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

FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☒ **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**

OR

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

DATE OF EVENT REQUIRING THIS SHELL COMPANY REPORT _____

Commission file number: **000-30902**

Compugen Ltd.

(Exact name of registrant as specified in its charter and translation of registrant's name into English)

Israel

(Jurisdiction of incorporation or organization)

Azrieli Center, 26 Harokmim Street, Building D, Holon 5885849 Israel

(Address of principal executive offices)

Ari Krashin, Chief Financial Officer

Phone: +972-3-765-8585, Fax: +972-3-765-8555

Azrieli Center, 26 Harokmim Street, Building D, Holon 5885849 Israel

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

Title of each class

Ordinary shares, par value NIS 0.01 per share

Name of each exchange on which registered

The Nasdaq Stock Market LLC
(The Nasdaq Global Market)

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: **59,849,784 Ordinary Shares**

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

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

☐ Yes ☒ No

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

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

☒ Yes ☐ No

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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 ☐

[†] The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒

International Financial Reporting Standards as issued
by the International Accounting Standards Board ☐

Other ☐

Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

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CAUTIONARY STATEMENT REGARDING

FORWARD-LOOKING STATEMENTS

This annual report on Form 20-F includes “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements include words such as “will,” “may,” “assume,” “expect,” “anticipate,” “could,” “project,” “estimate,” “possible,” “potential,” “believe,” “suggest,” and “intend,” and describe opinions about future events. We have based these forward-looking statements on information available to us as of the date hereof, and on our current assumptions, intentions, beliefs, expectations and projections about future events. We assume no obligation to update any such forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of Compugen to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause our actual results to differ materially from those projected in the forward-looking statements include, without limitation, the risk factors set forth under “Item 3. Key Information -D. Risk Factors,” the information about us set forth under “Item 4. Information on the Company” and information related to our financial condition under “Item 5. Operating and Financial Review and Prospects.”

All references in this annual report on Form 20-F to “Compugen,” the “Company,” “we,” “us,” “our,” or similar references refer to Compugen Ltd. and our wholly owned subsidiary Compugen USA, Inc., except where the context otherwise requires or as otherwise indicated.

We have prepared our consolidated financial statements in United States dollars and in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. All references herein to “dollars” or “\$” are to United States dollars, and all references to “Shekels” or “NIS” are to New Israeli Shekels.

PART I.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3. KEY INFORMATION

A. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data are derived from our audited consolidated financial statements which have been prepared in accordance with U.S. GAAP. The selected consolidated financial data as of December 31, 2018 and 2017 and for the years ended December 31, 2018, 2017 and 2016 have been derived from our audited consolidated financial statements and notes thereto included elsewhere in this annual report. The selected consolidated financial data as of December 31, 2016, 2015 and 2014 and for the years ended December 31, 2015 and 2014 have been derived from audited consolidated financial statements not included in this annual report. The selected consolidated financial data set forth below should be read in conjunction with and are qualified by reference to “Item 5. Operating and Financial Review and Prospects” and our consolidated financial statements and notes thereto included elsewhere in this annual report.

Selected Financial Data

	Year ended December 31,				
	2014	2015	2016	2017	2018
	(US\$ in thousands, except share and per share data)				
Consolidated Statement of Operations Data					
Revenues	\$ 12,367	\$ 9,277	\$ 712	\$ -	\$ 17,800
Cost of revenues	3,344	1,633	223	-	1,034
Total operating expenses ⁽¹⁾	21,360	28,562	33,072	37,405	39,993
Operating loss	(12,337)	(20,918)	(32,583)	(37,405)	(23,227)
Financial and other income, net	1,758	1,145	1,097	339	628
Equity loss	(155)	-	-	-	-
Losses before taxes on income	(10,734)	(19,773)	(31,486)	(37,066)	(22,599)
Taxes on income	(360)	(390)	(20)	-	-
Net loss	(11,094)	(20,163)	(31,506)	(37,066)	(22,599)
Realized and unrealized gain (loss) from investment in marketable securities and from foreign currency derivative contracts	(3,406)	(801)	(414)	10	(17)
Total comprehensive loss	(14,500)	(20,964)	(31,920)	(37,056)	(22,616)
Basic net loss per share	<u>\$ (0.23)</u>	<u>\$ (0.40)</u>	<u>\$ (0.62)</u>	<u>\$ (0.72)</u>	<u>\$ (0.41)</u>
Weighted average number of ordinary shares used in computing basic net loss per share	<u>47,808,855</u>	<u>50,437,040</u>	<u>50,855,908</u>	<u>51,179,694</u>	<u>55,277,428</u>
Diluted net loss per share	<u>\$ (0.26)</u>	<u>\$ (0.40)</u>	<u>\$ (0.62)</u>	<u>\$ (0.72)</u>	<u>\$ (0.41)</u>
Weighted average number of ordinary shares used in computing diluted net loss per share	<u>48,387,063</u>	<u>50,437,040</u>	<u>50,855,908</u>	<u>51,179,694</u>	<u>55,277,428</u>

⁽¹⁾ Includes stock based compensation – see Note 7 to our 2018 consolidated financial statements.

As of December 31,					
2014	2015	2016	2017	2018	
(US\$ in thousands)					

Consolidated Balance Sheet Data

Cash and cash equivalents, short-term bank deposits and restricted cash	\$	73,328	\$	81,421	\$	61,527	\$	30,438	\$	45,675
Trade receivable		-		7,800		-		-		-
Investment in marketable securities		1,054		426		-		-		-
Long-term bank deposits		35,026		-		-		-		-
Total assets		114,986		99,307		71,139		38,746		53,180
Deferred Revenues		1,789		312		-		-		-
Deferred participation in R&D expenses, including long term		-		-		-		-		4,092
Research and development funding arrangements and others		421		-		-		-		-
Accumulated deficit		(219,296)		(239,459)		(270,965)		(308,242)		(330,841)
Total shareholders' equity	\$	106,116	\$	89,897	\$	63,519	\$	29,297	\$	37,243

For additional financial information, please see “Item 5. Operating and Financial Review and Prospects – A. Operating Results,”

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

An investment in our ordinary shares involves a high degree of risk and many factors could affect our financial condition, cash flows and results of operations. You should carefully consider the following risk factors, as well as the other information in this Annual Report. If we do not successfully, or cannot, address the risks to which we are subject, we could experience a material adverse effect on our business, results of operations and financial condition, which could include the need to limit or even discontinue our business operations, and accordingly our share price may decline and you could lose all or part of your investment. We can give no assurance that we will successfully address any of these risks. The principal risks we face are described below.

Risks Related to our Business, Financial Results and Financing Needs

Our corporate restructuring may not be successful.

On February 26, 2019, we announced a corporate restructuring to reduce costs by consolidating and streamlining R&D operations (the “2019 Restructuring”). Anticipated cost reductions are expected to extend our cash runway through mid-2020 to enable the planned expansion of the ongoing Phase 1 study for COM701. In addition, we will maintain investment in our proprietary computational discovery platform and will continue to advance our earlier stage immuno-oncology pipeline programs, which are our two long-term core value drivers.

The 2019 Restructuring includes reducing our workforce by 35%, consolidating R&D activities in one location in Israel and outsourcing certain preclinical activities to third-party service providers. Clinical development and business development activities will continue to operate in the United States. We anticipate savings of up to \$10 million on an annual basis. However, our restructuring activities may also result in unexpected risks or costs, such as:

- loss of knowledge in the translational science to develop product candidates;

- loss of internal capabilities in therapeutic antibody development;

- inability to efficiently transfer and consolidate R&D activities to Israel;

- inability to effectively manage our internal R&D efforts;

- finding appropriate external expertise for intended outsourced preclinical activities at a reasonable cost and in necessary timing to competitively advance our pipeline programs;

- inability to maintain and motivate our remaining employees and identify, recruit, and integrate additional employees; and

- employee claims and contractual disputes.

Actual financial and other impacts of the reductions could vary materially from the outcomes anticipated. If any of these risks materialize, they may have a material adverse effect on our results of operations or financial condition or may result in delays in our therapeutic antibody development or advance our therapeutic drug products through clinical development.

We cannot provide assurance that our business model will succeed in generating substantial revenues.

Our business model is primarily based on expected future revenues in various forms, including upfront fees, research funding, in-kind funding, milestone payments, license fees, royalties on product sales and other revenue sharing payments from commercialization of products by third parties, pursuant to various forms of collaborations for our novel targets and related drug product candidates at various stages of research and development. Our primary focus in immuno-oncology utilizes our computational target discovery infrastructure to identify novel drug targets and develop first-in-class therapeutics in the field of cancer immunotherapy. Drug target candidates discovered by our computational platform undergo initial target validation studies and, in selected cases, are advanced to the discovery and development of the therapeutic product candidate. Such drug target candidates and their related therapeutic product candidates serve as the basis for licensing and other forms of third-party collaborations. Our existing third-party collaboration and licensing agreements have been entered into at early development stages, each of which has an inherent risk of high failure. The inability to derive adequate revenues from our business model would materially harm our business, financial condition and results of operations and could result in the need to limit or even discontinue our business operations.

We have a history of losses, we expect to incur future losses and we may never achieve or sustain profitability.

As of December 31, 2018, we had an accumulated deficit of approximately \$330.8 million and had incurred net losses of approximately \$31.5 million in 2016, approximately \$37.1 million in 2017 and approximately \$22.6 million in 2018, in large part due to the expenditures associated with our ongoing research and development and limited revenues received to date. In addition, we expect to continue to incur net losses in the future due to our anticipated costs and expenses, primarily associated with our preclinical and clinical pipeline activities. Since we began focusing on our discovery capabilities in 2010, we have entered into three commercial arrangements with respect to our pipeline programs under which we have received to date a total amount of \$55.2 million, including a \$12 million investment. We cannot be certain that we will receive additional revenues under our existing collaborations or enter into additional arrangements for our pipeline programs or our computational discovery capabilities, or that such additional arrangements will provide sufficient revenues to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We may need to raise additional funds in the future, and if we are unable to raise such additional funds, we may need to limit or curtail or cease operations. To the extent any such funding is based on the sale of equity, our existing shareholders would experience dilution of their shareholdings.

We believe that our existing cash and cash equivalents and short-term bank deposits will be sufficient to fund our current level of operations through mid-2020, without considering the possible receipt of any additional funds, such as proceeds from existing or additional licensing and/or collaborative agreements, or from financings. However, we cannot predict with any degree of certainty when, or even if, we will achieve profitability, and therefore may need additional funds to continue financing our discovery, validation, development, clinical and commercialization activities. In 2018, we received net proceeds of approximately \$20 million through a registered direct public offering (which also included the issuance of warrants to the purchasers), as well as \$12 million pursuant to an investment from a strategic partner. We may seek additional capital due to favorable market conditions and strategic considerations even if we believe we have sufficient funds for our current and future operating plans.

Additional funds, including proceeds from license or collaborative agreements, or from other financings, may not be available to us on acceptable terms, or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our existing shareholders. For example, if we raise additional funds by issuing equity securities, our existing shareholders would experience dilution of their shareholdings. Debt financing, if available, may involve restrictive covenants that could limit our flexibility in conducting future business activities. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail one or more of our research or development programs. We also could be required to seek funds through arrangements with collaborators or other investors that may require us to enter into arrangements on terms that would otherwise not be acceptable to us.

Our therapeutic programs have reached more costly stages of research and development, including preclinical and clinical development of therapeutic product candidates. If we are not able to secure the funding or the capabilities required for such activities, we may be required to abandon, postpone, or attempt to license out certain drug target candidates or therapeutic product candidates at an earlier than anticipated stage. Any failure to raise funds as and when needed would materially harm our business, financial condition and results of operations, and result in the inability to have some or all of such therapeutic product candidates developed to fit potential commercialization and have a negative impact on our ability to pursue our business strategy.

We have a limited operating history with respect to the commercialization aspects of our business model upon which investors can base an investment decision or upon which to predict future revenues.

Our ability to generate revenues from collaborations for our current novel drug targets and related therapeutic product candidates at various stages of research and development has been limited to date. Since we began focusing on our discovery capabilities in 2010, we have entered into three commercial arrangements with respect to our pipeline programs under which we have received to date a total amount of \$55.2 million, of which \$12 million was an investment. We recognized revenue of \$17.8 million in 2018, no revenue in 2017 and \$0.7 million in revenue in 2016.

We cannot be certain that our focus on discovery, research and development efforts in the field of immuno-oncology, along with our decision to advance select programs to later drug development stages partially or fully at our own expense, will generate a stable or significant revenue stream. Moreover, we have very limited experience with respect to the financial arrangements and terms that may be available for our candidates at their various R&D stages. Also, and financial terms for agreements by other companies, to the degree disclosed, vary greatly. The inability to derive adequate revenues within our field of focus would materially harm our business, financial condition and results of operations and could result in the need to limit or even discontinue our business operations. Moreover, our operating history with respect to the commercialization aspects of our business model provides a limited basis to assess our ability to generate significant fees, research revenues, milestone payments, royalties or other revenue sharing payments from the licensing, development and anticipated future commercialization of pipeline programs based on our existing and future novel drug targets and related therapeutic product candidates.

Risks Related to our Discovery and Development Activities

Our computational target discovery activities are primarily focused on the discovery of new drug target candidates and our therapeutic pipeline is based on Compugen discovered targets.

While we believe that our drug target programs represent a compelling and unique opportunity to generate first-in-class therapeutic products, they require significant investment in the research and validation of the drug target candidate and in the discovery and development of the respective therapeutic product candidate. The computational discovery of new drug target candidates is a source for the development of potential first-in-class drug candidates, but the inherent lack of sufficient published scientific data to support the potential of these new drug targets candidates to serve as therapeutic opportunities, increases the risk of failure. Although we have built the target validation and drug discovery infrastructure and capabilities required to scientifically validate our new drug targets and to later translate them into therapeutic antibody development programs, we cannot be assured that our investment in such programs will result in validated drug targets that will enable the development of cancer immunotherapies, nor that we will realize success in product development or our ability to commercialize such opportunities and generate revenues.

In addition, our computational target discovery platform will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to allocate the necessary resources, the appropriately talented human resources or continue to identify new drug targets. If we are unable to allocate such resources when needed or identify suitable additional novel drug targets for preclinical and clinical development, our ability to develop therapeutic products and obtain product revenues in the future could be compromised, which could result in significant harm to our financial position and adversely impact our share price.

Our approach to the discovery of therapeutic products is based on our proprietary computational target discovery infrastructure is unproven clinically, and we do not know whether we will be able to discover and develop additional potential product candidates or products of commercial value.

Our method of identifying novel drug targets is based on our computational discovery platform and involves first identifying unmet needs in the field of cancer immunotherapy, where we believe our predictive capabilities would be relevant, or could be modified to be relevant. We focus on the discovery of drug targets that could serve as the basis for the development of possible treatments for patients non-responsive or refractory to existing cancer immunotherapies. In this field, we apply our computational target discovery capabilities, or develop new capabilities, to identify novel drug targets for addressing such unmet patient need.

While we believe that applying our computational target discovery capabilities to identify new drug targets may potentially enable the development of first-in-class therapeutics, our capabilities are still unproven clinically and our efforts may not result in the discovery and development of commercially viable therapeutic products. Although our approach has resulted in the discovery of several novel drug targets and their related first-in-class therapeutic product candidates, they are in early stages of research and development, with two having entered the clinic in 2018. Our approach may not result in time savings, higher success rates or reduced costs, and if not, we may not attract collaborators or develop new drugs as quickly or cost effectively or at all and therefore we may not be able to commercialize our approach as expected.

We are focusing our discovery and therapeutic development activities on mAb therapeutics for uses in immuno-oncology. If our current candidates fail, and we fail to continue to discover and develop therapeutic mAb candidates of industry interest in this field our business will likely be materially harmed.

The focus of our therapeutic development activities is on monoclonal antibodies, or mAb, therapeutics in the field of immuno-oncology. As a result, we are not undertaking internal discovery and development in other life science areas or for other drug modalities, and presently we only intend to pursue such opportunities, in collaboration with third parties. With respect to immune checkpoints, although there have been positive clinical results reported by others with respect to a number of products resulting in some products gaining approval by the U.S. Food and Drug Administration, or FDA, based on this positive data, there can be no assurance that our therapeutic product candidates or our earlier stage immuno-oncology target candidates in our pipeline, will provide similar clinical advantages or interest, that no long term adverse effects will be seen, or that other classes of targets or other products will not be discovered and developed with comparable or superior attributes. In the event of any of these occurrences, the actual and/or perceived value of a substantial portion of our pipeline would likely be reduced in which case our business may be materially harmed. To date, we have signed three commercial agreements involving our drug targets and/or product candidates. There is no assurance that we will be able to enter into additional collaborations or agreements on reasonable terms, if at all. In addition, if we fail to continue to discover and validate drug targets or develop product candidates of industry interest in our field of focus, our business will likely be materially harmed. There are many risks associated with this decision focus on immuno-oncology that include, among others:

- not utilizing the full scope of our target discovery capabilities;
- choosing a therapeutic area with a very high degree of competition;
- choosing a therapeutic area of great biological complexity and with very high failure rates in product development;
- not choosing the right drug targets or therapeutic area;
- having insufficient knowledge, personnel or capabilities in our chosen therapeutic area to select the right unmet medical needs, or novel drug target, or to timely, properly and efficiently validate the targets and/or select the appropriate mAb for further development as therapeutic product candidates, or to timely, properly or efficiently further them in development; and
- the inherent risk of high program failure rate throughout therapeutic development.

In each case, our failure could be due to lack of experience, delays in our internal research programs or applying the wrong criteria or experimental systems and procedures, or unanticipated scientific, safety or efficacy issues with our selected drug targets or product candidates, with the possible result that none of our product candidates result in licensed or marketable products. If any of these risks should materialize, our business, financial condition and results of operations would be materially harmed.

Our computational novel target discovery platform typically results in a significant number of potential discoveries of interest with each discovery process. If we or our partners fail to select the right drug target to validate and/or progress in the therapeutic development, due to either lack of experience or applying the wrong criteria throughout the development process, the selected drug target may never result in approvable or marketable therapeutic products and our business, financial condition and results of operations will be materially harmed.

Our computational target discovery approach to identify novel drug targets typically results in a significant number of potential discoveries of interest with each discovery process. Following each discovery process, we assess which of such potential discoveries to move forward into target validation based on various available scientific and business criteria, which may or may not be correct or sufficient, and this assessment continues on an on-going basis. In addition, since our research and development resources are limited we are able to progress with only a fraction of our discoveries in parallel. If at any stage in such assessment, we or our partners fail to select the right drug targets to validate and/or progress in development, due to either lack of experience or applying the wrong criteria throughout the development process, the selected drug targets may never result in licensable or marketable products, and our business, financial condition and results of operations may be materially harmed.

Our focus on developing our pipeline has resulted in a substantial increase in activities, certain of which we will undertake for the first time and may result in therapeutic product candidate failures, or fewer therapeutic product candidates being available for partnering or commercialization.

Until recently, our target validation studies resulted with the functional analysis of the drug target candidate and their respective expression profile. Upon completion of such activities, or earlier, we initiated our efforts to enter into collaborations for such drug target candidates which we found to be at an earlier stage than customary for licensing in the pharmaceutical industry. As a result, we currently advance our programs beyond their initial target validation stage, including advancing our therapeutic pipeline into preclinical and clinical activities, with two therapeutic product candidates against Compugen-discovered novel targets having begun Phase 1 clinical trials in 2018. This decision to move forward certain of our programs beyond the initial target validation stage requires us to undertake certain activities for the first time. Any failure to successfully undertake these new activities may result in therapeutic product candidate delays or failures either due to our lack of expertise, unsupportive findings, or lack of an appropriate technology, or the inherent risk of failure with respect to such activities and our ability to develop therapeutic drug candidates. Furthermore, due to our limited resources, we must choose which drug targets to advance further into extensive target validation studies, followed by preclinical and clinical therapeutic product development. This could result in fewer drug target candidates being available for partnering or commercialization at advanced stages or at all, due to our available resources being insufficient to further advance all programs. If any of these risks materialize, our business, financial condition and results of operations may be materially harmed.

We have limited experience in the development of therapeutic product candidates.

Our experience in the development of therapeutic product candidates, which was undertaken in our South San Francisco facilities, is limited, and our experience is now further limited due to the 2019 Restructuring. As a result of the 2019 Restructuring, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. To successfully develop and commercialize therapeutic products, we must either access such expertise via collaborations, consultants or service providers, and/or enhance and improve our internal expertise and capabilities. We may not be able to retain our remaining scientific and clinical personnel, or attract qualified scientific and clinical personnel with the required expertise in a timely manner, if at all, and/or engage any or all of the collaborators, consultants, service providers or other experts that we need in order to do so.

If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives or fail to have available, at the appropriate times, the required experience and expertise for the further development and commercialization of our therapeutic product candidates, we may be unsuccessful in these activities, or these activities may be significantly delayed and as a result we may be unable to implement our business strategy and our business would be materially harmed.

There are risks that are inherent in the development and commercialization of therapeutic products, and if any of these risks materialize, our business and financial results may be materially harmed.

We and our collaborators face a number of risks of failure that are inherent in the process of developing and commercializing novel therapeutic products. These risks, which typically result in very high failure rates even for successful biopharmaceutical companies, include, among others, the possibility that:

- our new target candidates will prove to be inappropriate targets for mAb therapeutics;
- our new target candidates will prove to be inappropriate targets for immunotherapy;
- we will not succeed in choosing the appropriate mAb for these targets
- our therapeutic product candidates will fail to progress to preclinical studies or clinical trials;
- our early stage development efforts may provoke competition by potential partners;
- our products covered by our collaborations may face internal competition from our partners' internal pipeline;

- our therapeutic product candidates will be found to be therapeutically ineffective;
- our therapeutic product candidates will be found to be toxic or to have other unacceptable side effects;
- our therapeutic product candidates will be inferior, or not show added value, compared to competing products;
- we or our collaborators will fail to receive required regulatory approvals;
- we or our collaborators will not be able to generate differentiation for our therapeutic product candidates;
- we or our collaborators will fail to manufacture our therapeutic product candidates in the quantity or quality needed for preclinical studies or clinical trials on a large scale and in a cost-effective manner;
- the commercialization of our therapeutic product candidates or our drug targets may infringe third-party intellectual property rights;
- the development, marketing or sale of our therapeutic product candidates will fail because of our inability or failure to protect or maintain our own intellectual property rights;
- once a product is commercially available, there will be little or no demand for it for a number of possible reasons, including lack of acceptance by the medical community or by patients, lack of or insufficient coverage and payment by third-party payors, inefficient or insufficient marketing and sales activities or as a result of there being more attractive, less risky or less expensive, products available for the same use; and
- the product will be withdrawn from the market, or sales limited due to side effects observed in clinical practice.

