company's facilities in Leiden, the Netherlands, can be terminated in 2019.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Mymetics Corporation

March 29, 2019

By: /s/ Ronald Kempers
Name Ronald Kempers
Title Chief Executive Officer / Chief Financial Officer

March 29, 2019

By: /s/ Ulrich Burkhard
Name: Ulrich Burkhard
Title: Director

March 29, 2019

By: /s/ Ernest Stern
Name: Ernest Stern
Title: Director

March 29, 2019

By: /s/ Thomas Staehelin
Name: Thomas Staehelin
Title: Director

POWERS OF ATTORNEY

Each person whose signature appears below constitutes and appoints Ronald Kempers as his true and lawful attorney-in-fact and agents, with full power of substitution and re substitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorney-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or their substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Mymetics Corporation

March 29, 2019

By: /s/ Ronald Kempers
Name Ronald Kempers
Title Chief Executive Officer / Chief Financial Officer

March 29, 2019

By: /s/ Ulrich Burkhard
Name: Ulrich Burkhard
Title: Director

March 29, 2019

By: /s/ Ernest Stern
Name: Ernest Stern
Title: Director

March 29, 2019

By: /s/ Thomas Staehelin
Name: Thomas Staehelin
Title: Director

Exhibit 14.1

CODE OF ETHICS

The Chief Executive Officer ("CEO") and all senior financial officers, including the Chief Financial Officer and principal accounting officer of Mymetics Corporation (the "Company"), and of any subsidiary that becomes subject to the periodic reporting requirements under Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, are bound by the provisions set forth in this Code of Ethics relating to ethical conduct, conflicts of interest, compliance with law and standards designed to deter wrongdoing. The CEO and senior financial officers are subject to the following specific policies:

1. The CEO and all senior financial officers are responsible for full, fair, accurate, timely and understandable disclosure in the periodic reports required to be filed by the Company with the SEC. Accordingly, it is the responsibility of the CEO and each senior financial officer promptly to bring to the attention of the Company's Audit Committee any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings or otherwise assist the Audit Committee in fulfilling its responsibilities as specified in the Company's financial reporting policies and applicable law.

2. The CEO and each senior financial officer shall promptly bring to the attention of the Audit Committee any information he or she may have which he or she reasonably believes reflects or indicates (a) significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's financial reporting, audits or internal controls or (c) any attempt to improperly influence, coerce or mislead the Company's independent auditors in violation of Section 303(a) of the Sarbanes-Oxley Act of 2002 and the rules of the SEC passed there under.

3. The CEO and each senior financial officer shall promptly bring to the attention of the General Counsel or the CEO and to the Audit Committee any information he or she may have which he or she reasonably believes reflects or indicates a violation of this Code of Ethics or any actual or apparent conflicts of interest between personal and professional relationships, involving any management or other employees who have a significant role in the Company's financial reporting, audits or internal controls.

4. The CEO and each senior financial officer shall promptly bring to the attention of the General Counsel or the CEO and to the Audit Committee any information he or she may have which he or she reasonably believes indicates a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof.

5. The Board of Directors shall determine, or designate appropriate persons to determine, appropriate actions to be taken in the event of violations of the Code of Ethics or of these additional procedures by the CEO and the Company's senior financial officers. Such actions shall be reasonably designed to deter wrongdoing and to promote accountability for adherence to this Code of Ethics and to these additional procedures, and shall include written notices to the individual involved that the Board has determined that there has been a violation and the action to be taken, which action may include censure by the Board, demotion or re-assignment of the individual involved, suspension with or without pay or benefits (as determined by the Board) or termination of the individual's employment. In determining what action is appropriate in a particular case, the Board of Directors or such designee shall take into account all relevant information, including without limitation the nature and severity of the violation, whether the violation was a single occurrence or repeated occurrences, whether the violation appears to have been intentional or inadvertent, whether the individual in question had been advised prior to the violation as to the proper course of action and whether or not the individual in question had committed other violations in the past.

6. Any waiver of this Code of Ethics may be made only by the Board of Directors of the Company and shall be disclosed to the persons in the manner provided by applicable law and by any regulatory agency having authority over the Company.

Exhibit 21.1

SUBSIDIARIES

Mymetics Corporation has three subsidiaries:

1. Mymetics S.A. (a wholly-owned subsidiary of Mymetics Corporation) is a company organized under the laws of Switzerland and did business under the names “Mymetics S.A.” during 2018.

2. Bestewil Holding B.V. (a wholly-owned subsidiary of Mymetics Corporation) is a company organized under the laws of the Netherlands and did business under the name "Bestewil Holding B.V." during 2018.

3. Mymetics B.V. (a wholly-owned subsidiary of Mymetics Corporation, via Bestewil Holding B.V.) is a company organized under the laws of the Netherlands and did business under the names “Mymetics B.V.” and "Virosome Biologicals B.V." during 2018.

Exhibit 31.1

Certification

I, Ronald Kempers, certify that:

1. I have reviewed this annual report on Form 10-K of Mymetics Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e))and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 28, 2019

/s/ Ronald Kempers
Ronald Kempers
Chief Executive Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Mymetics Corporation (the "Company") on Form 10-K for the year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald Kempers, Chief Executive Officer of the Company and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Ronald Kempers
Ronald Kempers
Chief Executive Officer

By: /s/ Ronald Kempers
Ronald Kempers
Chief Financial Officer

March 28, 2019