If one or more of these risks or any similar risks should materialize, our business and financial results may be materially harmed.

Risks Related to Development, Manufacturing, Clinical Trials and Government Regulation

In the near term, we are dependent on the success of COM701. If we are unable to advance COM701 through clinical development or obtain marketing approval for or successfully commercialize COM701, either alone or with a collaborator, or if we experience significant delays in doing so, our business could be substantially harmed.

We currently have no products approved for sale and are investing a significant portion of our efforts and financial resources in the clinical development of COM701. Our prospects are substantially dependent on our ability, or that of any future collaborator, to develop, obtain marketing approval for and successfully commercialize COM701.

We are early in our development efforts, with only our lead program, COM701, in clinical development and our other product candidate, COM902, and other future product candidates in preclinical or earlier stages of development. We have invested substantially all of our efforts and financial resources in the identification of targets and early stage, preclinical and clinical development of therapeutic mAbs, including the development of our lead pipeline program, COM701. COM701 is currently in clinical development in Phase 1 clinical trial.

The success of COM701 will depend on several factors, including the following:

- timely initiation, enrollment and completion of clinical trials;
- a safety, tolerability and efficacy profile, alone or in combination with other approved or investigational products, that is satisfactory to the U.S. Food and Drug Administration, or FDA;
- timely receipt of marketing approvals from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party suppliers of raw materials and drug substance and drug product manufacturers;

- establishment of arrangements with third-party manufacturers to obtain finished drug product that is appropriately packaged for sale;
- adequate ongoing availability of raw materials and drug product for clinical development and any commercial sales;
- protection of our rights in our intellectual property portfolio;
- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- successful identification of biomarkers for patient selection.

Many of these factors are beyond our control, including clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive marketing approval for and successfully commercialize COM701, on our own or with any future collaborator, or experience delays as a result of any of these factors or otherwise, our business could be substantially harmed.

If clinical trials of any product candidates that we, or any future collaborators, may develop fail to satisfactorily demonstrate safety and efficacy to the FDA, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates and may substantially harm our business and financial results.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any therapeutic product candidate in the United States without obtaining marketing approval from the FDA. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy of our therapeutic product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our therapeutic product candidates is susceptible to the risk of failure inherent at any stage of product development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA that a therapeutic product candidate may not continue development or is not approvable. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Despite the safety results reported from our preclinical studies for COM701, we do not know whether the clinical trials we or potential partners may conduct will demonstrate adequate efficacy and safety to result in the advancement of our clinical trials or regulatory approval to market of COM701, or any other of our product candidates when they reach the clinic, in any particular jurisdiction or jurisdictions. It is also possible that, even if one or more of our therapeutic product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if we, or any future collaborators, are required to conduct additional clinical trials or other testing of our product candidates beyond the trials and testing that we or they contemplate, if we, or they, are unable to successfully complete clinical trials of our product candidates or other testing, or the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators, may:

- incur additional unplanned costs;

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining marketing approval.

Our failure to successfully initiate and complete clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business.

We depend on enrollment of patients in our clinical trials in order for us to continue development of our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

We are conducting a Phase 1 clinical trial of COM701 in patients with advanced solid tumors. Our anticipated time to data in this trial is subject to our ability to recruit sufficient eligible patients and the number of cohorts that will need to be enrolled prior to observing activity, if achieved at all. There can be no assurance that we will complete enrollment or have data from the trial when we anticipate. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. Patient enrollment is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the size of the patient population required for analysis of the trial's primary endpoints, the proximity of patients to study sites, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, the risk that patients enrolled in clinical trials will drop out of the trials before completion, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that COM701 and our future potential drug products may target. Additionally, other pharmaceutical companies may clinically investigate their own products against PVRIG, the target of COM701. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients. The delay or inability to meet planned patient enrollment may result in increased costs and delay or termination of our trials, which could have a harmful effect on our ability to develop products.

Clinical development involves a lengthy and expensive process, with an uncertain outcome. We may encounter substantial delays or even an inability to begin clinical trials for any specific product, or may not be able to conduct or complete our trials on the timelines we expect.

Obtaining marketing approval from regulatory authorities for the sale of any therapeutic product requires substantial preclinical development and then extensive human clinical trials to demonstrate the safety and efficacy of such product candidates. It is impossible to predict when or if any of our programs or those of our collaborators based on our target discoveries will yield products that will be approved for human testing, or, if such testing is proven sufficiently safe and effective to receive regulatory approval for marketing. Preclinical and clinical testing is expensive, time consuming, and subject to uncertainty and will require significant additional financial and management resources. As a company, we have limited experience in conducting clinical trials and have never progressed a product candidate through to regulatory approval. In part because of this lack of experience, our clinical trials may require more time and incur greater costs than we anticipate. We cannot guarantee that any of our therapeutic drug candidates from our pipeline will be advanced into clinical trials or that our clinical trials will be conducted as planned or completed on schedule, if at all. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for such products.

We submitted to the FDA an Investigational New Drug application, or IND, for COM701, which was cleared by the FDA in June 2018. However, there can be no assurance that we will submit additional INDs, nor if submitted, the actual timing for such submission, nor that such submissions will be accepted by the FDA allowing clinical trials to begin. There can be no assurance that clinical trials will begin at any predicted date or will be completed on schedule, if at all. Moreover, even if these clinical trials begin, issues may arise that could result in the suspension of or termination of such clinical trials. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- lack of authorization from regulators or institutional review boards, or IRBs, or ethics committees to allow us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- inability to generate sufficient preclinical, toxicology, or other scientific data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing, or controlling a manufacturing process suitable for clinical trials;
- delays in reaching a consensus with collaborators or regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- imposition of a temporary or permanent clinical hold by the FDA, or a similar delay imposed by foreign regulatory agencies for a number of reasons, including after review of an IND, other application or amendment; (i) as a result of a new safety finding that presents unreasonable risk to clinical trial participants; (ii) a negative finding from an inspection of our clinical study operations or study sites; (iii) developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or (iv) if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties, or us to adhere to clinical trial and related regulatory requirements;
- failure to perform in accordance with the FDA’s Good Clinical Practice, or GCP, requirements, or similar applicable regulatory guidelines in other countries;
- the number of patients required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;
- delays or failure to secure supply agreements with suitable reagent suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary reagents; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Our product development costs will increase if we experience delays in clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, and once begun will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly.

We rely and expect to continue to rely on third parties to conduct our internal clinical trials. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may experience significant delays in the conduct of our clinical trials and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely and will continue to rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as CROs, to conduct or otherwise support our internal ongoing clinical trials. We rely and will rely heavily on these parties for execution of clinical trials for COM701 and any other future product candidates we may take internally to the clinic, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our internal clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on these third parties including CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our internal clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

If clinical investigators or CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such clinical investigators or CROs are associated with may be extended, delayed or terminated. As a result, we believe that our financial results and the commercial prospects for COM701, and any other future therapeutic product candidates we may take internally to the clinic, would be harmed, our costs could increase and our ability to generate revenue could be significantly adversely impacted.

It may be difficult to manufacture therapeutic products addressing our drug target candidates.

Our therapeutic pipeline is focused mainly on mAbs generated against our discovered targets. These types of therapeutics can be difficult to manufacture in the quantity and quality needed for preclinical, clinical and commercial use. The production of mAbs must be conducted pursuant to a well-controlled and reproducible process and the resulting product testing must conform to defined quality standards. Should it prove to be difficult to manufacture any therapeutics addressing our drug candidates in sufficient quantities, meeting the required quality standards or in an economical manner to conduct clinical trials and to commercialize any approved therapeutic candidate, our business, financial condition and results of operations would be materially harmed.

If we or any of our collaborators, or third-party manufacturers, fail to comply with regulatory requirements, we or they could be subject to enforcement or other regulatory actions, which could affect the marketability of Compugen-discovered therapeutic products and may significantly harm our financial status and/or reputation.

If we or any of our collaborators or third-party manufacturers with which we may enter into agreements in the future fail to comply with applicable federal, state or foreign laws or regulations, we or they could be subject to enforcement or other regulatory actions. These actions may include:

- warning letters;
- clinical trial holds;
- recalls, product seizures or medical product safety alerts;
- data lock, for failure to comply with applicable privacy and data security laws;
- restrictions on, or prohibitions against, marketing such products;
- restrictions on importation of such products;
- suspension of review or refusal to accept or approve new or pending applications;
- withdrawal of product approvals;
- injunctions;
- civil and criminal penalties and fines; or
- debarment or other exclusions from government programs.

If we or our collaborators become subject to such enforcement actions, these enforcement actions, could affect the ability to successfully develop, market and sell therapeutic products based on our discoveries and could significantly harm our financial status and/or reputation and lead to reduced acceptance of such products by the market. In addition, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, possible exclusion from government-funded healthcare programs, such as Medicare and Medicaid, additional integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations, if we are found to be in violation of U.S. federal, U.S. state or foreign healthcare fraud and abuse, transparency, or data privacy and security laws, among others, applicable to our current or future operations.

We are subject to a certain manufacturing risks, any of which could either result in additional costs or delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, or vendor or operator error leading to process deviations. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the products may need to be manufactured again and/or such manufacturing facilities may need to be closed for an extended time to investigate and remediate the contamination.

We have not contracted with alternate suppliers in the event we experience any problems with our current manufacturer. If we are unable to arrange for alternative third-party manufacturing sources, or are unable to do so on commercially reasonable terms or in a timely manner, we may incur additional costs or be delayed in the development or delivery of our current and future product candidates.

Our current and future relationships, and/or the relationships of any future collaborators through which we market, sell, and distribute our products, with healthcare professionals, principal investigators, consultants, customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to penalties.

Our current and future business operations, including, among other things, our clinical research activities and our or our future collaborators' business and financial arrangements and relationships with healthcare providers, physicians and other parties through which we or our future collaborators may market, sell and distribute our products, once approved, may be subject to extensive U.S. federal, U.S. state and foreign healthcare fraud and abuse, transparency, and data privacy and security laws. For example, U.S. federal civil and criminal laws and regulations prohibit, among other things: knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs; knowingly presenting or causing to be presented, a false or fraudulent claim for payment by a federal healthcare program; and knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including a private payor), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Many U.S. states and foreign countries have analogous prohibitions that may be broader and scope and apply regardless of payor. In addition, we may be subject to U.S. federal, U.S. state and foreign laws that require us to report information related to certain payments and other transfers of value to certain health care professionals, as well as ownership and investment interests in our company held by those health care professionals and their immediate family members, and data security and privacy laws that restrict our practices with respect to the use and storage of certain data.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. If we or our future collaborators are found to be in violation of any of these laws, we or our future collaborators could be subject to significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, additional integrity oversight and reporting obligations, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which, whether enforced against us or our future collaborators, could significantly harm our business and our royalties from any of our products, once approved, that we license to such future collaborators.

Risks Related to Our Dependence on Third Parties

We depend significantly on third parties to carry out the research, development and commercialization of our therapeutic product candidates. If we are unable to maintain our existing agreements or to enter into additional agreements with such third parties, including collaborators, in the future, our business will likely be materially harmed.

Our primary strategy for the further development and commercialization of products based on our drug target and therapeutic product candidates depends on third parties to carry out and/or finance, research, development and commercialization of such products, principally pharmaceutical and biotechnology companies and other healthcare related organizations either on their own or in collaboration with us. To date, we have entered into three commercial agreements with respect to our drug target candidates. We cannot be sure that any of the agreements will result in the successful development or commercialization of any product. Further, we cannot provide assurance that we will succeed in identifying additional suitable parties or entering into any other additional agreements on satisfactory terms or at all for the discovery, research, development and/or commercialization of our drug target or therapeutic product candidates. If we are unable to identify such additional suitable parties or enter into new agreements on satisfactory terms, or at all, our business will likely be materially harmed.

We anticipate that we will rely completely on third parties to manufacture or supply certain preclinical and all clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies for use in the conduct of our clinical trials, and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. In order to develop products, apply for regulatory approvals and commercialize our products, we will need to develop, contract for, or otherwise arrange for access to the necessary manufacturing capabilities. We rely and will continue to rely on contract manufacturing organizations, or CMOs, and other third-party contractors to manufacture formulations and produce larger scale amounts of drug substance and the drug product required for any clinical trials that we initiate. Such third parties may not be able to deliver in a timely manner, or at all, or may not have the required experience with the FDA's current Good Manufacturing Practice, or cGMP, to manufacture our drugs in the required quality. We have entered into manufacturing and supply agreements with third parties for the manufacturing and respective analytics of each of COM701, for which we have begun Phase 1 clinical trials in 2018, and COM902, for which we anticipate filing an IND in 2019. These agreements are sole source agreements. In addition, in October 2018, we entered into a clinical trial collaboration agreement with Bristol-Myers Squibb Company ("Bristol-Myers Squibb") to evaluate the safety and tolerability of COM701 in combination with Bristol-Myers Squibb's programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo®. Pursuant to this agreement, Bristol-Myers Squibb will provide Opdivo® at no cost to Compugen. Accordingly, if any of these third parties breach, terminate or otherwise are unable to fulfill their obligations under the agreements, we would need to identify an appropriately qualified alternative source, which could be time consuming, and we may not be able to do so without incurring material delays and costs in the development of our future products, including COM701 and COM902.

The manufacturing process for any products based on our technologies that we or our partners may develop is subject to the FDA regulation and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet cGMP requirements and foreign regulatory authority requirements on an ongoing basis. In addition, if we receive the necessary regulatory approval for any therapeutic drug candidate, we also expect to rely on third parties, including our commercial collaborators, to produce materials required for commercial supply. We may experience difficulty in obtaining adequate manufacturing capacity for our needs. If we are unable to obtain or maintain sufficient contract manufacturing for these product candidates, or to do so on commercially reasonable terms, we may not be able to successfully develop and commercialize our products.

To the extent that we enter into manufacturing or supply arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner and consistent with regulatory requirements, including those related to quality control and quality assurance. The failure of a third-party manufacturer or supplier to perform its obligations as expected could adversely affect our business in a number of ways, including:

- we may not be able to initiate or continue preclinical and clinical trials of products that are under development;
- we may experience significant disruption to our clinical supply chain and delay should we need to transfer the manufacturing process to a different third-party manufacturer;
- we may need to repeat clinical trials;
- we may be delayed in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- we may lose the cooperation of our collaborators;
- we may be required to cease distribution or recall some or all batches of our products; and
- ultimately, we may not be able to meet commercial demands for our products, if approved.

If a third-party manufacturer or supplier with whom we contract fails to perform its obligations, we may be forced to manufacture or otherwise obtain the materials ourselves, for which we do not currently and may not in the future have the capabilities or resources, or identify and qualify a different third-party manufacturer, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or processes required to manufacture our product may be unique to the original manufacturer and we may have difficulty transferring such skills or processes to a back-up or alternate manufacturer or supplier, or we may be unable to transfer such skills or processes at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We will also be required to demonstrate that the newly manufactured material is similar to the previously manufactured material, or we may need to repeat clinical trials with the newly manufactured material. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates or commercialize approved products in a timely manner or within budget. Furthermore, a manufacturer may possess technology related to the manufacture of our product candidate that such manufacturer owns independently, which would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our products.

Our dependence on collaboration agreements with third parties presents a number of risks, and if one or more of these risks materialize, our business may be materially harmed.

The risks that we face in connection with our existing collaborations, licenses and other business alliances as well as those that we may enter into in the future include, among others, the following:

- we may be unable to reach mutually agreeable terms and conditions with respect to potential new collaborations;

- we may be unable to comply or fully comply with our obligations under collaboration agreements into which we enter, and as a result, we may not generate royalties or milestone payments from such agreements, and our ability to enter into additional agreements may be harmed;
- our obligations under existing or future collaboration agreements may harm our ability to enter into additional collaboration agreements;
- our collaborators have significant discretion in electing whether to pursue any of the planned activities and the manner in which it will be done, including the amount and nature of the resources to be devoted to the development and commercialization of our product candidates;
- our collaborators have significant discretion in terminating the collaborations for scientific, clinical, business or other reasons;
- if our collaborators breach or terminate an agreement with us, the development and commercialization of our therapeutic product candidates could be adversely affected because at such time we may not have sufficient financial or other resources or capabilities to successfully develop and commercialize these therapeutics on our own or find other partners or enforce our rights under breached or terminated agreement;
- our collaborators may fail to design and implement appropriate preclinical and/or clinical trials;
- our collaborators may fail to manufacture our therapeutic product candidates needed for either clinical trials or for commercial purposes on a sufficiently large scale, in the required quality and/or in a cost effective manner;
- our collaborators may fail to develop and market products based on our discoveries due to various regulatory restrictions;
- our collaborators may fail to develop and market products based on our discoveries prior to the successful marketing of competing products by others or prior to expiry of the patents protecting such products;
- changes in a collaborator's business strategy may negatively affect its willingness or ability to complete its obligations under its arrangement or to continue with its collaboration with us;
- our collaborators may terminate the program or the agreement and then compete against us in the development or commercialization of similar therapeutics;
- ownership of the intellectual property generated under or incorporated in our collaborations may be disputed;
- our ownership of rights in any intellectual property or products that may result from our collaborations may depend on additional investment of money that we may not be able or willing to make;
- prospective collaborators may pursue alternative products or technologies, by internally developing them or by preferring those of our competitors;
- disagreements between us and our collaborators may lead to delays in, or termination of, the collaboration;
- our collaborators may fail to develop or commercialize successfully any products based on our novel drug targets or therapeutic product candidates to which they have obtained rights from us;
- our early stage collaborations may face internal competition by our partners' internal pipelines;
- prospective collaborators may hesitate to pursue collaborations on novel target candidates that lack robust validation to serve as a basis for the development of therapeutics; and
- our collaboration partners may be acquired by, acquire, or merge with, another company, and the resulting entity may have different priorities or competitive products to the collaboration product being developed previously by our partner.

If any of these risks should materialize, our business, financial condition and results of operations may be materially harmed.

Our existing agreements for our pipeline program drug target candidates are subject to many risks. If such an agreement is terminated by our partner, our business and financial condition may be materially harmed.

In August 2013, we entered into a Research and Development Collaboration and License Agreement with Bayer Pharma AG, or Bayer, for the research, development, and commercialization of antibody-based therapeutics for cancer immunotherapy against a novel, Compugen-discovered immune checkpoint regulators –CGEN-15001T/ILDR2, for which the therapeutic antibody BAY1905254 is currently being evaluated in a Phase 1 clinical trial, the Bayer Collaboration. Then, in March 2018, we entered into an exclusive license agreement with MedImmune Limited, the global biologics research and development arm of AstraZeneca, or AstraZeneca, to enable the development of bi-specific and multi-specific immuno-oncology antibody products. Each of these agreements were entered into for Compugen-discovered drug targets and is subject to all of the risks as set forth above with respect to our dependence in general on collaboration agreements with third parties.

The Bayer Collaboration continues until Bayer is no longer required to make payments under the agreement or until otherwise terminated by either party in accordance with the terms of the agreement. Bayer may also terminate the agreement, at any time with or without cause on a product-by-product and/or country-by country basis, upon prior written notice. Upon any termination of the agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of any products and or various payment and royalty obligations in the event of such continuation of the development and commercialization.

Under the terms of the license agreement with AstraZeneca, we provided an exclusive license for the development of bi-specific and multi-specific antibody products derived from our pipeline program. Subject to termination rights for material breach, bankruptcy or by Compugen for patent challenge by MedImmune, the term of the license agreement continues until the expiration of the last Royalty Term in the Territory, each as defined in the license agreement. In addition, MedImmune may terminate the agreement for convenience upon prior written notice.

If significant adverse unforeseen events occur in either the Bayer Collaboration, the agreement with AstraZeneca or either agreement is terminated, particularly prior to our signing additional collaboration agreements, our business and financial condition may be materially harmed.

Our reliance on third parties for the performance of key research, validation and development activities heightens the risks faced by our business.

We invest significant efforts and resources into outsourcing certain key functions with third parties, including certain research, validation and development activities, manufacturing operations, and others. Following the 2019 Restructuring and the consolidation of our R&D activities in one location in Israel, we intend to outsource additional preclinical activities to third-party service providers. We do not control the third parties to whom we outsource these functions, nor, following the 2019 Restructuring, may we continue to have the internal knowledge to appropriately manage their activities, but we depend on them to undertake activities and provide results or materials, including the production of certain biological reagents, which may be significant to us. If these third parties fail to properly or timely perform these activities, or provide us with incorrect or incomplete results, or fail to produce and/or provide certain materials this could lead to significant delays in the program or even program failure, along with significant additional costs. In addition, should any of these third parties fail to comply with the applicable laws and regulations and/or research and development or manufacturing accepted standards in the course of their performance of services for us, there is a risk that we could be held responsible for such violations of law as well. Any such failures by third parties could have a material adverse effect on our business, financial condition or results of operations.

Moreover, we do not always independently verify the results obtained by such third parties and in some cases, rely upon the data provided by the third-party. If we fail to identify and obtain accurate and quality services technologies and/or data from such third parties, or if the contractual demands of such third parties become unreasonable and we are not able to reach satisfactory agreements with such third parties, we may not be able to obtain the required services and/or technologies, in which event we may lose our investment in these services, fail to receive the expected benefits from our discoveries, and our validation and development capabilities or activities, may be significantly harmed or delayed.

Additionally, we have entered into an agreement to obtain access to a highly diverse human phage display antibody library to generate antibodies against novel target candidates for our pipeline. The current term of this agreement terminates in June 2019, unless we pay certain renewal fees. In addition, if we fail to comply with the provisions of this agreement, the third-party from which we have obtained license to this library may terminate our rights to use the library, which could harm our business, financial condition or results of operations.

We rely on access to public and commercial databases to feed our discovery capabilities, including our individual discovery platforms. If we are denied access to these databases, if the quality of available information is poor, or if the quantity of the available information is insufficient, our operations and business may be harmed.

In the development, validation and continued expansion and enhancement of our computational target discovery platform and other tools, as well as in connection with the resulting drug target and therapeutic product candidates, we rely on our ability to access and use public and commercially available databases. The quality of our platforms, tools and discoveries is in part dependent on the quality and quantity of the data in these databases. If we are denied access to these databases, if we are granted access to such databases on terms which are not commercially reasonable, if the quality of data available from those databases is poor, or if the quantity of the available information is insufficient, each of which has occurred in the past, our business and our results of operations may be materially harmed.

We rely on access to high-quality biological samples supported by detailed clinical records to conduct parts of our discovery and validation activities. If we fail to identify and purchase or otherwise obtain such samples, if the quality of available biological samples is poor, or if the quantity of the available biological samples is insufficient, which has occurred in the past, our discovery and validation capabilities may be harmed.

In carrying out our discovery process and validation of drug target candidates and our therapeutic candidates, we rely on our ability to access and use biological samples whether commercially available or through collaborations with academic research centers and hospitals. The quality of our discoveries and validation is in part dependent on the quality and quantity of available biological samples. If we fail to identify and purchase or otherwise obtain such samples for any reason, if the quality of available biological samples is poor, if the quality of the data generated from these samples is poor, if the samples have not been obtained and made available for secondary use in accordance with applicable law, if the clinical annotation of the samples is incorrect, or if the quantity of the available biological samples is insufficient, which has occurred in the past, our discovery and validation capabilities may be harmed.

Risks Related to Competition and Commercialization

We operate in a highly competitive and rapidly changing industry.

Biopharmaceutical product development is highly competitive and subject to consolidation and rapid and significant technological advancements. Our success is highly dependent upon our ability to identify, develop and obtain regulatory approval for therapeutic products based on Compugen-discovered novel drug targets. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase as a result of advances in the commercial applicability of technologies similar to our computational target discovery platform and greater availability of capital for investment in these industries. Over the last several years, there has been an increase in the interest of both pharmaceutical companies and the healthcare community in applying computational methodologies, mostly Artificial Intelligence (AI) and Machine Learning (ML) algorithms, to the field of data-driven drug discovery/healthcare. This interest may be seen in the increase in the number of companies within the pharmaceutical and biotech industries which focus on this area, including by way of establishing internal AI and/or ML capabilities or receiving investments or entering into partnerships in furtherance thereof. Our competitors may succeed in developing products that are more effective or less costly than any product candidate that we may develop.

In addition, there is a trend towards consolidation in the pharmaceutical, diagnostic and biotechnology industry, which may result in the remaining companies having greater financial resources and discovery and technological capabilities, thus intensifying competition in our industry. This trend may also result in fewer potential collaborators or licensees for our therapeutic product candidates. Also, if a consolidating company is already doing business with our competitors, we may lose existing or potential licensees or collaborators as a result of such consolidation. In addition, if a consolidating company is already doing business with us, we may lose the interest of the consolidating parties in our discovery capabilities or individual discoveries as a result of a modified strategy and new priorities of such consolidated entity. This trend may adversely affect our ability to enter into agreements for the development and commercialization of our therapeutic product candidates, and as a result may harm our business.

Established biopharmaceutical companies may invest heavily to accelerate discovery and development of novel drug targets or therapeutic products or to in-license novel drug targets or therapeutic products that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

Potential collaborators, including major pharmaceutical companies, might be hesitant to pursue target validation and preclinical and clinical development programs based on novel targets lacking robust experimental validation results particularly those discovered through computational discovery approach.

There is a need for new drug targets generating new treatment options for patients who are non-responsive or refractory to current immunotherapies. Our business model includes selectively entering into collaborations for novel targets and related therapeutic product candidates at various stages of research and development. Entering into collaborations with product candidates and targets at an early stage in the validation or drug discovery process is significantly more challenging than identifying partnerships for later-stage products that would have a more complete data package. In addition, although we have demonstrated success in validating our computational target discovery capabilities with two product candidates entering human clinical trials in 2018, major pharmaceutical companies may be hesitant to enter into early stage collaborations based on novel targets, more so if discovered by computer, as opposed to drug targets with human clinical trial data, or product candidates with significant published experimental validation. Therefore, we cannot assure that our business model to enter into commercialization arrangements for our early stage novel targets will be successful.

Our business model is challenging to implement and to date has not yielded significant revenues.

The success of our business model includes providing to third parties for commercialization, through licensing agreements and other forms of collaboration, our novel drug targets and related therapeutic product candidates at various stages of research and development, i.e., the Bayer Collaboration, or the rights to develop such candidates, i.e., the agreement with AstraZeneca, in each case based on our discovered novel drug targets. Additionally, our business model includes establishing research and discovery collaborations aimed at applying our computational target discovery capabilities towards the partners' specific focus on unmet patient needs. Our objective is that these collaborations, anticipated to be primarily with pharmaceutical and biotechnology companies, will be based on novel target and products, mostly derived from our existing and future drug targets, with us having the right to receive various forms of revenue including upfront fees, research funding, in-kind funding, milestones, license fees, royalties and other revenue-sharing payments from such products commercialized by, or on behalf of, such third-party. Our partnering efforts are challenging to implement. To date, we have entered into the three commercial arrangements with respect to our pipeline programs.

There can be no assurance that any current or future agreements for novel targets based on our discoveries and associated product candidates will be successful and thus provide significant revenues to our Company, nor can there be any assurance that we will be able to enter into additional future agreements. If we are unable to succeed in securing additional license agreements or other collaboration arrangements related to our discoveries, our business will be materially harmed.

In addition, the majority of our internal programs are in the target discovery, research and validation stage, and/or in the early preclinical development stage. Two product candidates against Compugen-discovered novel targets, one initiated by us and the second by Bayer under the Bayer Collaboration, entered Phase 1 clinical trials in 2018. The research and validation data generated to date for our preclinical and early stage pipeline targets may not be sufficient to attract interest from prospective collaborators. Furthermore the drug target candidates or prospective therapeutic product candidates may not fit their corporate or clinical strategy. These companies may require more data, including their independent testing of our therapeutic product candidate, before considering a collaboration. We are therefore dependent on the potential fit of our programs with individual pharmaceutical company strategies and, there can be no assurance that we will be able to identify additional partners interested in our programs at their current stages of research and development. This may adversely affect our ability to enter into additional agreements for the research, development, license or other form of collaboration or commercialization of our therapeutic product candidates, and as a result may harm our business.

Additionally, we may not be able to obtain efficacy or approval for and commercialize our products as monotherapy treatments. We may be required to combine our product candidates with other products to provide sufficient data for approval by FDA and other regulatory authorities, at all or in specific indications (which may require our dependency on third-party drugs). As part of our business strategy, we are looking to establish clinical collaborations with pharmaceutical and biotechnology companies to specifically test the hypothesis that there may be greater effects when combining our products with other products. In October 2018, we entered into a clinical trial collaboration agreement with Bristol-Myers Squibb to evaluate the safety and tolerability of COM701 in combination with Bristol-Myers Squibb's programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo®. See "Business Strategy and Partnerships – Bristol-Myers Squibb Collaboration" below. There can be no assurance that we will be able establish additional clinical collaborations, if our strategies do not match those of our potential pharmaceutical company partners. Failure to enter into combination clinical collaborations, may materially harm our business. These potential combination products may include both marketed as well as investigational products, and as such, adverse events resulting from combining the products or investigational agents are unknown and could be severe, including resulting in death of the patient due to these unknown toxicities. There is an industry trend towards drug combinations in the field of cancer immunotherapy which may result in a situation under which our therapeutic product candidates will serve in a combination product and may therefore be entitled to only a fraction of the anticipated product revenues. These trends may adversely affect any revenues we may be entitled to receive and as a result may harm our business.

The agreement cycle for potential collaborations is complex and long to implement and, if we are not able to establish collaborations on commercially reasonable terms, we may expend substantial funds and management resources with no assurance of success.

In general, each potential license agreement or other form of collaboration we may enter into will require negotiating with our potential partner a large number of scientific, legal and business terms and conditions that can vary significantly in each instance due to the specific drug target or the therapeutic product candidate or candidates involved, the potential market opportunity and the potential partner's licensing, development and business operations and strategy. The accommodation of these requirements mandates a thorough consideration of both the scientific and business aspects of each transaction. Furthermore, the diversity and wide applicability of our computational target discovery capabilities and our therapeutic product candidates, adds additional levels of complexity to our business development efforts.

Whether we reach a definitive agreement for new collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our business and drug targets and therapeutic product candidates. We may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. If we are unable to do so, we will need to expend substantial funds and substantial key personnel time and effort into these business development activities with no assurance of successfully entering into agreements with potential collaborators and this could harm our business.

We rely on our computational discovery platform to identify drug targets. Our competitive position could be materially harmed if our competitors develop a platform similar to our computational target discovery platform and identify and develop rival drug targets and product candidates.

We rely on unpatented know-how and other proprietary computational processes and tools, to maintain our competitive computational discovery position. We consider know-how to be our primary intellectual property with respect to our computational target discovery platform. Know-how can be difficult to protect and enforce. In particular, we anticipate that with respect to our platform, this know-how may over time be disseminated within the industry through independent development and the movement of skilled personnel.

We cannot rule out that our competitors may have or obtain the knowledge necessary to identify and develop novel drug targets or products that could compete with the drug targets we identify. Our competitors may have significantly greater experience and algorithmic tool development to identify targets and greater experience in using translational science to develop product candidates and may also have significantly greater financial, product development, scientific, technical and human resources than we do to discover novel drug targets and develop product candidates.

We may not be able to prohibit our competitors from using methods to develop product candidates, including such methods that are the same as or similar to our own. If our competitors use methods to identify and develop products that compete with COM701 OR COM902 or any future product candidates we develop, our ability to develop and commercialize a promising product candidate may diminish substantially, which could have a material adverse effect on our business prospects, financial condition, and results of operations.

The biotechnology and pharmaceutical industries are highly competitive, and we may be unable to compete effectively.

The biotechnology and pharmaceutical industries in general, and the immuno-oncology field in particular, are highly competitive. Numerous entities in the United States, Europe and elsewhere compete with our efforts to discover, validate, develop and partner with licensees and/or collaborators to commercialize drug target and therapeutic products candidates. Recent clinical trial failures of novel agents in the immuno-oncology field may adversely impact our ability to sign early stage collaborations, and as a result we may be required to advance our programs internally further into clinical development before we may attract potential collaborators or other investors. Our competitors include pharmaceutical and biotechnology companies, academic and research institutions and governmental and other publicly funded agencies. We face, and expect to continue to face, competition from these entities to the extent they develop products that have a function similar or identical to or competing with the function of our therapeutic product candidates in the field of immuno-oncology that may attract our potential collaborators or that may reach the market sooner. We also face, and expect to continue to face, competition from entities that seek to develop technologies that enable the discovery of novel targets and antibodies in the field of oncology. These competitors include traditional pharmaceutical and biotechnology companies and additionally, an increasing number of new entities looking to apply AI or ML technologies to the field of target discovery. Many of our competitors have one or more of the following:

- much greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization process;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing and marketing diagnostics therapeutics;
- more extensive experience in oncology and immuno-oncology and in the fields of mAb therapeutics;
- more extensive experience in oncology and immuno-oncology and in the field of target discovery;
- greater resources and means to compete with us on target discovery and as well as in acquiring or generating technologies complementary to, or necessary for, our programs as well as in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites;
- products that have been approved or are in late stages of development;
- reduced reliance on collaborations or partnerships with third parties in order to further develop and commercialize competitive therapeutic products; and
- collaborative arrangements in our target markets with leading companies and research institutions.

Since we are a small company with limited human and financial resources, we are not able to work with a large number of collaborators in parallel and/or advance a large number of drug target or therapeutic product candidates in parallel. Our competitors may develop or commercialize products with significant advantages over any therapeutic products we, our collaborators or third-party licensees may develop. They may also obtain patents and other intellectual property rights before us, or broader than ours, and thereby prevent us from pursuing the development and commercialization of our discoveries. They may also develop products faster than us and therefore limit our market share. Our competitors may therefore be more successful in developing and/or commercializing products than we, our collaborators, or third-party licensees are, which could adversely affect our competitive position and business. If we are unable to compete successfully against existing or potential competitors, our financial results and business would be materially harmed.

Healthcare policy is volatile and changes in healthcare policy could increase our expenses, decrease our revenues and impact sales of, and reimbursement for, our products.

Our ability to commercialize our future therapeutic product candidates successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for these product candidates will be available from government health programs, such as Medicare and Medicaid in the United States, private health insurers and other third-party payors. At present, significant changes in healthcare policy, in particular the continuing efforts of the U.S. and other governments, insurance companies, managed care organizations and other payors to contain or reduce health care costs are being discussed, considered and proposed. Drug prices in particular are under significant scrutiny and continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis.

For example, in the United States, there have been several initiatives implemented to achieve these aims. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “ACA”), represents the biggest regulatory overhaul to the health care system in decades and substantially changes the way health care is financed by both governmental and private insurers. However, the ACA has faced legislative, judicial, executive and political challenges from Congress, the Trump administration, state governments, consumer groups and business organizations. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, ACA-related provisions have been enacted as part of tax reform or federal budget legislation that, among other things, affect the implementation of certain taxes under the ACA and increase discounts owed by certain drug manufacturers under Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

Further, other legislative changes have been proposed and adopted since the PPACA was enacted that have, among other things, reduced reimbursement to several healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products that has led to several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a “Blueprint”, or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

It is too early to predict specifically what effect efforts to institute pricing controls or repeal the ACA and the implementation of any replacement or any future healthcare reform legislation or policies in the United States or other countries will have on our business, including our ability to set prices for our product candidates which we believe are fair, and therefore our ability to generate revenues and achieve and maintain profitability. Yet, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition.

Risks Related to our Operations and Other Risks Related to our Business

We may experience difficulties in managing our current activities and future growth given our level of managerial, operational, financial and other resources.

On February 26, 2019, we announced the 2019 Restructuring which included a reduction of our workforce by 35%, consolidating R&D activities in one location in Israel and outsourcing certain preclinical activities to third-party service providers. We will need to manage our operations and clinical trials, continue our preclinical development activities and commercialize our therapeutic candidates with our reduced workforce. Our personnel, systems and facilities currently in place may not be adequate to support our current activities or future growth. See “Risks Related to our Business, Financial Results and Financing Needs – *Our corporate restructuring may not be successful.*”

Our need to effectively execute our business strategy requires that we:

- manage our COM701 clinical trial effectively, which is being conducted at multiple trial sites, as well as additional clinical trials we may initiate in the future;
- manage our internal research and development efforts effectively; and
- maintain and motivate our remaining employees and identify, recruit, and integrate additional employees.

If we are unable to maintain or expand our managerial, operational, financial and other resources to the extent required to manage our development and commercialization activities, our business will be materially adversely affected.

We may be unable to hire or retain key personnel or sufficiently qualified management, clinical and scientific personnel, in which case our business may be harmed.

Our business is highly dependent upon the continued services of our senior management and key scientific and clinical personnel. While members of our senior management and other key personnel have entered into employment or consulting agreements and non-competition and non-disclosure agreements, they can terminate their employment agreements with us at any time without cause. We cannot be sure that these key personnel and others will not leave us or compete with us, which could harm our business activities and operations. It is difficult to find suitable and highly qualified personnel in certain aspects of our industry, mainly in the field of immuno-oncology.

It can also be difficult for us to find employees with appropriate experience for our business. We require a multidisciplinary approach and some of our researchers require an understanding in both exact and biological sciences. In addition, we require experience in drug development and immuno-oncology, for which there is significant competition for highly qualified personnel in these fields. As a result, we may face higher than average employee turnover or challenges in hiring due to such competition. During 2018, we added clinical expertise, which we expect to continue to expand in 2019 which will require significant efforts to attract the required personnel with the required expertise and experience.

The competition for qualified personnel in the pharmaceutical and biotech industry is intense. The loss of service of any of our key scientific and clinical personnel could harm our business. Due to our limited resources, we may not be able to effectively retain our existing scientific and clinical personnel or attract and recruit additional qualified key scientific and clinical personnel.

We may be unable to safeguard the integrity, security and confidentiality of our data or third parties' data, and if we are unable to do so, our business may be harmed.

We rely heavily on the use and manipulation of large amounts of data and on the secure and continuous use of our internal computers, communication networks and software and hardware systems. We have implemented and maintain physical and software security measures to preserve and protect our computers and communication, hardware and software systems as well as our data and third parties' data. However, these methods may not fully protect us against fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins or similar events. In addition, these measures may not be sufficient to prevent unauthorized access, use or publication of such proprietary data. A party who is able to circumvent our security measures could misappropriate or destroy (partially or completely) proprietary information or cause interruptions in our operations. In addition, a party, including an employee or a contractor, who obtains unauthorized access to our proprietary data or breaches a confidentiality agreement with us could publish or transfer large portions or all of our proprietary data. Some of our proprietary data is maintained in secured cloud services that may also be subject to security breach, including by employees of the cloud services provider. Such publication of proprietary data could materially harm our intellectual property position, thereby seriously harming our competitive position. Such security breaches, if significant, could materially harm our operations and even cause our business to cease.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our pipeline.

Our business is increasingly dependent on critical, complex and interdependent information technology systems to support business processes as well as internal and external communications. Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While, to our knowledge, we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from the clinical trials of our therapeutic product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, our systems are potentially vulnerable to data security breaches, whether by employees or others, which may expose sensitive data to unauthorized persons. Although we have invested in measures at our sites in Israel and the U.S. to reduce these risks, we cannot assure you that these measures will be successful in preventing compromise and/or disruption of our information technology systems and related 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 therapeutic candidates could be delayed.

If a successful liability claim or other claim for damages or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.

The use of any of our therapeutic product candidates in clinical trials might expose us to liability. We have obtained clinical trial insurance coverage in amounts that we believe are reasonable and customary in our industry based on the size and design of our clinical trials. However, there can be no assurance that such insurance coverage will fully protect us against some or all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

If we do not comply with laws regulating the use of human tissues or other human biological samples or the conduct of experiments involving animals, our business could be adversely affected.

We use human tissue samples and other human biological samples and conduct experiments involving animals for the purpose of development and validation of our technologies, discoveries and drug and therapeutic product candidates. Our access to and use of human tissue samples and other human biological samples and the conduct of experiments involving animals are subject to government regulation in the United States, Israel and elsewhere and may become subject to additional regulation. For example, the Israeli Ministry of Health requires, among other things compliance with the principles of the Helsinki Declaration, the Public Health Regulations (Clinical Trials in Human Subjects) 5741-1980, the Genetic Information Law, 5761-2000, the provisions of the Israel Ministry of Health Guidelines for Clinical Trials in Human Subjects and the provisions of the current Harmonized Tripartite Guideline for Good Clinical Practice. Our use of clinical data related to any tissue or other human biological samples must comply with applicable local, national and international privacy law. Our use of animal models for preclinical research must comply with applicable laws. Our failure, or the failure of our subcontractors or collaborators, to comply with these or similar regulations could negatively impact our business and results of operations.

If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.

Our research and development activities involve the use of hazardous materials and chemicals, and we maintain quantities of microbial agents, various flammable and toxic chemicals in our facilities. Although we believe our safety and other procedures for storing, handling and disposing these materials in our facilities comply with applicable governmental and local regulations and guidelines, the risk to our employees or others of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which may exceed our financial resources and may seriously harm our business. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of biohazardous materials. We may be subject to liability and may be required to comply with new or existing laws and regulations regulating pharmaceuticals or be subject to substantial fines or penalties if we violate any of these laws or regulations.

Risks Related to Intellectual Property.

We may not be able to obtain or maintain patent protection for our inventions and if we fail to do so, our business will likely be materially harmed.

We have applied for patents covering targets, therapeutic and diagnostic product candidates and their method of use, and the success of our business depends, to a large extent, on our ability to obtain and maintain such patents and any additional patents covering our future product candidates. We design our patent strategy to fit the business competitive landscape and continual legislative changes. In addition, we periodically analyze and examine our patent portfolio to align it with our pipeline strategy and business needs. As of March 1, 2019, we had a total of 45 issued and allowed patents, of which 30 are U.S. patents, five are European patents, four are Israeli patents, three are Australian patents, one is a patent in Canada, one is a patent in Japan, and one is a patent in Singapore. Our issued and allowed patents expire between 2021 and 2037. We also have 84 pending patent applications, which as of March 1, 2019, included 17 patent applications that have been filed in the United States, eight patent applications that have been filed in Europe, five patent applications that have been filed in Israel, five patent applications that have been filed in Australia, six patent applications that have been filed in Canada, four patent applications that have been filed in Japan, three patent applications that have been filed in India, four patent applications that have been filed in China, two patent applications that have been filed in Brazil, three patent applications that have been filed in Korea, three patent applications that have been filed in New Zealand, two patent applications that have been filed in the Russian Federation, two patent applications that have been filed in Singapore, three patent applications that have been filed in Mexico, three patent applications that have been filed in South Africa, three patent applications that have been filed in Hong Kong, one patent application that has been filed in Egypt, one patent application that has been filed in Argentina, one patent application that has been filed in Brunei, one patent application that has been filed in Chile, one patent application that has been filed in Colombia, one patent application that has been filed in Eurasia, one patent application that has been filed in Indonesia, one patent application that has been filed in Malaysia, one patent application that has been filed in Taiwan and two applications that have been filed under the Patent Cooperation Treaty for which we have not yet designated the countries of filing. We plan to continue to apply for patent protection for our therapeutic and diagnostic inventions, but we cannot be sure that any of our patent applications will be accepted, or that they will be accepted to the extent that we seek. Additionally, we file for patent protection in selected countries and not in all countries of the world. Therefore, we are exposed to competition in those countries in which we have no patent protection. Also, due to our early stage business model, we may be required to seek patent protection at a very early stage. This may cause us to file with insufficient supportive data, possibly making it difficult to obtain patents in jurisdictions that do not accept post filing evidence to support the claims, and thus enabling others to compete with us. This may also cause issuance of a patent at an earlier stage creating a shorter commercialization period under patent protection, possibly enabling others to compete with us. Delays in filing patents may preclude us from obtaining protection on some or all of our product candidates due to others filing ahead of us. Patent applications filed before us, but yet unpublished may cause us to spend significant resources in areas that due to these previously filed patents or applications we are not able to obtain patent protection or that the scope of protection is much narrower than contemplated.

Because the patent position of biopharmaceutical companies involves complex legal and factual questions, we cannot predict the validity, scope or enforceability of patents with certainty. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our patents may be challenged in the courts or patent offices in the United States and abroad which may result in such patents being narrowed, invalidated, or held unenforceable. Our pending patent applications, and those we may file in the future may not result in patents being issued. Furthermore, even if our patents do issue, and even if they are unchallenged, our patents may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents we hold is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, product candidates and expose us to unexpected competition that could have a material adverse impact on our business.

The process of obtaining patents for inventions that cover our products is uncertain for a number of reasons, including but not limited to:

- the patenting of inventions involves complex legal issues relating to intellectual property laws, prosecution and enforcement of patent claims across a number of patent jurisdictions, many of which have not yet been settled;
- legislative and judicial changes, or changes in the examination guidelines of governmental patent offices may negatively affect our ability to obtain patent claims to certain biologic molecules- and/or use of certain therapeutic targets;
- in view of the finite number of human proteins, we face competition from other biotechnology and pharmaceutical companies who have already sought patent protection relating to proteins and protein based products, as well as therapeutic antibodies or other modulators specifically binding these proteins, and their utility based discoveries that we may intend to develop and commercialize; such prior patents may negatively affect our ability to obtain patent claims on antibodies or certain proteins or other biologic modulators, or may hinder our ability to obtain sufficiently broad patent claims for our inventions, and/or may limit our freedom to operate;
- publication of data on gene products by non-commercial and commercial entities may hinder our ability to obtain sufficiently broad patent claims for our inventions;
- even if we succeed in obtaining patent protection, such protection may not be sufficient to prevent third parties from circumventing our patent claims;
- even if we succeed in obtaining patent protection, we may face freedom to operate (FTO) issues;
- even if we succeed in obtaining patent claims protecting our inventions and product candidates, our patents could be subject to challenge and litigation by our competitors, and may be partially or wholly invalidated as a result of such legal/judicial challenges;
- there are significant costs that may need to be incurred in registering and filing patents;
- our data may be insufficient to support our claims and/or may support others in strengthening their patents;
- seeking patent protection at an early stage may prevent us from providing comprehensive data supporting the patent claims and may prevent allowance of certain patent claims or limit the scope of patent claim coverage;

- we may not be able to supply sufficient data to support our claims, within the legally prescribed time following our initial filing in order to support our patent claims and this may harm our ability to get appropriate patent protection or protection at all;
- our claims may be too broad and not have sufficient enablement, in which case such claims might be rejected by patent offices or invalidated in court; and
- we may not succeed in obtaining patent protection from the European Patent Office (EPO) for therapeutic antibodies where there are other known therapeutic antibodies for the same target. Pursuant to EPO provisions, additional antibodies in the absence of superiority over prior art antibodies in at least one technical feature often are deemed to lack the requirement of “inventiveness.” If we fail to demonstrate a unique technical feature for our antibodies as compared to existing prior art, our claims might be rejected by the EPO.

If we do not succeed in obtaining patent protection for our inventions (should it be discoveries, drug targets candidates and product candidates) to the fullest extent for which we seek protection, or if we fail to select the best inventions to seek such protection, our business and financial results could be materially harmed.

We may not be able to protect our non-patented proprietary data, know-how, technologies or discoveries, and that may materially harm our business.

Aside from our patented information, we also rely on a combination of patents, trade secrets, know-how, technology and trademarks to maintain our competitive position. The protective measures that we employ may not provide adequate protection for our trade secrets and know-how. Our business collaborators, licensees, employees, advisers and consultants may disclose our proprietary know-how or trade secrets in violation of their obligations to us. We may not be able to meaningfully protect our rights in our proprietary know-how or trade secrets against such unauthorized disclosure and any consequent unauthorized publication. In addition, others may independently discover trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

If we are not able to adequately protect our proprietary know-how and trade secrets, competitors may be able to develop technologies and resulting discoveries and inventions that are the same or similar to our own discoveries and inventions. That could erode our competitive advantage and materially harm our business.

The existence of third-party intellectual property rights may prevent us from developing our discoveries or require us to expend financial and other resources to be able to continue to do so.

In selecting a drug target or a therapeutic product candidate for development, we take into account, among other considerations, the existence of third-party intellectual property rights that may hinder our right to develop and commercialize that product candidate. To our knowledge, third parties, including our competitors, have been filing patent applications covering an increasing portion of the human proteome or antibodies directed thereto. As a result of the existence of third-party intellectual property rights, we have been and may be further required to:

- forgo the research, development and commercialization of certain drug target candidates and product candidates that we discover, notwithstanding their promising scientific and commercial merits; or
- invest substantial management and financial resources to either challenge or in-license such third-party intellectual property, and we cannot be sure that we will succeed in doing so on commercially reasonable terms, if at all.

We do not always have available to us, in a timely manner, information of the existence of third-party intellectual property rights related to our own discoveries. The content of U.S. and other patent applications remains unavailable to the public for a period of approximately 18 months from the filing date. In some instances, the content of U.S. patent applications remains unavailable to the public until the patents are issued. Moreover, when patents ultimately are issued, the claims may be substantially different from those that were originally published, and may vary from country to country. Furthermore, there may be issued patents or pending patent applications that we are aware of, but that we think are irrelevant to our therapeutic product candidates, but which may ultimately be found to be infringed by the manufacture, sale, or use of such product candidates. As a result, we can never be certain that programs that we commence will be free of third-party intellectual property rights. If we become aware of the existence of third-party intellectual property rights only after we have commenced a particular program, we may have to forgo such project after having invested substantial resources in it or, to the extent such third-party right has not expired, obtain a license which may involve substantial financial resources.

In addition, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented to enable third-party challenges of the validity of a patent. This reform adds uncertainty to the possibility of a challenge to our patents in the future. We may also become involved in similar opposition proceedings in the European Patent Office or similar offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidate.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs.

The U.S. 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. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Changes in patent law could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

We, or a potential collaborators and licensees, may infringe third-party rights and may become involved in litigation, which may materially harm our business.

If a third-party accuses us or a potential collaborator and licensee of infringing its intellectual property rights or if a third-party commences litigation against us or a potential collaborator and licensee for the infringement of patent or other intellectual property rights, we may incur significant costs in obtaining a license or defending such action, whether or not we ultimately prevail. We are aware of U.S. and foreign issued patents and pending patent applications controlled by third parties that may relate to the areas in which we are developing therapeutic products. Because all issued patents are entitled to a presumption of validity in many countries, including the United States and many European countries, issued patents held by others with claims related to products, may limit our freedom to operate unless and until these patents expire or are declared invalid or unenforceable in a court of applicable jurisdiction, if we do not obtain a license or other right to practice the claimed inventions. Typically, patent litigation in the pharmaceutical and biotechnology industry is expensive and prolonged. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Costs that we may incur in defending third-party infringement actions would also result in the diversion of management's and technical personnel's time. In addition, parties making claims against us may be able to obtain injunctive or other equitable relief that could prevent us or our collaborators and licensees from further developing our discoveries or commercializing our products.

In the event of a successful claim of infringement against us or a potential collaborator and licensee, we may be required to pay damages, including treble damages and attorney's fees if we are found to be willfully infringing a third-party's patent, or obtain one or more licenses from the prevailing third-party (if not obtained prior to such litigation), which may not be available to us on commercially reasonable terms, if at all. Even if we were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. If we are not able to obtain such a license or not able to obtain such a license at a reasonable cost, we could be prevented from commercializing a product until the relevant patents expired, or we could be forced to redesign our products, or to cease some aspect of our business operations, and we could encounter delays in product introductions and loss of substantial resources while we attempt to develop alternative products. Defense of any lawsuit or failure to obtain any such license could prevent us or our partners from commercializing available products and could cause us to incur substantial expenditures, and would divert management's attention from our core business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe, misappropriate or otherwise violate our patents, trademarks, copyrights or other intellectual property, or those of our licensors. To counter infringement, misappropriation, unauthorized use or other violations, we may be required to file legal claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel.

We may not be able to prevent, alone or with our licensees or any future licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patents do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

In any infringement, misappropriation or other intellectual property litigation, any award of monetary damages we receive may not be commercially valuable. 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 litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Patent reform and other legislative changes in the U.S. and other countries may affect our ability to obtain and enforce our patents.

Changes in either the patent laws or interpretation of the patent laws in the U.S. or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the United States passed comprehensive patent reform laws in the "America Invents Act", or the "Act". These changes may affect our ability to obtain and enforce patents in a number of ways. First, the Act provides a new procedure of the Inter Partes Review, which replaces a previous inter partes reexamination procedure, for challenging the validity of a U.S. patent. The Inter Partes Review can be used to challenge the patentability of one or more claims in a US patent on a ground that could be raised under 35 U.S.C. §§ 102 or 103, and on the basis of prior art consisting of patents or printed publications. Second, the Act provides for a period of ex parte post-grant review with expanded grounds for challenging validity, including §§101, 102, 103 and 112, of a patent for nine months after grant of a patent. If the validity of one of our U.S. patents is successfully challenged, some or all of the claims may be invalidated, such that we could not enforce the patent and hence may not be able to protect one or more of our therapeutic product candidates. Other countries may also pass legislative changes to their patent laws which could materially affect – and even invalidate – one or more of our already filed patent applications, or even granted patents.

In addition, there is a trend in the USPTO to narrower antibody claim scope, mainly through stringent “written description requirements”, which increasingly limit an applicant’s ability to claim antibodies by describing them functionally and thus limiting the patent claims to specific antibody sequences. The written description requirement in antibodies may result in difficulties to obtain early broad patent protection on antibody inventions and in significant patent vulnerabilities. An example of this trend is a recent U.S. Supreme Court decision in the *Amgen v. Sanofi* case. In October 2017, in *Amgen v. Sanofi*, the Federal Circuit overturned the “newly characterized antigen” test, which permitted patentees to claim a genus of antibodies by describing the structure of a corresponding antigen, rather than by describing the structure of the claimed antibodies themselves. The Federal Circuit abolished the newly characterized antigen test on the grounds that it failed to satisfy the written description requirement found in Section 112 of the Patent Act, 35 U.S.C. § 112. In doing so, the Federal Circuit not only eliminated a favored claiming strategy, it also called into question the validity of numerous existing patents. On Jan. 7, 2019, the U.S. Supreme Court declined to hear an appeal of the Federal Circuit’s ruling, effectively changing the landscape for antibody patents for the foreseeable future. In the current IP environment in the U.S., and particularly after *Amgen v. Sanofi*, we may not be able to obtain broad, early patent protection on our antibody inventions. Other countries may also pass legislative changes to their patent laws which could materially affect – and even invalidate – one or more of our already filed patent applications, or even granted patents.

Increased progress in our scientific and technological environment may reduce our chances of obtaining a patent.

In order to obtain a patent to protect one of our therapeutic product candidates, we must show that the underlying invention (that is, the product candidate itself or its use) is inventive. As an increasing amount of scientific knowledge is becoming available regarding genes, proteins and biological mechanisms, the bar is increasingly raised to show sufficient inventiveness, as inventiveness is judged against all publicly available information available prior to filing of the patent application (the exact date may vary by country or due to other circumstances). As an increasing amount of scientific knowledge is becoming available for various proteins and their potential use as drug targets, with time we may be limited or may not be able to obtain patents for our product candidates due to the increased information published in this area. Collective patent applications, in which a large number of candidates are included in one patent application, are also challenged due to the raised bar for information that must be included in a patent application, as well as due to the availability of other publications. Our own published patent applications and other publications also serve as prior art against our new inventions and patent applications, and may prevent us from obtaining new patents.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We enter into assignment of invention agreements with our employees pursuant to which such individuals agree to assign to us all rights to any inventions created in the scope of their employment or engagement with us. A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967, or the Patent Law, inventions conceived by an employee due to and during his or her employment with a company are regarded as “service inventions”, which belong to the employer, unless there exists an specific agreement between the employee and employer stating otherwise, except if the company waived the service invention within six months of receipt of a notice by employee regarding the creation of the service invention (in accordance with provisions of the Patent Law). The Patent Law also provides that if there is no agreement with respect to whether the employee is entitled to remuneration for his or her service invention, to what extent and under what conditions, such entitlement and terms shall be determined by the Israeli Compensation and Royalties Committee, or the Committee, a body constituted under the Patent Law. Decisions by the Committee and Israeli courts have created some uncertainty in this area. Although our employees have agreed to assign to us service invention rights, we may face claims demanding remuneration in consideration for assigned service inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current and/or former employees, or be forced to litigate such claims, which could negatively affect our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, 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.

The USPTO and various foreign patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions to maintain patent applications and issued patents. Noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case.

We may be subject to claims that we or our employees, consultants, contractors or advisors have infringed, misappropriated or otherwise violated the intellectual property of a third-party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the intellectual property and other proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these employees have used or disclosed such intellectual property or other proprietary information. Litigation may be necessary to defend against these claims.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property. To the extent that we fail to obtain such assignments, such assignments do not contain a self-executing assignment of intellectual property rights or such assignments are breached, we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make products that are similar to our products but that are not covered by the claims of our patent rights;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to file patent applications on the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we may own or that we exclusively license in the future may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities 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;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Operations in Israel

Conditions in the Middle East and in Israel may adversely affect our operations.

Our headquarters and part of our research and development facilities are located in Israel. Accordingly, we are directly influenced by the political, economic and military conditions affecting Israel. Specifically, we could be adversely affected by:

- hostilities involving Israel;
- the interruption or curtailment of trade between Israel and its present trading partners;
- a downturn in the economic or financial condition of Israel; and
- a full or partial mobilization of the reserve forces of the Israeli army.

Israel has been subject to a number of armed conflicts that have taken place between it and its Middle Eastern neighbors. While Israel has entered into peace agreements with both Egypt and Jordan, Israel has no peace arrangements with any other Arab country. Further, all efforts to improve Israel's relationship with the Palestinians have failed to result in a permanent peaceful solution, and there have been numerous periods of hostility in recent years. This state of hostility, varying from time to time in intensity and degree, has led to security and economic problems for Israel.

Israel is, from time to time, engaged in armed conflicts with Hamas, a militia group and political party controlling the Gaza Strip. These conflicts have involved missile strikes against civilian targets in various parts of Israel, last in November 2018, as well as civil insurrection of Palestinians in the West Bank, on the border with the Gaza Strip and in Israeli cities.

In addition, the continuation of the civil war in Syria and renewed conflict with Hezbollah (a Lebanese Islamist Shiite militia group and political party), adjacent to Israel's northern border, including the discovery and destruction of attack tunnels from Lebanon into Israel in December 2018 has contributed to the tension in the region.

Also, relations between Israel and Iran remain hostile due to the fact that Iran is perceived by Israel as a sponsor of Hamas and Hezbollah, while maintaining a military presence in Syria, and with regard to Iran's nuclear program. During 2018 the parties engaged in military strikes against each other adjacent to Israel's northern border.

All of the above raise a concern as to the stability in the region which may affect the political and security situation in Israel and therefore could adversely affect our business, financial condition and results of operations.

Furthermore, the continued conflict with the Palestinians is already disrupting some of Israel's trading activities. Certain countries, primarily in the Middle East but also in Malaysia and Indonesia, as well as certain companies and organizations in different parts of the world, continue to participate in a boycott of Israeli brands others doing business with Israel and Israeli companies. The boycott, restrictive laws, policies or practices directed towards Israel or Israeli businesses could, individually or in the aggregate, have a material adverse effect on our business in the future. Further deterioration of our relationship with the Palestinians or countries in the Middle East could expand the disruption of international trading activities in Israel, may materially and negatively affect our business conditions, could harm our results of operation and adversely affect the share price of our Company. In addition, a number of our employees who are Israeli citizens are subject to an obligation to perform reserve military service. In case of further regional instability such employees who may include one or more of our key employees may be absent for extended periods of time which may materially adversely affect our business.

We can give no assurance that the political, economic and security situation in Israel will not have a material impact on our business in the future.

Furthermore, our Company's insurance does not cover any loss arising of events related to the security situation in the Middle East. While the Israeli government currently covers the reinstatement value of direct damages caused by acts of war or terror attacks, we cannot be certain that such coverage will be maintained.

Our results of operations may be adversely affected by the exchange rate fluctuations between the dollar and the New Israeli Shekel.

We hold most of our cash, cash equivalents and short-term and long-term bank deposits in U.S. dollars but incur a significant portion of our expenses, principally salaries and related personnel expenses and administrative expenses for our Israeli based operations, in NIS. As a result, we are exposed to exchange rate fluctuations between the U.S. dollar and the NIS, which may have a material adverse effect on our financial condition. In 2018, the U.S. Dollar appreciated against the NIS by 8.1%, in 2017 and 2016 the U.S. Dollar depreciated against the NIS by 9.8% and 1.5%, respectively, and, as a result, our NIS denominated expenses were affected by these fluctuations. We entered into foreign currency derivative contracts to hedge a portion of our anticipated NIS payroll and certain operation expenses. For more information, see Note 2s of our 2018 consolidated financial statements.

We may not be entitled to certain tax benefits.

We may be entitled to benefit in the future from certain government programs and tax legislation, particularly as a result of the 'Approved Enterprise' status granted to some of our operations by the Investment Center in the Israeli Ministry of the Economy and the 'Benefiting Enterprise' status that resulted from our eligibility for tax benefits under the Israel Law for Encouragement of Capital Investments, 1959 (an "Approved Enterprise", a "Benefiting Enterprise" and the "Investment Law", respectively). The availability of these tax benefits, however, is subject to certain requirements under the Investment Law including, among other things, making specified investments in fixed assets and equipment. The tax benefits that we anticipate receiving under our current "Approved Enterprises" and "Benefiting Enterprises" programs may not be continued in the future at their current levels or at all. To date, we have not actually received any such tax benefits because we have not yet generated any taxable income.

It may be difficult to enforce a U.S. judgment against us, or our officers and directors or to assert U.S. securities law claims in Israel.

We are incorporated under the laws of the State of Israel. Service of process upon our directors and officers, the majority of whom reside outside the United States, may be difficult to obtain within the United States. Furthermore, because the majority of our assets and investments, and a majority of our directors and officers are located outside the United States, any judgment obtained in the United States against us or any of them may not be collectible within the United States. Additionally, it may be difficult to enforce civil liabilities under U.S. federal securities laws in original actions instituted in Israel.

It may be difficult for an investor, or any other person or entity, to assert U.S. securities law claims in original actions instituted in Israel. Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear such a claim, it is not certain whether Israeli law or U.S. law will be applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proven as a fact by expert witnesses, which can be a time consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel that addresses the matters described above.

Provisions of Israeli law may delay, prevent or make undesirable an acquisition of all or a significant portion of our shares or assets.

Israeli corporate law regulates mergers and requires that a tender offer be effected when certain thresholds of percentage ownership of voting power in a company are exceeded (subject to certain conditions). Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders whose country of residence does not have a tax treaty with Israel granting tax relief to such shareholders from Israeli tax. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which certain sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred. See "Item 10. Additional Information - B. Memorandum and Articles of Association — Change of Control."

Furthermore, due to our receipt of grants from the Israel Innovation Authority, or the IIA (formerly known as the Office of Chief Scientist, or the OCS), we are subject to the Restrictive Trade Practices Law, 1988 and under the Israeli law for the Encouragement of Industrial Research and Development of 1984 and regulations promulgated thereunder, which we refer to as the R&D Law. Under these laws, approvals regarding a change in control (such as a merger or similar transaction) may be required in certain circumstances. For more information regarding such required approvals please see “Item 5. Operating and Financial Review and Prospects– C. Research and Development, Patents and Licenses – The Israel Innovation Authority.”

These provisions of Israeli law could have the effect of delaying or preventing a change in control and may make it more difficult for a third-party to acquire us or our shareholders to elect different individuals to our board of directors, even if doing so would be beneficial to our shareholders, and may limit the price that investors may be willing to pay in the future for our ordinary shares.

We received grants from the IIA (formerly OCS) that may restrict the transfer of know-how that we develop.

We have received research and development grants from the IIA. Therefore, even following full repayment of any IIA grants, and unless agreed otherwise by the applicable authority of the IIA, we must nevertheless continue to comply with the requirements of the R&D Law. Accordingly, the transfer of know-how or technologies developed under the programs submitted to the IIA and as to which we received the grants, or manufacturing or rights to manufacture based on and/or incorporating such know-how to third parties, might require the prior consent of the IIA, and may require certain payments of increased royalties to the IIA. Although such restrictions do not apply to the export from Israel of the Company’s products developed with such know-how, they may prevent us from engaging in transactions involving product or other asset transfers with our affiliates, customers or other third parties outside Israel, involving product or other asset transfers, which might otherwise be beneficial to us. For more information regarding such restrictions please see “Item 5. Operating and Financial Review and Prospects– C. Research and Development, Patents and Licenses – The Israel Innovation Authority.”

Being a foreign private issuer exempts us from certain SEC and Nasdaq requirements.

We are a “foreign private issuer” within the meaning of rules promulgated by the SEC. As such, we are exempt from certain provisions applicable to U.S. public companies including:

- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q and current reports on Form 8-K;
- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the provisions of Regulation FD aimed at preventing issuers from making selective disclosures of material information; and
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and establishing insider liability for profits realized from any “short-swing” trading transaction (a purchase and sale, or sale and purchase, of the issuer’s equity securities within less than six months).

In addition, we may follow home country practice in Israel in lieu of certain Nasdaq listing requirements with regard to, among other things, shareholder approval for certain matters and approval of equity-based incentive plans for our employees. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on Nasdaq may provide less protection than is accorded to investors under the Nasdaq Listing Rules applicable to domestic issuers. For more information regarding specific exemptions we chose to adopt, please see “Item 16G — Corporate Governance.”

We may lose our status as a foreign private issuer, which would increase our compliance costs and could negatively impact our operations results.

We may lose our foreign private issuer status if (a) a majority of our outstanding voting securities are either directly or indirectly owned of record by residents of the United States and (b)(i) a majority of our executive officers or directors are U.S. citizens or residents, (ii) more than 50% of our assets are located in the United States or (iii) our business is administered principally outside the United States. If we will not be a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more extensive than the forms available to a foreign private issuer. We would also be required to follow U.S. proxy disclosure requirements, including the requirement to disclose, under U.S. law, more detailed information about the compensation of our senior executive officers on an individual basis. We may also be required to modify certain of our policies to comply with accepted governance practices associated with U.S. domestic issuers. Such conversion and modifications will involve increased costs. In addition, we would lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers, as described in the previous risk factor above.

Your rights and responsibilities as a shareholder will be governed by Israeli law which differs in some material respects from the rights and responsibilities of shareholders of U.S. companies.

Because we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our Articles of Association (“Articles”) and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith and in a customary manner in exercising its rights and performing its obligations towards the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to a company’s articles of association, an increase of a company’s authorized share capital, a merger of a company and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from discriminating against other shareholders. In addition, a controlling shareholder or a shareholder who knows that it possesses the power to determine the outcome of a shareholders’ vote or to appoint or prevent the appointment of an office holder in a company or has another power with respect to a company, has a duty to act in fairness towards such company. Israeli law does not define the substance of this duty of fairness and there is limited case law available to assist us in understanding the nature of this duty or the implications of these provisions. These provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

Risks Related to our Ordinary Shares

U.S. holders of our ordinary shares may suffer adverse tax consequences if we are classified as a passive foreign investment company for U.S. federal income tax purposes.

For U.S. federal income tax purposes, we will generally be classified as a passive foreign investment company, or PFIC, for any taxable year in which either: (i) 75% or more of our gross income is passive income or (ii) at least 50% of the average value (determined on a quarterly basis) of our total assets for the taxable year produce or are held for the production of passive income. For purposes of these tests, passive income includes dividends, interest, and gains from the sale or exchange of investment property and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. Additionally, a look-through rule generally applies with respect to 25% or more owned subsidiaries. If we are characterized as a PFIC, U.S. holders of our ordinary shares may suffer adverse tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income rather than capital gain, the loss of the preferential tax rate applicable to dividends received on our ordinary shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and the proceeds of sales of our ordinary shares.

Based on our analysis of our income, assets, activities and market capitalization, we believe that we were not a PFIC for the taxable year ended December 31, 2018; however, there can be no assurances that the U.S. Internal Revenue Service will not challenge our analysis or our conclusion regarding our PFIC status. In addition, with respect to the current and future taxable years, because the PFIC tests are based upon the value of our assets, including any goodwill and going concern value, and the nature and composition of our income and assets, which cannot be known at this time, we cannot predict whether we will or will not be classified as a PFIC. Our status as a PFIC is a fact-intensive determination made on an annual basis and we cannot provide any assurances regarding our PFIC status for the current or future taxable years. If we are determined to be a PFIC for U.S. federal income tax purposes, highly complex rules would apply to U.S. holders owning our ordinary shares and such U.S. holders could suffer adverse U.S. tax consequences. For more information, please see “Item 10. Additional Information – E. Taxation – Certain Material U.S. Federal Income Tax Considerations – Passive Foreign Investment Company.”

New or future changes to tax laws could materially adversely affect our company.

On December 22, 2017, President Trump signed into law H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018”, informally titled the Tax Act, which significantly revises the Internal Revenue Code of 1986, as amended, or, the Code. The Tax Act, among other things, reduces the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limits the tax deduction for interest expense to 30% of adjusted taxable income (except for certain small businesses), implements a “base erosion anti-abuse tax” which requires U.S. corporations to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates, taxes certain non-U.S. corporations’ earnings considered to be “global intangible low taxed income” (also referred to as “GILTI”), repeals the alternative minimum tax, or AMT, for corporations and changes a taxpayer’s ability to either utilize or refund the AMT credits previously generated, changes the attribution rules relating to shareholders of certain “controlled foreign corporations”, limits the deduction for net operating losses carried forward from taxable years beginning after December 31, 2017 to 80% of current year taxable income and eliminates net operating loss carrybacks, imposes a one-time tax on offshore earnings at reduced rates regardless of whether they are repatriated, eliminates U.S. tax on foreign earnings (subject to certain important exceptions), allows immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifies or repeals many business deductions and credits. Notwithstanding the reduction in the U.S. corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. We are unable to predict what federal tax law may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. We urge holders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our shares.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

The net operating loss, or NOL, carryforwards of our U.S. subsidiary, Compugen USA, Inc., could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Compugen USA, Inc.’s NOLs generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Act, Compugen USA, Inc.’s federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of federal NOLs generated in tax years beginning after December 31, 2017 is limited. It is uncertain if and to what extent various states will conform to the Tax Act.

In addition, under Section 382 of the Code and corresponding provisions of state law, 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 or taxes may be limited. It is possible that Compugen USA, Inc. has in the past undergone, and in the future may undergo, ownership changes that could result in additional limitations on its net operating loss carryforwards.

Consequently, Compugen USA Inc. may not be able to utilize a material portion of its net operating loss carryforwards and certain other tax attributes, which could have a material adverse effect on cash flow and results of operations.

Future sales of our ordinary shares or securities convertible or exchangeable for our ordinary shares may depress our share price.

If our existing shareholders or holders of our options or warrants sell, or indicate an intention to sell, substantial amounts of our ordinary shares in the public market, the trading price of our ordinary shares could decline. The perception in the market that these sales may occur could also cause the trading price of our ordinary shares to decline. As of December 31, 2018, we have a total of 59,849,784 shares of ordinary shares outstanding.

Based on the number of shares subject to outstanding awards under our 2000 Option Plan and 2010 Plan, or available for issuance under our 2010 Plan as of December 31, 2018, 10,046,971 shares of ordinary shares that are either subject to outstanding options or reserved for future issuance under our employee share incentive plans will be eligible for sale in the public market, subject to, in the case of shares issued to directors, executive officers and other affiliates, the volume limitations under Rule 144 under the Securities Act. If these additional shares of ordinary shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

In addition, our directors, executive officers and other affiliates may establish, and certain executive officers, directors and affiliates have established, programmed selling plans under Rule 10b5-1 of the Exchange Act, for the purpose of effecting sales of our ordinary shares. Any sales of securities by these shareholders, or the perception that those sales may occur, including the entry into such programmed selling plans, could have a material adverse effect on the trading price of our ordinary shares.

If we sell ordinary shares in future financings, shareholders may experience immediate dilution and, as a result, our share price may decline.

In order to raise additional capital, we may at any time offer additional ordinary shares or other securities convertible into or exchangeable for our ordinary shares at prices that may not be the same as the price you paid for our ordinary shares. The price per share at which we sell additional ordinary shares, or securities convertible or exchangeable into ordinary shares, in future transactions may be higher or lower than the price per share paid by our existing shareholders. If we issue ordinary shares or securities convertible into ordinary shares, our shareholders would experience additional dilution and, as a result, our share price may decline.

In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities or ordinary shares. Whether or not we issue additional shares at a discount, any issuance of ordinary shares will, and any issuance of other equity securities or of options, warrants or other rights to purchase ordinary shares may, result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline. New investors could also gain rights, preference and privileges senior to those of our shareholders, which could cause the price of our ordinary shares to decline. Debt securities may also contain covenants that restrict our operational flexibility or impose liens or other restrictions on our assets, which could also cause the price of our ordinary shares to decline.

Our ordinary shares are traded on more than one market and this may result in price variations.

In addition to being traded on The Nasdaq Global Market, our ordinary shares are also traded on the Tel Aviv Stock Exchange, or TASE. Trading in our ordinary shares on these markets take place in different currencies (U.S. dollars on Nasdaq and NIS on the TASE), and at different times (resulting from different time zones, trading days and public holidays in the United States and Israel). The trading prices of our ordinary shares on these two markets may differ due to these and other factors. Any decrease in the price of our ordinary shares on one market could cause a decrease in the trading price of our ordinary shares on the other market.

Our share price and trading volume have been volatile and may be volatile in the future and that could limit investors' ability to sell our shares at a profit and could limit our ability to successfully raise funds.

During the calendar years 2017 and 2018, our share price on Nasdaq has traded from a low of \$2.00 to a high of \$5.40 and trading volume is volatile from time to time. The volatile price of our shares and periodic volatile trading volume may make it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our ordinary shares including:

- global macroeconomic developments;
- our success (or lack thereof) in entering into collaboration agreements and achieving certain research and developmental milestones thereunder;
- our need to raise additional capital and our success or failure in doing so;
- our ability (or lack thereof) to disclose key discoveries or developments due to competitive concerns or need to secure our intellectual property position;
- achievement or denial of regulatory approvals by us or our competitors;

- announcements of technological innovations or new commercial products by our competitors;
- developments concerning proprietary rights, including patents;
- developments concerning our existing or new collaborations;
- regulatory developments in the United States, Israel and other countries;
- changes in the structure of healthcare payment systems;
- delay or failure by us or our partners in initiating, completing or analyzing preclinical or clinical trials or the unsatisfactory design or results of such trials;
- period to period fluctuations in our results of operations;
- changes in financial estimates by securities analysts;
- changes in senior management or the board of directors;
- our ability (or lack thereof) to disclose the commercial terms of, or progress under, our collaborations;
- our ability (or lack thereof) to show and accurately predict revenues; and
- transactions with respect to our ordinary shares by insiders or institutional investors.

We are not able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, have experienced extreme price and volume fluctuations that may be unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our ordinary shares, regardless of our operating performance.

Furthermore, the market prices of equity securities of companies that have a significant presence in Israel may also be affected by the changing security situation in the Middle East and particularly in Israel. As a result, these companies may experience volatility in their stock prices and/or difficulties in raising additional financing required to effectively operate and grow their businesses. Thus, market and industry-wide fluctuations and political, economic and military conditions in the Middle East may adversely affect the trading price of our ordinary shares, regardless of our actual operating performance.

As a result of the volatility of our share price, we could be subject to securities litigation, which could result in substantial costs and divert management's attention and company resources from our business.

Shareholder activism can negatively affect our business.

In recent years, shareholder activists have become involved in numerous public companies. Shareholder activists could propose to involve themselves in the governance, strategic direction and operations of a company. We encountered such activism prior to our 2017 annual general shareholders' meeting, when we received a formal request from an individual private shareholder, holding approximately 1.3% of the Company's voting rights, to add to the agenda of the meeting the proposed appointment of two new director candidates, both of whom were not recommended by management. This proposal was rejected by the shareholders at the meeting. Shareholder activism, including potential proxy contests, could divert our management's and board of directors' attention and resources from our business, could give rise to perceived uncertainties as to our future direction and could result in the loss of potential business opportunities and make it more difficult to attract and retain qualified personnel for positions in both management and on the board level. If nominees advanced by activist shareholders are elected or appointed to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plans or to realize long-term value from our assets. Also, we may be required to incur significant expenses including legal fees related to activist shareholder matters. Further, our share price could be subject to significant fluctuations or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

History

Our legal and commercial name is Compugen Ltd. We were incorporated on February 10, 1993 as an Israeli corporation and operate under the Israeli Companies Law, 5759-1999, as amended together with all regulations promulgated thereunder (the "Companies Law"). Our principal offices are located at 26 Harokmim Street, Holon 5885849, Israel, and our telephone number is +972-3-765-8585. Our web address is www.cgen.com. Information contained on our website does not constitute a part of this Annual Report.

Our agent for service of process in the United States is Compugen USA, Inc., our wholly owned U.S. subsidiary located at 250 E. Grand Avenue, Suite 65, South San Francisco, CA 94080, which was incorporated in Delaware in March 1997 and is qualified to do business in California. This subsidiary did not have any significant operations from 2008 to March 2012.

Principal Capital Expenditures

In the years ended December 31, 2018, 2017 and 2016, our capital expenditures were \$0.2 million, \$0.4 million and \$2.6 million, respectively, and for the year 2016 were spent primarily on leasehold improvements for the new facilities in Holon, Israel (see “Item 4. Information on the Company – D. Property, Plants and Equipment”), laboratory equipment, general computer software and hardware. As of December 31, 2018, we have no current significant commitments for capital expenditures.

B. BUSINESS OVERVIEW

Summary

Compugen is a clinical-stage, therapeutic discovery and development company utilizing its proprietary computational discovery platforms to identify novel drug targets and develop first-in-class therapeutics in the field of cancer immunotherapy. Our therapeutic pipeline consists of immuno-oncology programs against novel drug targets we have discovered computationally, including T cell immune checkpoints and other early-stage immuno-oncology programs focused largely on myeloid targets. Our pipeline consists of two clinical stage programs. COM701 is a first-in-class therapeutic antibody targeting PVRIG, developed internally; and BAY 1905254 is a first-in-class therapeutic antibody targeting ILDR2, partnered to Bayer. Both targets are novel immune checkpoints discovered computationally by us and currently in Phase 1 studies in patients with advanced solid tumors; each initiated in September 2018. Our business model is to enter into collaborations for our novel targets and related drug product candidates at various stages of research and development. In 2018, we entered into two agreements with leading pharmaceutical companies – a clinical collaboration agreement with Bristol-Myers Squibb in connection with our lead immuno-oncology program, COM701, and an exclusive license agreement with AstraZeneca for the development of bi-specific and multi-specific antibody products derived from one of Compugen’s immuno-oncology programs. The first agreement we entered into in connection with one of our immuno-oncology programs was with Bayer in 2013 for the research, development, and commercialization of immuno-oncology therapeutics against novel targets identified by Compugen. Under this agreement we collaborate with Bayer on the development BAY 1905254. Compugen also engages in collaborations with leading academic research centers in the United States to advance its research and development efforts.

The Company is headquartered in Holon, Israel. Its clinical development and business development activities operate from its U.S. site in South San Francisco, California.

Our Strategy

Our pipeline strategy for the development of first-in-class cancer immunotherapies is differentiated in the competitive landscape of immuno-oncology. It is based on novel targets discovered by our proprietary computational discovery platforms and on robust scientific rationale guiding our drug development process. Our strategy consists of the following:

- Targeting novel pathways, identified internally, with potential to address the unmet need of patients non-responsive to cancer immunotherapies;
- Applying a science-driven approach to identify optimal drug combinations, through deep understanding of the biology of these novel pathways; and
- Using the same scientific understanding of the new pathways, to design a robust biomarker strategy for patient selection.

In our therapeutic pipeline, our most advanced programs are:

- **COM701** is our lead immuno-oncology pipeline program. It is a first-in-class antibody targeting PVRIG, a novel immune checkpoint, that operates together with TIGIT as part of the DNAM axis. Phase 1 studies for COM701 were initiated in September 2018 to evaluate it as a monotherapy and in combination with a PD-1 inhibitor in patients with advanced solid tumors. In October 2018, Compugen entered into a clinical collaboration with Bristol-Myers Squibb, according to which it will supply Opdivo, its PD-1 immune checkpoint inhibitor, to the combination arms of the study.

PVRIG is broadly expressed in both PD-L1+ and PD-L1- tumors and we see clinical opportunities in tumor types with high unmet need, such as endometrial, ovarian, breast, lung and other solid tumors. Our clinical combination strategy is informed by the pathway biology and by a mechanistic understanding of key checkpoint pathway interactions with supporting data from relevant preclinical models.

- **BAY 1905254** targeting ILDR2, a new immune checkpoint identified by us, is being developed by Bayer pursuant to a research and discovery collaboration and license agreement signed in 2013. Bayer initiated its Phase 1 study in patients with solid tumors in September 2018, which triggered a milestone payment of \$7.8 million.

BAY 1905254 has exhibited anti-tumor activity as a monotherapy in various mouse models and was also shown to have additive anti-tumor effects in combination with other cancer therapy approaches in those models, indicating the possibility for multiple combination uses in cancer immunotherapy.

- **COM902** is a therapeutic immuno-oncology antibody targeting TIGIT. The development of an internal anti-TIGIT program was pursued as an integral part of the COM701 program to enable clinical combinations. Our preclinical data suggests that in certain tumor indications the blockage of both TIGIT and PVRIG may be required to sufficiently stimulate an anti-tumor immune response. IND-enabling studies are ongoing, and an IND application is expected to be submitted in 2019.

Research Focus – Immuno-Oncology

Our target discovery and drug development efforts focus on identifying novel drug targets and developing first-in-class therapeutics in the field of cancer immunotherapy.

Cancer immunotherapies represents a significant commercial market. Sales of therapies targeting immune checkpoints registered \$16.6 billion worldwide in sales in 2018. Industry analysts estimate that the cancer immunotherapy market has a significant growth potential and annual sales' projections of some of these analysts range between \$28 billion and \$40 billion by 2025.

The immune system is naturally programmed to seek out and destroy abnormal cells. Cancer is believed to thrive, in part, because of a number of cellular mechanisms that aid in the evasion of immune response. Such mechanisms of immune system evasion include masking or reducing the expression of tumor antigens to avoid detection, recruiting T-cell suppressor cells or expressing inhibitory molecules that suppress immune activation, inducing conditions in the tumor microenvironment that promote tumor cell proliferation and survival, and a number of other factors. Immuno-oncology therapies that overcome immune suppression by stimulating responses directed to cancer cells are emerging as a powerful means of counteracting the cellular mechanisms that enable the growth and spread of tumors. Immuno-oncology agents are expanding as a potential path to durable and long-lasting responses in certain patients.

Compugen's initial discovery efforts in this field were directed at identifying novel immune checkpoints that activate T cells in cancer patients. Once activated T cells are capable of destroying tumor cells, and therefore may be used for cancer immunotherapy treatment. Over the past two years our discovery efforts were focused on myeloid targets, addressing a range of mechanisms of action. Myeloid targets is a growing field in immuno-oncology which may offer a complimentary strategy to checkpoint inhibition, and consequently may provide treatment solutions for non-responsive or relapsing patients. More recently, we have expanded our discovery capabilities to investigate mechanisms of immune resistance to currently available immunotherapies.

While immunotherapy revolutionized the landscape for oncology treatments by providing a new treatment option leading to lasting benefits for patients; the response rates to immunotherapy vary greatly across different cancer indications, averaging only 20 to 30% across all cancer patients thereby leaving a significant unmet medical need for many patients and a continuing challenge to discover new biological pathways relevant for new cancer immunotherapies.

Compugen is targeting novel pathways to develop cancer immunotherapies addressing the non-responsive patient populations.

Pipeline

COM701 – a therapeutic antibody targeting PVRIG

Preclinical data and expression analysis

PVRIG is a novel immune checkpoint target candidate discovered computationally by Compugen. Validation studies show that expression of PVRIG in T cells inhibits their activation by melanoma cells, consistent with an immune suppressive role of the target in the tumor microenvironment. The target possesses signature immune checkpoint receptor characteristics, including expression in relevant subsets of T- and NK-cells, with particularly high expression in lymphocytes that populate the tumor microenvironment (known as tumor infiltrating lymphocytes or TILs). PVRL2 was identified as the binding partner for PVRIG, placing it in the immune regulatory TIGIT/DNAM signaling axis on T-cells. Expression analysis of PVRL2 shows it to be highly expressed in a number of cancer indications, including breast, ovarian, and endometrial tumors, suggesting that the PVRIG/PVRL2 signaling pathway may be a dominant mechanism of immune suppression in those patient populations.

In preclinical studies we demonstrated that inhibition of PVRIG by COM701 results in increased activation of both normal and tumor derived T cells, consistent with in vitro activity demonstrated by other immune checkpoint inhibitors. Treatment of T cells with COM701 in combination with PD-1 or TIGIT inhibitors further increased T cell activation, demonstrating the combination potential of COM701 with other checkpoint inhibitors. The combination effect was particularly strong with TIGIT inhibitors, supporting the hypothesis that both inhibitory arms of the DNAM axis must be antagonized for full activation of DNAM costimulatory signaling.

Genetic ablation of the PVRIG gene in mice results in reduced tumor growth, which can be further enhanced by treatment with PD-1 pathway blockers. This combination effect is seen with antibody blockade of PVRIG together with PD-1 or TIGIT pathway inhibition, again supporting COM701 clinical combination with other checkpoint inhibitors.

Clinical Development

In September 2018, we dosed our first patient in the Phase 1 clinical study of COM701 [OR we initiated our first-in-human Phase 1 clinical study for COM701]. The Phase 1 study is conducted in the United States and as of March 1, 2019 we had five sites recruiting for the study. The study is expected to include up to ten sites and enroll approximately 140 patients. Furthermore, we reported on March 1, 2018 that the third single subject dose cohort has been completed with no dose-limiting toxicities (DLTs) reported. Currently, clinical and laboratory assessment for safety and tolerability is ongoing for the fourth dosing cohort.

In October 2018, we entered into a clinical trial collaboration agreement with Bristol-Myers Squibb to evaluate the safety and tolerability of COM701 in combination with Bristol-Myers Squibb's programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo®. See "Business Strategy and Partnerships – Bristol-Myers Squibb Collaboration" below. Bristol Meyers Squibb will supply its PD-1 immune checkpoint inhibitor, Opdivo® for the dual combination portions of the studies in accordance with our collaboration.

A schema of the study, patient population, key study objectives and biomarker strategy are summarized in the chart below:

COM701 PHASE 1 CLINICAL STUDY – INITIATED SEPT 2018

ClinicalTrials.gov Identifier: NCT03667716



Phase 1a Arm A of the study will evaluate the safety and tolerability of COM701 monotherapy through sequential dose escalations. The study is implementing an accelerated titration dose design before moving to a 3+3 study design as dose escalations continue. At the completion of the monotherapy dose escalation study, we will have a recommended Phase 2 dose of COM701.

The patient population enrolled will be all comers and will include patients who have failed prior therapies including other checkpoint inhibitors and have no other available approved therapies.

To evaluate the long-term safety and efficacy of COM701 monotherapy, at the completion of the COM701 monotherapy dose-escalation, cohort dose expansion will be performed with the enrollment of patients with relapsed or refractory disease and the following tumor types: Non-small cell lung cancer, ovarian cancer, breast cancer (including Triple negative breast cancer) and endometrial cancer. These tumor types have been selected based on the preclinical data demonstrating a high expression of PVRIG and PVRL2. With the exception of non-small cell lung cancer, the other tumor types typically have low PDL-1 expression relative to PVRL2 (based on our preclinical data) and are not usually responsive to PD-1 inhibitors. In addition, our biomarker strategy will evaluate these clinically relevant endpoints (clinical activity and safety) with immune phenotyping, PVRIG pathway expression and target coverage by COM701. Our biomarker analysis will be a retrospective analysis, which if confirmed, will serve for patient selection at later stages of the trial.

Phase 1a Arm B of the study will evaluate the safety and tolerability of COM701 in combination with a PD-1 inhibitor using a 3+3 study design. A similar patient population, as enrolled for the cohort expansion in Arm A will be preferred for enrollment for this part of the study.

In **Phase 1b** part of the study, we will enroll patients with these specific tumor types where the preclinical data has demonstrated high expression of PVRL2 and PVRIG – these are non-small cell lung cancer, ovarian cancer, breast cancer and endometrial cancer. Other tumor indications may be explored based on the earlier clinical data. All subjects in this part of the study will have measurable disease so we are able to potentially evaluate the clinical activity of the doublet.

BAY 1905254 – a therapeutic antibody targeting CGEN-15001T/ILDR2

ILDR2, (formerly CGEN-15001T) a novel immune checkpoint target discovered by Compugen, was partnered to Bayer pursuant to a research and discovery collaboration and license agreement signed in August 2013. See “Business Strategy and Partnerships – Bayer Collaboration” below. Studies testing the immune function of ILDR2 demonstrated inhibitory effects on T cells consistent with it being an immune checkpoint ligand. ILDR2 appears to have a unique mechanism of action relative to other immune checkpoints currently being targeted in clinical testing. ILDR2 is expressed in lymph nodes, suggesting that BAY 1905254 exerts its effects on immune cell priming rather than on directly enhancing immune cell killing effects in the tumor microenvironment.

In April 2018, Bayer disclosed BAY 1905254 a human/mouse cross-reactive antibody blocking the immunosuppressive activity of ILDR2. BAY 1905254 has exhibited anti-tumor activity as a monotherapy in various mouse models and was also shown to have additive anti-tumor effects in combination with other cancer therapy approaches, indicating the possibility for multiple combination uses in cancer immunotherapy.

BAY 1905254 is currently being evaluated in a Phase 1 study in patients with advanced solid tumors. The study, sponsored and conducted by Bayer, is an open-label, dose escalation study designed to evaluate the safety and tolerability of BAY 1905254. The Phase 1 study is currently enrolling patients in the United States.

COM902 – a therapeutic antibody targeting TIGIT

COM902 is being developed as an integral component of the COM701 program, to provide the company with an internally-developed antibody to facilitate the combination strategy for COM701 – to test COM701 and COM902 as a dual combination, as well as in triple combination with PD-1 inhibitors. TIGIT was identified as a potential immune checkpoint by Compugen's predictive target discovery platform in 2009. Based on the pathway association of PVRIG with TIGIT, we explored whether combined inhibition of both PVRIG and TIGIT would lead to increased activation of T cells beyond inhibition of each separately.

Expression studies show that PVRIG and TIGIT, and their respective ligands, are expressed in a broad variety of tumor types, such as breast, endometrial, ovarian, lung, kidney, and head & neck cancers. These results indicate that within the same tumor indications there are variations with respect to the dominance of the two pathways, and that in patient populations where the two pathways are operative, the blockade of both TIGIT and PVRIG may be required to sufficiently stimulate an anti-tumor immune response.

IND-enabling studies are currently undergoing for this program and an IND application is expected to be submitted in 2019.

Early stage pipeline

Compugen's early stage programs are focused largely on myeloid targets addressing a range of mechanisms of action. Myeloid biology is a critical component of immune suppression. The myeloid lineage of the immune system includes suppressive macrophages, immune cells that are highly immune suppressive in the tumor microenvironment, and that can affect the anti-tumor immune response via multiple mechanisms of action. As such, blocking myeloid targets may offer a complementary strategy to immune checkpoint inhibition, providing new treatment solutions for non-responsive or relapsing patients and expanding the patient population responsive to immunotherapies. The Company's discovery platform has been enhanced to identify new myeloid targets within the tumor microenvironment. Myeloid CGEN-target candidates have been identified within the tumor microenvironment of multiple cancers and are pursued by the Company.

Our Computational Discovery Approach

While our computational discovery infrastructure has potentially broad applicability and is not limited to a certain indication or therapeutic field, we decided to focus our computational discovery efforts on the discovery of novel drug targets for the development of first-in-class therapeutic antibodies for an unmet clinical need in the field of immuno-oncology. We have thrice discovered new targets through computational prediction which are being clinically evaluated, offering support for the power and validity of our computational capabilities. COM701 targeting PVRIG and BAY 1905254 targeting ILDR2 are being tested in Phase 1 studies by us and Bayer, under our collaboration agreement, respectively. Anti-TIGIT inhibitors are being tested by others; while COM02, our anti-TIGIT antibody, is currently in preclinical development.

Our target discovery is a predictive, proprietary computational process that we initiated from a clinical need and which combines our expertise in both genome analysis as well as analysis of vast amounts of publicly available, as well as proprietary, expression data. Our multi-omics data analysis is designed to identify first-in-class drug target candidates, which are generally difficult to identify using traditional experimental approaches. We contend that biology, including target discovery, consists of complex scientific systems requiring an integrative approach relying on multiple tools to generate the best results, and should not be bound to a specific technology. The unmet clinical need and the therapeutic strategy dictate the target discovery approach, the appropriate tools and most relevant data to be employed, rather than fitting a specific tool or data type to all target discovery problems. Our target discovery process is a flexible process enabling tailor-made solutions designed to address a clinical need and consists of a toolbox of various -omics data, a suite of computational tools and purpose built algorithms, with human expertise to optimize the output. Our computational approach is diverse and not limited to a certain data type or data technology, but rather is able to handle a wide variety of data types. We have demonstrated the applicability of our discovery approach in multiple therapeutic and diagnostic areas and have demonstrated advantages of our methodologies in identifying new drug targets. This long-term focused effort was the basis for most of our discoveries, specifically the immune checkpoint discovery in which we identified TIGIT, PVRIG and ILDR2.

To date, our discovery capabilities have resulted in the following achievements:

An innovative immuno-oncology pipeline: three therapeutic programs addressing targets we discovered computationally and validated in-house, two of which are currently in Phase I clinical trials, one sponsored by us and one sponsored by Bayer

Strategic collaborations with both leading pharmaceutical companies and academia

Patents and publications: over 120 granted and pending patents and over 80 peer reviewed publications

Predictive discovery of novel immune checkpoints:

A key Compugen accomplishment in this field is the discovery of novel protein members belonging to various known and clinically important protein families by our predictive discovery platform. This platform was developed for the identification of novel immune checkpoints, and more specifically, immunomodulators belonging to the B7/CD28 protein family of costimulators/co-inhibitors. The platform consists of specialized algorithms developed internally based on protein characteristics among known CD28 proteins, such as gene structure, protein domains, predicted cellular localization and expression pattern and was applied for the identification of new immune checkpoints. Applying this discovery platform resulted in the identification of a number of putative immune checkpoint B7/CD28-like protein candidates, some of those we have disclosed are CGEN-15001T/ILDR2 (partnered to Bayer), PVRIg, and TIGIT.

Predictive discovery of myeloid targets:

In order to identify myeloid targets, we have used a combination of various of our discovery approaches, principally our expression platforms, which incorporate vast amounts of expression data from a wide variety of data sources, for the discovery of targets that are expressed within the suppressive myeloid lineages, such as tumor associated macrophages (TAMs). TAMs are an important component of the tumor microenvironment and play a major role in creating the immunosuppressive environment that enables tumor development. Proteins having the potential to modulate the tumor microenvironment may serve as potential targets for cancer immunotherapy.

Business Strategy and Partnerships

Our business strategy includes entering into various forms of revenue-sharing collaborations with pharmaceutical or biotechnology partners for our product candidates in our pipeline at both early and later stages of development. Through these collaborations we seek to create and further develop and commercialize therapeutic product candidates directed to our novel drug targets. Such collaborations or various types of partnering arrangements might include one or more of our therapeutic pipeline programs, including our novel early target candidates, as well as COM701 - together with or without COM902. Potential revenue sources in line with this business model could include upfront fees, research funding, in-kind funding, milestones payments, license fees, royalties and other revenue sharing payments. We may also seek co-development arrangements pursuant to which we would further advance partnered programs under any such partnership in order to retain higher value from future sales revenues.

Additionally, our discovery capabilities are designed to allow for research and discovery collaborations aimed at harnessing our infrastructure capabilities towards a potential partner's pipeline needs. In these arrangements, we would utilize our discovery approaches to identify novel proteins and/or targets addressing a specific unmet need of interest to our partner.

Bayer Collaboration

On August 5, 2013, Compugen and Bayer entered into the Bayer Collaboration for the research, development, and commercialization of antibody-based therapeutics against two novel, Compugen-discovered immune checkpoint regulators, BAY 1905254 (formerly CGEN 15001T/ILDR2) and CGEN 15022.

Under the terms of the Bayer Collaboration, we received an upfront payment of \$10 million, and, following the return of the CGEN 15022 program, we are eligible to receive an aggregate of over \$250 million in potential milestone payments for both programs, not including aggregate milestone payments of approximately \$23 million received to date. Additionally, we are eligible to receive mid- to high single digit royalties on global net sales of any approved products under the collaboration.

In 2014, we achieved the first and second preclinical milestones and in 2015 we achieved the third preclinical milestone with respect to BAY 1905254. Pursuant to the terms of the Bayer Collaboration, this program was transferred to Bayer's full control for further preclinical and clinical development activities, and worldwide commercialization under milestone and royalty bearing licenses from Compugen. In September 2018, we were informed that Bayer dosed the first patient in the Phase 1 clinical trial of BAY 1905254.

The Bayer Collaboration continues until Bayer is no longer required to make payments under the Agreement or until otherwise terminated by either party in accordance with the terms of the Agreement. Bayer may also terminate the Bayer Collaboration, either in whole or only with respect to one of the programs, and in each case also on a product-by-product and/or country-by-country basis, at any time without cause, upon prior written notice. Either party may also terminate the Bayer Collaboration, either in whole or with respect to only one of the programs, if the other party is in material breach and such breach has not been cured within the applicable cure period. Upon any termination of the Agreement, depending upon the circumstances, the parties have varying rights and obligations with respect to the continued development and commercialization of any products and certain payment and royalty obligations.

Bristol-Myers Squibb Collaboration

On October 11, 2018, we entered into a Master Clinical Trial Collaboration Agreement, MCTC, with Bristol-Myers Squibb to evaluate the safety and tolerability of COM701 in combination with Bristol-Myers Squibb's programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo® (nivolumab), in patients with advanced solid tumors.

Pursuant to the MCTC, we are responsible for and will continue sponsoring the ongoing two-part Phase 1 trial, which includes the evaluation of the combination of COM701 and Opdivo® in up to four tumor types that may include non-small cell lung, ovarian, breast and endometrial cancer. Bristol-Myers Squibb will provide Opdivo® at no cost to Compugen for the combination arm of this trial.

The collaboration is also designed to address potential future combinations, including trials sponsored by Bristol-Myers Squibb to investigate combined inhibition of checkpoint mechanisms, such as PVRIG and TIGIT. The clinical combination of multiple immune checkpoint inhibition is designed to clinically test the synergistic activity demonstrated in preclinical models. Bristol-Myers Squibb and Compugen will each supply the other company with its own compound for the other party's study, and otherwise each party will be responsible for all costs associated with the study that it is conducting. Any combination trial performed under this agreement is referred to as a Combined Therapy Study.

Ownership of, and global commercial rights to, COM701 remain solely with us under the MCTC (subject to the rights granted to Bristol-Myers Squibb). If Compugen wishes to license the right to commercialize COM701 in any territory during the time prior to the end of the Combination Therapy Studies plus 6 months, but, in certain circumstances, no later than 12 months following completion of the Compugen sponsored Combined Therapy Study (the "Exclusivity Period"), Compugen must first negotiate with Bristol-Myers Squibb for a period of three months (the "Negotiation Period") to grant an exclusive license to develop and commercialize COM701 in that territory. If Bristol-Myers Squibb and Compugen do not reach an agreement for an exclusive license within the Negotiation Period, then Bristol-Myers Squibb will have no further first negotiation rights, and Compugen will be free to license COM701 (subject to all other rights afforded to Bristol-Myers Squibb under the MCTC) to other parties, in such territory. After the expiration of the Exclusivity Period, Compugen is free to license COM701 without any further obligation to Bristol-Myers Squibb.

The MCTC also contains certain exclusivity provisions that run through the Exclusivity Period. We agreed not to conduct any preclinical or clinical research with, or grant rights to, certain restricted third parties regarding the combination of an anti-PD-1 antagonist or anti-PD-L1 antagonist together with COM701. We remain free to conduct any preclinical or clinical research involving such restricted combination on our own or in collaboration with academic or other non-profit entities.

Subject to termination rights for breach, bankruptcy or a material safety issue or clinical hold, the term of the MCTC will continue in effect until completion by all centers or institutions participating in the Combined Therapy Studies, the delivery of study data to both parties and the completion of any then agreed upon protocol(s), statistical analysis and bioanalysis plan. In the event a third-party merges with or acquires us, we are free to assign or transfer the Agreement without the consent of Bristol-Myers Squibb.

In conjunction with the signing of the MCTC, Bristol-Myers Squibb made a \$12 million investment in us, purchasing 2,424,243 of our ordinary shares at a purchase price of \$4.95 per share. The share price represented a 33% premium over the average closing price of our ordinary shares for twenty (20) Nasdaq trading days prior to the execution of the securities purchase agreement. Please see “Item 5. Operating and Financial Review and Prospects Finance – B. Liquidity and Capital Resources.”

MedImmune License

In March 2018, we entered into an exclusive license agreement with AstraZeneca, to enable the development of bi-specific and multi-specific immuno-oncology antibody products.

Under the terms of the license agreement, we provide an exclusive license to AstraZeneca for the development of bi-specific and multi-specific antibody products derived from one of our pipeline programs. AstraZeneca has the right to create multiple products under this license and will be solely responsible for all research, development and commercial activities under the agreement. We received a \$10 million upfront payment and are eligible to receive up to \$200 million in development, regulatory and commercial milestones for the first product as well as tiered royalties on future product sales. If additional products are developed, additional milestones and royalties would be due to us for each product. We retained all other rights to its entire pipeline of programs as monotherapies and in combination with other products.

Subject to termination rights for material breach, bankruptcy or by Compugen for patent challenge by AstraZeneca, the term of the license agreement continues until the expiration of the last Royalty Term in the Territory, each as defined in the license agreement. In addition, AstraZeneca may terminate the agreement for convenience upon prior written notice.

Main Academic Collaborations

We also advance our pipeline through academic collaborations with leading researchers and key opinion leaders in the field of immuno-oncology.

Johns Hopkins School of Medicine

The collaboration focuses on the evaluation of novel T cell and myeloid checkpoint targets identified by us for the potential treatment of cancer. The scope of the collaboration includes identifying differentiating features of our novel targets relative to known immuno-oncology targets, and the therapeutic potential of drugs modulating the activity of those novel drugs. Research is conducted under the leadership of Drew Pardoll, M.D., Ph.D., Abeloff Professor of Oncology, Medicine, Pathology, and Molecular Biology and Genetics at Johns Hopkins University, School of Medicine, and Director of the Bloomberg-Kimmel Institute for Cancer Immunotherapy and Co-Director of the Cancer Immunology Program at the Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins, and Chairman of Compugen's Scientific Advisory Board.

Mount Sinai

This collaboration focuses on the research and target validation of selected myeloid candidates discovered by us for their potential to serve as a basis for cancer immunotherapy treatments, including the validation of their role in innate immunity and involvement in tumor biology. Research is conducted under the leadership of Miriam Merad, MD, PhD, Director of the Precision Immunology Institute and Co-Leader of the Cancer Immunology program and Mount Sinai Professor in Cancer Immunology at the Icahn School of Medicine at Mount Sinai in New York, and a member of Compugen's Scientific Advisory Board.

Competition

The biotechnology and pharmaceutical industries are highly competitive and characterized by the rapid evolution of new technologies and the adoption of new therapies. Additionally, the oncology therapeutic space, and in particular the immunotherapy subsector, represents the therapeutic area with the highest industry focus and investment. Our competitors include biotechnology and pharmaceutical companies both small and large, the research and discovery groups within pharmaceutical companies, academic and research institutions, newly funded companies and governmental and other publicly funded agencies.

Any product candidates that we successfully develop will compete with currently approved therapies and new therapies that may become available in the future. We face, and expect to continue to face, ongoing competition from entities that discover novel targets and develop novel products, and that have therapeutic product candidates or products that act by similar, or possibly identical, mechanism of action (MOA) as well as by different mechanisms, but address the same clinical unmet need. Our potential competitors are also comprised of companies that discover and develop monoclonal antibody therapies and/or therapeutic proteins to novel targets for oncology diseases. Specifically, in the field of immune checkpoints and myeloid drug targets for cancer immunotherapy, there are several leading pharmaceutical and biotechnology companies as well as smaller biotechnology companies and academic institutions that are developing cancer immunotherapies to enhance immune response towards tumors, some of which may be based on the same targets we have discovered. If approved, such cancer immunotherapy products would compete with our product candidates for commercialization or approved products in the respective fields.

Our discovery program depends, in large part, on our discovery platforms and other capabilities and our proprietary data to make inventions and establish intellectual property rights in protein-based products, including proteins and antibodies. There are a number of other means by which such inventions and intellectual property can be generated. We believe that our computational capabilities, and specifically our discovery platforms, provide us with a competitive advantage in predicting new protein functions and linking proteins to specific diseases, and as a result, predicting new drug targets. We believe that this advantage is made possible by building an infrastructure for predictive discovery based on the integration of scientific understanding and predictive models and the resultant better research capabilities that we have developed, as well as our unique team of multidisciplinary research scientists, who have vast experience in handling such data analysis approaches, and who over time have generated dozens of peer reviewed publications of certain of our findings and capabilities in scientific journals.

Many of our potential competitors, either alone or with their collaborative partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of therapeutics, obtaining FDA and other regulatory approvals, and commercialization of products. Accordingly, our competitors may be more successful than we may be in identifying product candidates, protecting them with patent applications, developing them, accelerating their development process, obtaining FDA and other regulatory approvals and achieving widespread market acceptance. We anticipate that we will face intense and increasing competition as advanced technologies become available.

Intellectual Property Rights

Our intellectual property assets are our principal assets. These assets include the intellectual property rights subsisting in our proprietary know-how and trade secrets underlying our predictive biology capabilities and discovery platforms, our patents and patent applications, particularly with respect to Compugen discovered targets, therapeutic and diagnostic product candidates. We seek to vigorously protect our rights and interests in our intellectual property. We expect that our commercial success will depend on, among other things, our ability to obtain commercially valuable patents, especially for our therapeutic and diagnostic product candidates, maintain the confidentiality of our proprietary know-how and trade secrets, and otherwise protect our intellectual property. We design our patent strategy to fit the business competitive landscape and continual legislative changes. In addition, we periodically analyze and examine our patent portfolio to align it with our pipeline strategy and business needs. We seek patent protection for certain promising inventions that relate to our therapeutic and diagnostic product candidates. As of March 1, 2019, we had a total of 45 issued and allowed patents, of which 30 are U.S. patents, five are European patents, four are Israeli patents, three are Australian patents, one is a patent in Canada, one is a Japanese patent and one is a patent in Singapore. The patents issued in the U.S. for COM701 and COM902 were issued in 2017 and 2018, respectively, under the USPTO's pilot program providing early review for patent applications pertaining to cancer immunotherapy in support of the USPTO's Cancer Moonshot Pilot Program providing early examination of patent applications pertaining to cancer immunotherapy. Our issued and allowed patents expire between 2021 and 2037. We also have 84 pending patent applications, which as of March 1, 2019, included 17 patent applications that have been filed in the United States, eight patent applications that have been filed in Europe, five patent applications that have been filed in Israel, five patent applications that have been filed in Australia, six patent applications that have been filed in Canada, four patent applications that have been filed in Japan, three patent applications that have been filed in India, four patent applications that have been filed in China, two patent applications that have been filed in Brazil, three patent applications that have been filed in Korea, three patent applications that have been filed in New Zealand, two patent applications that have been filed in the Russian Federation, two patent applications that have been filed in Singapore, three patent applications that have been filed in Mexico, three patent applications that have been filed in South Africa, three patent applications that have been filed in Hong Kong, one patent application that has been filed in Egypt, one patent application that has been filed in Argentina, one patent application that has been filed in Brunei, one patent application that has been filed in Chile, one patent application that has been filed in Colombia, one patent application that has been filed in Eurasia, one patent application that has been filed in Indonesia, one patent application that has been filed in Malaysia, one patent application that has been filed in Taiwan and two applications that have been filed under the Patent Cooperation Treaty for which we have not yet designated the countries of filing. Our general policy is to continue patent filings and maintenance for our therapeutic and diagnostic product candidates, only with respect to candidates or programs that are being actively pursued internally or with partners, or that we believe to have future commercial value. We routinely abandon patent applications and may choose to abandon maintenance of patents supporting candidates or programs that do not meet these criteria.

We also seek protection for our proprietary know-how and trade secrets that are not protectable or protected by patents, by way of safeguarding them against unauthorized disclosure. This is done through the extensive use of confidentiality agreements and assignment agreements with our employees, consultants and third parties as well as by technological means. We use license agreements both to access third-party technologies and to grant licenses to third parties to exploit our intellectual property rights.

Manufacturing

We currently rely on contract manufacturers or our collaborative partners to produce materials and drug substances for drug products required for our research and development activities. We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of our therapeutic drug candidates. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in human clinical trials. We expect to rely on CMOs and third-party contractors to generate formulations and produce larger scale amounts of cGMP drug substance and the drug product required for our clinical trials for the foreseeable future. We also plan to contract with CMOs and third-party contractors for the labeling, packaging, storage and distribution of investigational drug products.

In 2016 and 2017, we entered into agreements for the manufacturing and respective analytics of COM701 and COM902, respectively. Our manufacturing strategy is currently structured to support the advancement of our therapeutic drug development into the clinic. Although we believe the general manufacturing strategy developed for the United States will be applicable in other geographies, specific strategies for other geographies will be developed as part of our clinical and commercial plans for such other geographies. See “Item 3. Key Information – D. Risk Factors – Risks Related to Our Dependence on Third Parties - We anticipate that we will rely completely on third parties to manufacture certain preclinical and all clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels or prices.”

Government Regulation

Regulation of Therapeutic Product Candidates

In the United States, the FDA regulates pharmaceutical and biologic products under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, other statutes and regulations and implementing regulations. We anticipate that our product candidates will be regulated as biologics. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies in compliance with the FDA’s GLP or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCPs, to establish the safety and efficacy of the product for its intended use;
- submission to the FDA of a biologics license application, or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug or biologic is produced to assess compliance with current Good Manufacturing Practice, or cGMP, to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity; and
- FDA review and approval of the BLA.

Once a pharmaceutical candidate is identified for development it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, among other information, to the FDA as part of the IND. The sponsor will also include a clinical protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase lends itself to an efficacy evaluation. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during a clinical trial due to, among other things, safety concerns or non-compliance with applicable requirements.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. An IRB at each institution participating in the clinical trial must review and approve the study plan for any clinical trial before it commences at that institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also reviews the information regarding the trial, participant recruiting materials and the informed consent form that must be provided to each trial subject or his or her legal representative before participating in the trial. In addition, the IRB will monitor the trial until completed.

Each new clinical protocol must be submitted to the FDA, and to the IRBs. Protocols detail, among other things, the objectives of the study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and determine efficacy.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1:* The product candidate is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products, usually for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.
- *Phase 2:* Involves studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- *Phase 3:* Involves studies undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product labeling and approval.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports for serious and unexpected adverse events must be submitted to the FDA and the investigators more frequently. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the applicable regulations or IRB requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product within required specifications and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests, proposed labeling, and other relevant information are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The FDA initially reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept a BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA may refer the BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee.

The review process is lengthy, and the FDA may issue a complete response letter rather than approve a BLA if the applicable regulatory criteria are not satisfied or may require the submission of additional clinical or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval will be limited to specific diseases and dosages or the approved indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a company to conduct post-approval testing and clinical trials, to further assess a product's safety and effectiveness after BLA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized including Risk Evaluation and Mitigation Strategy (REMS) programs to ensure that the benefits of a product outweigh its risks.

Post-approval Requirements

Approved biologics are subject to extensive and continuing regulation by the FDA, including, among other things, cGMP compliance, record-keeping requirements, reporting of adverse experiences, providing the FDA with updated safety and efficacy information, and complying with FDA promotion and advertising requirements. After an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if serious problems occur after the product reaches the market. Biologics may be promoted for use only for the approved indication or indications and in accordance with the provisions of the approved label. The FDA and other federal and state agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to criminal and civil penalties.

Other Healthcare Laws

Our current and future business operations, including, among other things, our clinical research activities and our business and financial arrangements and relationships with healthcare providers, physicians and other parties through which we may market, sell and distribute our products, once approved, may be subject to extensive U.S. federal, U.S. state and foreign healthcare fraud and abuse, transparency, and data privacy and security laws. For example, U.S. federal civil and criminal laws and regulations prohibit, among other things: knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs; knowingly presenting or causing to be presented, a false or fraudulent claim for payment by a federal healthcare program; and knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program (including a private payor), or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Many U.S. states and foreign countries have analogous prohibitions that may be broader in scope and apply regardless of payor. In addition, we may be subject to U.S. federal, U.S. state and foreign laws that require us to report information related to certain payments and other transfers of value to certain health care professionals, as well as ownership and investment interests in our company held by those health care professionals and their immediate family members, and data security and privacy laws that restrict our practices with respect to the use and storage of certain data.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. If we are found to be in violation of any of these laws, we could be subject to significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, additional integrity oversight and reporting obligations, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Healthcare Policy and Reform

Our ability to commercialize our future therapeutic product candidates successfully, alone or with collaborators, will depend in part on the extent to which coverage and reimbursement for these product candidates will be available from government health programs, such as Medicare and Medicaid in the United States, private health insurers and other third-party payors. At present, significant changes in healthcare policy, in particular the continuing efforts of the U.S. and other governments, insurance companies, managed care organizations and other payors to contain or reduce health care costs are being discussed, considered and proposed. Drug prices in particular are under significant scrutiny and continue to be subject to intense political and societal pressures, which we anticipate will continue and escalate on a global basis.

For example, in the United States, there have been several initiatives implemented to achieve these aims. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “ACA”), represents the biggest regulatory overhaul to the health care system in decades and substantially changes the way health care is financed by both governmental and private insurers. However, the ACA has faced legislative, judicial, executive and political challenges from Congress, the Trump administration, state governments, consumer groups and business organizations. For example, since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, ACA-related provisions have been enacted as part of tax reform or federal budget legislation that, among other things, affect the implementation of certain taxes under the ACA and increase discounts owed by certain drug manufacturers under Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017, or Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Further, other legislative changes have been proposed and adopted since the PPACA was enacted that have, among other things, reduced reimbursement to several healthcare providers and increased the statute of limitations period for the government to recover overpayments to providers.

In addition, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products that has led to several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. For example, at the federal level, the Trump administration released a “Blueprint”, or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Non-U.S. Regulations

In addition to regulations in the United States, biologics are subject to a variety of foreign laws and regulations governing clinical trials and commercial sales and distribution before they may be sold outside the United States. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals from comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. In some countries, we will also have to get pricing approval.

Environmental Regulation

Some of our research and development activities involve the controlled use of biologic and chemical materials, a small amount of which could be considered to be hazardous. We are subject to laws and regulations in the U.S. and Israel governing the use, storage, handling and disposal of all these materials and resulting waste products. We store relatively small amounts of biologic and chemical materials. To our knowledge, we substantially comply with these laws and regulations. However, the risk of accidental contamination or injury from these materials cannot be entirely eliminated. In the event of an accident, we could be held liable for any resulting damages, and any liability could exceed our resources.

Regulation of Use of Human Tissue

We need to access and use various human or non-human tissue samples for the purpose of development and or validation of some of our product candidates. Our access and use of these samples is subject to government regulation, in the United States, Israel and elsewhere and may become subject to further regulation. The use of clinical data associated with human tissue samples is also heavily regulated in the United States, Israel and elsewhere. United States and other governmental agencies may also impose restrictions on the use of data derived from human or other tissue samples.

Regulations Concerning the Use of Animals in Research

We also are subject to various laws and regulations regarding laboratory practices and the use of animals in our research. In the United States, the FDA regulations describe good laboratory practices, or GLPs, for various types of nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA, including INDs. Nonclinical animal studies conducted by us or third parties on our behalf may be subject to the U.S. Animal Welfare Act, the U.S. Public Health Service Policy on Humane Animal Care and Use, U.S. Department of Agriculture regulations for certain animal species. In Israel, the Council on Animal Experimentation has regulatory and enforcement powers, including the ability to suspend, change or withdraw approvals, among other powers. To our knowledge, the Company and the third-party service providers we work with, as applicable, substantially comply with these regulatory requirements.

Regulation of Products Developed with the Support of Research and Development Grants

For a discussion of regulations governing products developed with research and development grants from the Government of Israel, see “Item 5. Operating and Financial Review and Prospects—C. - Research and Development, Patents and Licenses – The Israel Innovation Authority.”

C. ORGANIZATIONAL STRUCTURE

We were incorporated under the laws of the State of Israel on February 10, 1993 as Compugen Ltd., which is both our legal and commercial name. Compugen USA, Inc., a wholly owned subsidiary, was incorporated in Delaware in March 1997 and is qualified to do business in California.

D. PROPERTY, PLANTS AND EQUIPMENT

In December 2015, we moved to new facilities in Holon, Israel where we lease an aggregate of approximately 34,440 square feet of office and biology laboratory facilities under a lease that expires on March 15, 2021, with an option to extend the lease for two consecutive additional five-year periods. In addition, Compugen USA, Inc. currently leases 12,560 square feet of office and biology laboratory facilities in South San Francisco, California, under a lease that expires on May 31, 2021 and an additional 1,345 square feet of office space in a second location in South San Francisco, California under a lease that expires on August 31, 2020.

To our knowledge, there are no environmental issues that affect our use of the properties that we lease.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS FINANCE

The following discussion of our critical accounting policies and our financial condition and operating results should be read in conjunction with our consolidated financial statements and related notes, prepared in accordance with U.S. GAAP as of December 31, 2018, and with any other selected financial data included elsewhere in this annual report.

Background

We are a clinical-stage, therapeutic discovery and development company utilizing our proprietary computational discovery platforms to identify novel drug targets and develop first-in-class therapeutics in the field of cancer immunotherapy. Our therapeutic pipeline consists of immuno-oncology programs against novel drug targets we have discovered computationally, including T cell immune checkpoints and other early-stage immuno-oncology programs focused largely on myeloid target. Our pipeline consists of two clinical stage programs. COM701 is a first-in-class therapeutic antibody targeting PVRIG, developed internally; and BAY 1905254 is a first-in-class therapeutic antibody targeting ILDR2, partnered to Bayer. Both targets are novel immune checkpoints discovered computationally by us and currently in Phase 1 studies in patients with advanced solid tumors. Our business model is to enter into collaborations for our novel targets and related drug product candidates at various stages of research and development. Compugen is headquartered in Holon, Israel and our clinical development and business development activities operate from our U.S. site in South San Francisco, California.

A. OPERATING RESULTS

Overview

Since our inception, we have incurred significant losses and, as of December 31, 2018, we had an accumulated deficit of \$330.8 million. We expect to continue to incur net losses for the foreseeable future.

While our computational discovery infrastructure has potentially broad applicability and is not limited to a certain indication or therapeutic field, we decided to focus our computational discovery efforts on identifying novel drug targets and developing first-in-class therapeutics in the field of cancer immunotherapy. Compugen's initial discovery efforts in this field were directed at identifying novel immune checkpoints that activate T cells in cancer patients. Once activated T cells are capable of destroying tumor cells, and therefore may be used for cancer immunotherapy treatment. Over the past two years our discovery efforts were focused on myeloid targets, addressing a range of mechanisms of action. More recently, we have expanded our discovery capabilities to investigate mechanisms of immune resistance to currently available immunotherapies. In 2013 we entered into our first collaboration based on novel targets identified by Compugen. (the "Bayer Collaboration"). Under this collaboration we collaborated with Bayer on the development BAY 1905254. Over the years, we have significantly increased our research activities in the field of immuno-oncology to identify novel drug targets and develop first-in-class therapeutics in the field of cancer immunotherapy. In 2018, we entered into two agreements with leading pharmaceutical companies – a clinical collaboration agreement with Bristol-Myers Squibb in connection with our lead immuno-oncology program, COM701, and an exclusive license agreement with AstraZeneca for the development of bi-specific and multi-specific antibody products derived from one of Compugen's immuno-oncology programs. Compugen also engages in collaborations with leading academic research centers in the United States to advance its research and development efforts. We have built our target validation and drug discovery infrastructure and capabilities required to scientifically validate our new drug targets and to later translate them into therapeutic antibody development programs, however our computational target discovery platform will require substantial technical, financial and human resources We added personnel, equipment, new experimental systems and technologies to increase expertise and workload throughput.

We incurred net losses of approximately \$31.5 million in 2016, approximately \$37.1 million in 2017 and approximately \$22.6 million in 2018. We expect to continue to incur net losses for the foreseeable future due in part to the costs and expenses associated with our research, development and discovery activities. Our business model primarily involves establishing collaborations for our novel targets and related therapeutic product candidates at various stages of research and development providing us with potential milestone payments and royalties on product sales or other forms of revenue sharing payments.

Our research and development expenses are expected to continue to be our major operating expense in 2019, accounting for more than 70% of our expected total 2019 operating expenses. Our research and development expenditures have always comprised a significant portion of our total cash expenditures, although they are budgeted to decrease by approximately 20% in 2019 compared to 2018 due to the restructuring, see “Item 3. Key Information – D. Risk Factors – Risks Related to our Business, Financial Results and Financing Needs – Our corporate restructuring may not be successful” and Note 14 to our 2018 consolidated financial statements.

We believe that we have sufficient working capital in order to sustain our operations through mid-2020. For a detailed description of our cash and cash equivalents position, see “Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources.”

Critical Accounting Policies

The preparation of our consolidated financial statements and other financial information appearing in this annual report requires our management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. We evaluate on an on-going basis these estimates, mainly related to share based payments, deferred participation in research and development expenses, revenue recognition and commitments and contingencies.

We base our estimates on our experience and on various assumptions that we believe are reasonable under the circumstances. The results of our estimates form the basis for our management’s judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Share Based Payments

We account for stock-based compensation in accordance with ASC 718, “Compensation – Stock Compensation” (“ASC 718”), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The Company accounts for forfeitures as they occur. The value of the pro-rata portion of the award, assuming no forfeiture, is recognized in the Company’s consolidated statement of comprehensive loss as an expense over the requisite service periods. Upon forfeiture the expense is adjusted so that expense is recognized for the portion of the award that actually vested.

We selected the Black-Scholes-Merthon model, which is the most common model in use in evaluating stock options. This model evaluates the options as if there is a single exercise point, and thus considers expected option life (expected term). The input factored in this model is constant for the entire expected life of the option.

We recognize compensation expenses for the value of awards which have graded vesting based on the straight-line method over the requisite service period of each of the awards.

The computation of expected volatility is based on historical volatility of our stock. The risk-free interest rate assumption is the implied yield currently available on United States treasury zero-coupon issues with a remaining term equal to the expected life term of the options. We determined the expected life of the options based on historical experience, representing the period of time that options granted are expected to be outstanding.

We apply ASC 505-50, “Equity-Based Payments to Non-Employees” (“ASC 505-50”) with respect to options and warrants issued to non-employees. ASC 505-50 requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

Share-based compensation expense recognized under ASC 718 and ASC 505-50 was approximately \$3.1 million, \$2.6 million and \$2.2 million for the years ended December 31, 2016, 2017 and 2018, respectively.

Revenue recognition

Our revenues were generated mainly from collaborative and license agreements. The revenues are derived mainly from the upfront license payment, research and development services and contingent payments related to milestone achievements.

The Company has adopted the new revenue standard, Topic 606 – “Revenue from Contracts with Customers”, as of January 1, 2018, using a modified retrospective adoption transition to each prior reporting period presented. The adoption did not have an effect over the Consolidated Financial Statements on the adoption date and no adjustment to prior year consolidated financial statements was required.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 606. In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract - At contract inception, the Company assesses the goods or services promised in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.
- Determination of the transaction price - The Company considers the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.
- Allocation of the transaction price to the performance obligations in the contract - If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations based on the relative standalone selling prices. The relative selling price for each deliverable is estimated using objective evidence if it is available. If objective evidence is not available, the Company uses its best estimate of the selling price for the deliverable.
- Recognition of revenue when, or as, the Company satisfies a performance obligation - Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset, which for a service is considered to be as the services are received and used.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the transaction price is allocated to the performance obligations on the same basis as at contract inception.

The Company entered into an exclusive license agreement with AstraZeneca. Under the terms of the agreement, Compugen provided AstraZeneca with an exclusive license to intellectual property (“IP”) rights of the Company for the development of bi-specific and multi-specific antibody products derived from a Compugen pipeline program. Compugen received a \$10 million upfront nonrefundable payment and is eligible to receive up to \$200 million in development, regulatory and commercial milestones for the first product as well as tiered royalties on future product sales.

Under ASC 606, the Company determined the license to the IP to be a functional IP that has significant standalone functionality. The Company is not required to continue to support, develop or maintain the intellectual property transferred and will not undertake any activities to change the standalone functionality of the IP. Therefore, the license to the IP is a distinct performance obligation and as such revenue is recognized at the point in time that control of the license is transferred to the customer.

Future milestone payments are considered variable consideration and are subject to the variable consideration constraint (i.e. will be recognized once concluded that it is “probable” that a significant reversal of the cumulative revenues recognized under the contract will not occur in future periods when the uncertainty related to the variable consideration is resolved). Therefore, as the milestone payments are not probable, revenue was not recognized in respect to such milestone payments.

Sales or usage-based royalties to be received in exchange for licenses of IP are recognized at the later of when (1) the subsequent sale or usage occurs or (2) the performance obligation to which some or all of the sales or usage-based royalty has been allocated is satisfied (in whole or in part). As royalties are payable based on future Commercial Sales, as defined in the agreement, which did not occur as of the financial statements date, the Company did not recognize any revenues from royalties.

On April 17, 2016 the Company achieved the first substantive milestone with respect to the second licensed program, under the Bayer Collaboration according to which the Company recognized revenues in total amount of \$400 thousand in accordance with the criteria prescribed under ASC 605-28.

On September 20, 2018 the Company achieved the fourth substantive milestone with respect to the remaining licensed program, under the Bayer Collaboration according to which the Company recognized revenues in total amount of \$7.8 million in accordance with the criteria prescribed under ASC 606. See Note 2 to our 2018 consolidated financial statements.

Recent Accounting Pronouncements

See Note 2u to our 2018 consolidated financial statements.

Selected Financial Data

The following discussion and analysis is based on and should be read in conjunction with our audited consolidated financial statements, including the related notes, contained in “Item 18 – Financial Statements” and the other financial information appearing elsewhere in this annual report.

	Year ended December 31,		
	2016	2017	2018
	(US\$ in thousands, except share and per share data)		
Consolidated Statements of Operations Data			
Revenues	\$ 712	\$ -	\$ 17,800
Cost of revenues	223	-	1,034
Gross profit	489	-	16,766
Research and development expenses, net	24,549	28,583	30,318
Marketing and business development expenses	1,174	1,189	1,634
General and administrative expenses	7,349	7,633	8,041
Total operating expenses ^(*)	33,072	37,405	39,993
Operating loss	(32,583)	(37,405)	(23,227)
Financial and other income, net	1,097	339	628
Loss before taxes on income	(31,486)	(37,066)	(22,599)
Taxes on income	(20)	-	-
Net loss	\$ (31,506)	\$ (37,066)	\$ (22,599)
Realized gain arising during the period from marketable securities	(440)	-	-
Unrealized gain arising during the period from foreign currency derivative contracts	7	17	-
Realized loss (gain) arising during the period from foreign currency derivative contracts	19	(7)	(17)
Total comprehensive loss	\$ (31,920)	\$ (37,056)	\$ (22,616)
Basic net loss per share	(0.62)	(0.72)	(0.41)
Weighted average number of shares used in computing basic net loss per share	50,855,908	51,179,694	55,277,428
Diluted net loss per share	(0.62)	(0.72)	(0.41)
Weighted average number of shares used in computing diluted net loss per share	50,855,908	51,179,694	55,277,428

^(*) Includes stock based compensation – see Note 7 to our 2018 consolidated financial statements.

	As of December 31,		
	2016	2017	2018
	(US\$ in thousands)		
Consolidated Balance Sheet Data			
Cash and cash equivalents, short-term bank deposits and restricted cash	\$ 61,527	\$ 30,438	\$ 45,675
Total assets	71,139	38,746	53,180
Accumulated deficit	(270,965)	(308,242)	(330,841)
Total shareholders' equity	63,519	29,297	37,243

Years Ended December 31, 2018 and 2017

Revenues. Revenues for the year ended December 31, 2018 were \$17.8 million, compared with \$0 in the comparable period of 2017. The revenues for 2018 reflect the upfront payment of \$10 million from the license agreement with AstraZeneca and the \$7.8 million milestone payment from Bayer in connection with the dosing of the first patient in the Phase 1 study of BAY 1905254.

Cost of Revenues. Cost of Revenues for the year ended December 31, 2018 represents various milestones and royalty payments in connection with our revenues, including royalties to the IIA.

Research and Development Expenses. Research and development expenses during 2018 increased by 6% and totaled \$30.3 million compared with \$28.6 million in 2017. The increase was primarily attributed to expenses associated with the initiation of COM701 clinical trials during 2018, including CRO's fees, site and patient's enrolment and other regulatory expenses. Research and development expenses, as a percentage of total operating expenses, were 76% in each of 2018 and 2017.

Marketing and Business Development Expenses. Marketing and business development expenses were approximately \$1.6 million in 2018 compared with \$1.2 million in 2017. The increase is attributed mainly to commissions associated with our revenues during 2018. Marketing and business development expenses, as a percentage of total operating expenses, were 4% in 2018 compared to 3% in 2017.

General and Administrative Expenses. General and administrative expenses during 2018 increased by 5% and totaled \$8 million compared with \$7.6 million in 2017. The increase during 2018 was attributed mostly to legal expenses associated with the collaboration agreements with AstraZeneca and Bristol-Myers Squibb. General and administrative expenses, as a percentage of total operating expenses, were 20% in each of 2018 and 2017.

Financial Income (loss), Net. Financial and other income increased to approximately \$0.6 million in 2018 from approximately \$0.3 million in 2017. The increase is attributed mainly increased interest income due to higher level of interest rate and higher level of cash and deposits balances during 2018 compared with 2017

Years Ended December 31, 2017 and 2016

Revenues. During 2017, we did not recognize any revenues compared to approximately \$0.7 million in 2016. Our revenues during 2016 were attributed to milestones achieved in 2016 in the amount of \$0.4 million, as well as the remaining portion of the non-refundable upfront payment in the amount of \$0.3 million relating to the Bayer Collaboration.

Cost of Revenues. During 2017, we did not recognize any revenues and related cost of revenues. Our cost of revenues during 2016 were approximately \$0.2 million attributable to product candidate research and collaboration agreements/the Bayer Collaboration.

Research and Development Expenses. Research and development expenses increased by 16%, to approximately \$28.6 million for 2017, from approximately \$24.5 million for 2016. The increase was primarily due to a substantial increase in preclinical activities involving certain of our pipeline program candidates mainly related to COM701 and COM902. These activities include manufacturing costs, toxicology studies, regulatory consultants to support the preclinical activities and other related expenses. Research and development expenses, as a percentage of total operating expenses, were 76% and 74% in 2017 and 2016, respectively.

Marketing and Business Development Expenses. Marketing and business development expenses were approximately \$1.2 million in each of 2017 and 2016. Marketing and business development expenses, as a percentage of total operating expenses, were 3% in 2017 compared to 4% in 2016.

General and Administrative Expenses. General and administrative expenses increased by 4% to approximately \$7.6 million for 2017, from approximately \$7.3 million for 2016. The increase is attributed mainly to headcount related expenses as well as expenses associated with the engaging of additional advisers to the Company. General and administrative expenses, as a percentage of total operating expenses, were 20% in 2017 and 22% in 2016.

Financial Income (loss), Net. Financial income decreased to approximately \$0.3 million in 2017 from approximately \$1.1 million in 2016. The decrease is attributed mainly to reduction in interest income due to lower levels of cash deposits in 2017 and approximately \$0.4 million of realized gain from the sale of a portion of our holdings of Evogene Ltd. ordinary shares in 2016.

Governmental Policies that Materially Affected or Could Materially Affect Our Operations

Our income tax obligations consist of those of Compugen Ltd. in Israel and of Compugen USA, Inc. in its taxing jurisdictions.

The corporate tax rate in Israel was 23% in 2018 compared with 24% in 2017 and 25% in 2016.

In the future, if and when we generate taxable income, our effective tax rate may be influenced by, among others: (a) the split of taxable income between the various tax jurisdictions; (b) the availability of tax loss carry forwards and the extent to which valuation allowance has been recorded against deferred tax assets; (c) the portion of our income which is entitled to tax benefits pursuant to the Investment Law; (d) the changes in the exchange rate of the U.S. dollar to the NIS and (e) the Company's election to submit its tax returns for 2014 and onwards on a dollar basis, which may not be accepted by the Israeli Tax Authority. We may benefit from certain government programs and tax legislation, particularly as a result of the Approved Enterprise status granted to some of our operations by the Investment Center in the Israeli Ministry of Economy and the Benefiting Enterprise status that resulted from our eligibility for tax benefits under the Investment Law. To be eligible for these benefits, we need to meet certain conditions. Should we fail to meet such conditions, these benefits could be cancelled, and we might be required to refund the amount of the benefits previously received, if any, in whole or in part, together with interest and linkage differences to the Israeli CPI, or other monetary penalty. We also benefit from a Government of Israel program under which we received grants from the IIA. For more information, please see "Item 5 Operating and Financial Review and Prospects – C. Research and Development, Patents and Licenses – The Israel Innovation Authority." There can be no assurance that these programs and tax legislation will continue in the future or that the available benefits will not be reduced.

The termination or curtailment of these programs or the loss or reduction of benefits under the Investment Law could have a material adverse effect on our business, financial condition and results of operations.

Currently we have two Approved Enterprises and two Benefiting Enterprises programs under the Investment Law. The tax benefits period with respect to all of these programs has not yet begun as we have not yet generated any taxable income. These benefits should result in income recognized by us being tax exempt or taxed at a lower rate for a specified period of time after we begin to report taxable income and exhaust any net operating loss carry-forwards. However, these benefits may not be applied to reduce the U.S. federal tax rate for any income that our U.S. subsidiary may generate.

We have elected the alternative benefits route under the Investment Law with respect to our Approved Enterprises. Under this route we waived government grants in return for a tax exemption on undistributed income. Due to the geographic location of our facilities, such tax exemption on undistributed income will apply for a limited period of two years. In the event that such tax exempt income is thereafter distributed as a dividend or a deemed dividend, we will be required to pay the applicable corporate tax that would otherwise have been payable on such income. During the remainder of the benefits period applicable to us, a corporate tax rate not exceeding 25% will apply.

In April 2005, substantive amendments to the Investment Law came into effect. Under these amendments, eligible investment programs of the type in which we participated prior to the amendment were eligible to qualify for substantially similar benefits as a 'Benefiting Enterprise', subject to meeting certain criteria. This replaced the previous terminology of 'Approved Enterprise', which required pre-approval from the Investment Center of the Ministry of the Economy of the State of Israel. As a result of these amendments, tax-exempt income generated from Benefiting Enterprises under the provisions of the amended law will, if distributed upon liquidation or if paid to a shareholder for the purchase of his or her shares, be deemed distributed as a dividend and will subject the Company to the applicable corporate tax that would otherwise have been payable on such income. Therefore, a company may be required to record deferred tax liability with respect to such tax-exempt income, which would have an adverse effect on its results of operations.

Additional amendments to the Investment Law became effective in January 2011 and were further amended in August 2013 (the "2011 Amendment"). Under the 2011 Amendment, income derived by 'Preferred Companies' from 'Preferred Enterprises' (both as defined in the 2011 Amendment) would be subject to a uniform rate of corporate tax for an unlimited period as opposed to the incentives prior to the 2011 Amendment that were limited to income from Approved or Benefiting Enterprises during their benefits period. According to the 2011 Amendment, the uniform tax rate on such income, referred to as 'Preferred Income', would be 10% in areas in Israel that are designated as Development Zone A and 15% elsewhere in Israel during 2011-2012, 7% and 12.5%, respectively, in 2013, and 9% and 16%, respectively, thereafter. Income derived by a Preferred Company from a 'Special Preferred Enterprise' (as defined in the Investment Law) would enjoy further reduced tax rates for a period of ten years of 5% in Development Zone A and 8% elsewhere. As of January 1, 2014, dividends distributed from Preferred Income would subject the recipient to a 20% tax (or lower, if so provided under an applicable tax treaty), which would generally be withheld by the distributing company, provided however that dividends distributed from 'Preferred Income' from one Israeli corporation to another, would not be subject to tax. Under the transitional provisions of the 2011 Amendment, companies may elect to irrevocably implement the 2011 Amendment with respect to their existing Approved and Benefiting Enterprises while waiving benefits provided under the legislation prior to the 2011 Amendment or keep implementing the legislation prior to the 2011 Amendment. Should a company elect to implement the 2011 Amendment with respect to its existing Approved Enterprises and Benefiting Enterprises prior to June 30, 2015 dividends distributed from taxable income derived from Approved or Benefiting Enterprises to another Israeli company would not be subject to tax. We have not elected to implement the 2011 Amendment and we do not currently have any Preferred Enterprises. While a company may incur additional tax liability in the event of distribution of dividends from tax exempt income generated from its Approved and Benefiting Enterprises, as previously described, no additional tax liability will be incurred by a company in the event of distribution of dividends from Preferred Income.

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which includes Amendment 73 to the Law ("Amendment 73") was published. According to Amendment 73, a Preferred Enterprise located in development area A will be subject, under certain conditions, to a tax rate of 7.5% instead of 9% effective from January 1, 2017 and thereafter (the tax rate applicable to preferred enterprises located in other areas remains at 16%). The Amendment also prescribes special tax tracks for Technological Enterprises, which are subject to regulations issued by the Minister of Finance on May 16, 2017.

The new tax tracks under the Amendment are as follows:

Technological Preferred Enterprise - an enterprise for which total consolidated revenues of its parent company and all subsidiaries are less than NIS 10 billion. A Technological Preferred Enterprise, as defined in the Law, which is located in the center of Israel will be subject to tax at a rate of 12% on profits deriving from intellectual property (in development area A - a tax rate of 7.5%).

Special Technological Preferred Enterprise - an enterprise for which total consolidated revenues of its parent company and all subsidiaries exceed NIS 10 billion. Such enterprise will be subject to tax at a rate of 6% on profits deriving from intellectual property, regardless of the enterprise's geographical location.

Any dividends distributed to "foreign companies", as defined in the Law, deriving from income from the Technological Enterprises will be subject, under certain conditions, to tax at a rate of 4%.

As of December 31, 2018, our net operating loss carry-forwards for Israeli tax purposes amounted to approximately \$244.8 million. Under Israeli law, these net operating losses may generally be carried forward indefinitely and offset against certain future taxable income.

As of December 31, 2018, the net operating loss carry-forwards of our U.S. subsidiary for federal income tax purposes amounted to approximately \$6.0 million. These losses are available to offset any future U.S. taxable income of our U.S. subsidiary and will expire between 2021 and 2032.

Use of our U.S. net operating losses may be subject to substantial annual limitation due to the “change in ownership” provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

For a description of Israel government policies that affect our research and development expenses, and the financing of our research and development, see “Item 5. Operating and Financial Review and Prospects – C. Research and Development, Patents and Licenses – The Israel Innovation Authority.”

B. LIQUIDITY AND CAPITAL RESOURCES

Public Offering of Ordinary Shares

Cantor Controlled Equity OfferingSM Sales Agreement

On May 25, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement (the “ATM Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”), as sales agent, pursuant to which we may offer and sell, from time to time through Cantor, Compugen ordinary shares having an aggregate offering price of up to \$25 million (the “Shares”). Any Shares offered and sold under the ATM Sales Agreement will be issued pursuant to the Company’s 2016 Registration Statement, defined below, as supplemented by a prospectus supplement dated May 25, 2018. Under the ATM Sales Agreement, Cantor may sell Shares by any method permitted by law and deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on the Nasdaq Global Market, or on any other existing trading market for the Ordinary Shares. As of December 31, 2018, the Company sold 50,594 shares through the ATM Sales Agreement for an aggregate purchase price of \$0.2 million.

Registered Direct Offering

On June 14, 2018, we entered into a definitive securities purchase agreement with certain institutional investors and a placement agency agreement with JMP Securities LLC, in connection with a registered direct offering which resulted in the issuance of 5,316,457 of our ordinary shares at a purchase price of \$3.95 per share. In connection with the issuance of the ordinary shares, we also issued warrants to purchase up to approximately 4.3 million additional ordinary shares. The warrants have an exercise price of \$4.74 per share and have a term of five years from the date of issuance. Gross proceeds were approximately \$21 million, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The ordinary shares and warrants described above were offered by us pursuant to a shelf registration statement on Form F-3 (File No. 333-213007), which was declared effective on October 11, 2016 (the “2016 Registration Statement”) by the SEC as supplemented by a prospectus supplement dated June 14, 2018.

JMP Securities LLC acted as the exclusive placement agent for the registered direct offering.

2014 Underwritten Public Offering

On March 5, 2014 we closed an underwritten public offering of 6,900,000 ordinary shares, including 900,000 shares sold pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a price to the public of \$10.50 per share (the “2014 Offering”).

Gross proceeds to Compugen from the 2014 Offering were approximately \$72.5 million, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

The 2014 Offering was made pursuant the effective shelf registration statement on Form F-3 (File No. 333-185910), which was filed with the Securities and Exchange Commission (the “Commission”) on January 7, 2013 and declared effective by the Commission on January 16, 2013.

Jefferies LLC acted as the sole bookrunner for the 2014 Offering. JMP Securities LLC, Oppenheimer & Co. Inc. and Chardan Capital Markets acted as co-managers.

Securities Purchase Agreement

Bristol-Myers Squibb Securities Purchase Agreement

On October 10, 2018, the Company and Bristol-Myers Squibb entered into a Securities Purchase Agreement pursuant to which Bristol-Myers Squibb made a \$12 million investment in Compugen comprised of the purchase of 2,424,243 shares of Compugen ordinary shares at \$4.95 per share, which represented a 33% premium over the average closing price on the last 20 Nasdaq trading days. The investment closed on October 12, 2018.

License Agreement

MedImmune License Agreement

On March 30, 2018, the Company and AstraZeneca, entered into an exclusive license agreement to enable the development of bi-specific and multi-specific immuno-oncology antibody products for one of the Company's pipeline programs pursuant to which the Company received an upfront payment of \$10 million and is eligible to receive up to \$200 million in development, regulatory and commercial milestones for the first product as well as tiered royalties on future product sales.

Cash resources

In 2018, our primary sources of cash were:

proceeds from the 2014 Offering;

upfront payment from the MedImmune License;

proceeds from the 2018 Registered Direct;

proceeds from the Bristol-Myers Squibb investment; and

preclinical and clinical milestone payments under the Bayer Collaboration.

We used these funds primarily to finance our business operations.

We expect that our sources of cash for 2019 will include cash held in our bank accounts, and may include proceeds generated from the commercialization of our novel targets and therapeutic drug candidates and proceeds from issuance of ordinary shares as a result of the exercise of stock options or from financing transactions.

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately \$19.8 million in 2016, approximately \$30.7 million in 2017 and approximately \$13.3 million in 2018. Decrease in net cash used in 2018 reflects the proceeds related to the MedImmune upfront fee, Bayer clinical milestone and Bristol-Myers Squibb deferred participation in R&D expenses, offset by higher levels of research and development expenses associated with the initiation of COM701 clinical trials during 2018, including CRO's fees, site and patient's enrolment and other regulatory expenses.

Net Cash Provided by (used in) Investing Activities

Net cash provided by investing activities was approximately \$16.2 million in 2016 and approximately \$46.3 million in 2017, compared with net cash used in investing activities of approximately \$35.2 million in 2018. Changes in net cash during 2018 as compared to 2017 was attributed to substantial net investments in short-term bank deposits in 2018 compared with substantial net proceeds from short-term bank deposits in 2017.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was approximately \$2.5 million in 2016, approximately \$0.2 million in 2017 and approximately \$28.4 million in 2018. The principal source of cash provided by financing activities were proceeds received from the registered direct offering and from the Bristol-Myers Squibb Securities Purchase Agreement.

Net Liquidity

Liquidity refers to the liquid financial assets available to fund our business operations and pay for near-term obligations. These liquid financial assets mostly consist of cash and cash equivalents as well as short-term bank deposits. As of December 31, 2018, we had total cash and cash equivalents and short-term bank deposits of approximately \$45.1 million. We believe that our existing cash and cash equivalents, and short-term bank deposits will be sufficient to fund our operations through mid-2020.

We had cash and cash equivalents and short term bank deposits of \$45.1 million at December 31, 2018 compared to \$29.4 million at December 31, 2017.

On August 9, 2016, we filed a shelf registration statement on Form F-3 with the SEC under which we may offer and sell from time to time in one or more offerings, our ordinary shares, debt securities, rights, warrants and units having an aggregate offering price of up to \$200 million. This registration statement was declared effective by the SEC on October 11, 2016. We sold 5,316,457 ordinary shares and issued warrants to purchase up to approximately 4.3 million additional ordinary shares for gross proceeds of approximately \$21 million under this registration statement in the Registered Direct Offering and sold an additional 50,594 shares for gross proceeds of approximately \$0.2 million under this registration statement in the ATM Sales Agreement. We may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES

We invest heavily in research and development. Research and development expenses were our major operating expenses representing more than 74% of total operating expenses for each of 2018, 2017 and 2016. Our research and development expenses, net, were approximately \$30.3 million in 2018 compared to approximately \$28.6 million in 2017 and approximately \$24.5 million in 2016. As of December 31, 2018, 66 of our employees were engaged in research and development on a full-time basis. This represents approximately 74% of our entire work force.

We focus our efforts on the development of our discovery platforms and related technologies, and the discovery and validation of our drug targets and the development of our mAb drug candidates. During 2010 we initiated our pipeline program in which we continuously evaluate our predicted drug target candidates and are advancing certain drug target programs into preclinical and possible clinical development of therapeutic product candidates. We expect that in 2019 our research and development expenses will continue to be our major operating expense, representing more than 70% of our total operating expenses.

We believe that our future success will depend, in large part, on our ability to discover promising drug target candidates and therapeutic product candidates and to successfully advance the research and development of certain of our product candidates under our internal pipeline towards preclinical and clinical studies and to successfully license such product candidates to pharmaceutical companies. In addition, we expect to continue to expand our inventory of proprietary algorithms, predictive models and discovery infrastructure and platforms which provide opportunities for the discovery of promising therapeutic candidates for inclusion in our pipeline and pursuant to research and discoveries collaborations.

Research and Development Grants

We have participated in programs offered by the IIA that support research and development activities, and under the Israel-U.S. Binational Industrial Research and Development Foundation ("BIRD Foundation"). See note 2 to our 2018 consolidated financial statement. We did not apply for additional grants from the IIA for research and technological development in 2018.

The Israel Innovation Authority

The government of Israel encourages research and development projects in Israel through the Israel Innovation Authority (formerly known as the Office of the Chief Scientist), pursuant to and subject to the provisions of the R&D Law. We received grants from the IIA for several projects, and may receive additional grants in the future. Under the terms of the grants received, we will be required to pay royalties ranging between 3% to 5% of the revenues we generate from our products which incorporate know how developed with funds received from the IIA ("IIA Products") until 100% of the dollar value of the grant is repaid (plus LIBOR interest applicable to grants received on or after January 1, 1999). As of December 31, 2018, we received grants from the IIA in the amount of \$7.3 million. Therefore, our contingent obligation for royalties, net of royalties already paid in the sum of \$1.3 million, along with the accumulated LIBOR interest to date of approximately \$3.1 million, totaled to approximately \$9.1 million.

The R&D Law requires that the manufacture of IIA Products will be carried out in Israel, unless the IIA provides its approval to the contrary. This approval may be subject to various conditions, including the repayment of increased royalties equal to up to 300% of the total grant amount plus applicable interest and an increase of 1% in the royalty rate. The specific increase within this ceiling would depend on the extent of the manufacturing to be conducted outside of Israel. Transfer of the know-how developed with funds received from the IIA and any right derived therefrom to third parties is prohibited, unless such transfer was approved in accordance with the R&D Law. The Research Committee operating under the IIA may approve the transfer of know how between Israeli entities, provided that the transferee undertakes all the obligations in connection with the grant as prescribed under the R&D Law. The transfer of know how outside of Israel may be approved by the Research Committee operating under the IIA, at its discretion, in special cases, subject to the receipt of certain payments calculated according to a formula set forth in the R&D Law and regulations promulgated thereunder up to an amount equal to six (6) times the total amount of IIA grants plus applicable interest; and three (3) times such total amount, should the R&D activity related to the know how remain in Israel.

These restrictions may impair our ability to sell or partner our technological assets or to outsource or transfer developments or manufacturing activities with respect to any technology. These restrictions continue to apply even after full repayment of the IIA grants. However, we believe that these restrictions do not apply to licensing of product candidates that we discover by using our knowhow developed with funds received from the IIA.

D. TREND INFORMATION

Trend towards biologics

Biologics and monoclonal antibodies represent one of the fastest growing segments in the drug industry, making up a quarter of recently approved drugs (28% in 2018). The growth of this class has driven a large number of companies to invest in new technologies (e.g., bi-specific monoclonal antibodies, multi-specific antibodies, antibody fragments) and new approaches to fully exploit the potential of this class. In addition, the striking efficacy and recent approval of cell therapies for the treatment of cancer, such as CAR-T therapies, has also captured much attention in the pharma industry. Despite the increasing number of companies active in these areas, the majority of these technologies are directed towards a limited set of targets, which may increase the differentiation and attractiveness of our novel therapeutic candidates.

Trend towards consolidation

There is a trend towards consolidation in the pharmaceutical, diagnostic and biotechnology industries, which may negatively affect our ability to enter into agreements and may cause us to lose existing licensees or collaborators as a result of such consolidation. This trend often involves larger companies acquiring smaller companies, and this may result in the larger companies having greater financial resources and technological capabilities. This trend towards consolidation in the pharmaceutical, diagnostic and biotechnology industries may also result in there being fewer potential companies to license our products and services.

Trend towards reduction of in-house research and development programs within major pharmaceutical companies

Over the last few years, a number of major pharmaceutical companies have announced cutbacks in their in-house research and development programs. The effects of these cutbacks on our business opportunities could be positive or negative and are likely to vary on a company by company basis.

Trend towards reliance by major pharmaceutical companies on smaller company's product candidates to support their pipelines

There appears to be a trend towards larger companies relying on smaller companies' product candidates to fill their pipelines.

However, if this is not correct we may be required to invest a substantial amount of money and other resources to advance each of our future product candidates to later stages prior to licensing, without assurance that any such product candidates will be commercialized, and limiting the number of product candidates that we are able to so advance, while reducing resources available for our discovery activities, due to resource constraints.

If, consistent with our strategy for commercialization of our therapeutic product candidates, we are successful in commercializing our drug target candidates and/or our future product candidates at an early stage, our licensees may propose terms that we may not consider commercially desirable and the consideration that we may receive for each individual product may be relatively low. The consideration that we would expect to receive for commercializing our product candidates increases commensurately with the number of such products commercialized and the stage of development that we attain for them. Furthermore, considerations regarding our willingness to advance the product candidate at our risk would likely be of much less importance in research and discovery collaborations.

E. OFF-BALANCE SHEET ARRANGEMENTS

We entered into forward contracts to hedge against the risk of overall changes in future cash flow from payments of salaries and related expenses as well as other expenses denominated in NIS. As of December 31, 2018, we did not have any outstanding forward contracts.

F. TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

The table below summarizes our contractual obligations as of December 31, 2018, and should be read together with the accompanying comments that follow.

	Payments due by period (US\$ in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating Lease Obligations ⁽¹⁾	\$ 6,358	\$ 1,489	\$ 2,312	\$ 1,215	\$ 1,342
Accrued Severance Pay, net ⁽²⁾	491	-	-	-	491
Total	\$ 6,849	\$ 1,489	\$ 2,312	\$ 1,215	\$ 1,833

⁽¹⁾ Consists of operating leases for our facilities and for motor vehicles. Excluding an option to extend the lease of the Israeli facility for two consecutive additional five-year periods, following expiration of the current lease period.

⁽²⁾ Severance pay obligations to our Israeli employees, for more information please see “Item 6. Directors, Senior Management and Employees – D. Employees.”

The above table does not include royalties that we may be required to pay to the IIA. For more information, see “Item 5. Operating and Financial Review and Prospects – C. Research and Development, Patents and Licenses.”

The above table also does not include contingent contractual obligations or commitments that may crystallize in the future, such as contractual undertakings to pay royalties subject to certain conditions occurring.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**A. DIRECTORS AND SENIOR MANAGEMENT**

The following table sets forth information with respect to Compugen's directors and senior management as of March 1, 2019:

Name	Age	Positions
Paul Sekhri ⁽³⁾	60	Chairman of the Board of Directors (Chairman of the Nomination and Corporate Governance Committee)
Anat Cohen-Dayag, Ph.D.	52	President and Chief Executive Officer, Director
Prof. Yair Aharonowitz ⁽²⁾	78	Director
Jean-Pierre Bizzari, M.D.	64	Director
Gilead Halevy ⁽²⁾	52	Director
Kinneret Livnat Savitzky, Ph.D. ⁽¹⁾⁽³⁾	51	Director
Arie Ovadia, Ph.D. ⁽¹⁾⁽²⁾	69	Director (Chairman of the Audit Committee)
Sanford (Sandy) Zweifach ⁽¹⁾⁽²⁾⁽³⁾	63	Director (Chairman of the Compensation Committee)
Ari Krashin	46	Chief Financial and Operating Officer
Kirk Christoffersen	51	Senior Vice President – Corporate and Business Development
Henry Adewoye, MD	54	Chief Medical Officer
John Hunter, Ph.D.	56	Chief Scientific Officer
Zurit Levine, Ph.D.	51	Senior Vice President, Technology Innovation
Riki Schwartz, Ph.D.	49	Vice President Research and Discovery

(1) Member of our Compensation Committee

(2) Member of our Audit Committee

(3) Member of our Nomination and Corporate Governance Committee

Paul Sekhri joined Compugen's Board of Directors as its Chairman in October 2017. Paul Sekhri was appointed the President and CEO of eGenesis, Inc. in January 2019. Lycera Corp. in February 2015. Prior to joining eGenesis, Inc, Mr. Sekhri served as Preseident and CEO of Lycera Corp. from February 2015 through December 2018. From April 2014 through January 2015, Mr. Sekhri served as Senior Vice President, Integrated Care for Sanofi. From May 2013 through March 2014, Mr. Sekhri served as Group Executive Vice President, Global Business Development and Chief Strategy Officer for Teva Pharmaceutical Industries, Ltd. Prior to joining Teva, Mr. Sekhri spent five years as Operating Partner and Head of the Biotechnology Operating Group at TPG Biotech, the life sciences venture capital arm of TPG Capital. From 2004 to 2009, Mr. Sekhri was Founder, President, and Chief Executive Officer of Cerimon Pharmaceuticals, Inc. Prior to founding Cerimon, Mr. Sekhri was President and Chief Business Officer of ARIAD Pharmaceuticals, Inc. Previously, Mr. Sekhri spent four years at Novartis, as Senior Vice President, and Head of Global Search and Evaluation, Business Development and Licensing for Novartis Pharma AG. Mr. Sekhri also developed the Disease Area Strategy for Novartis, identifying those specific therapeutic areas upon which the company would focus. Mr. Sekhri's first role at Novartis was as Global Head, Early Commercial Development. Mr. Sekhri completed graduate work in Neuroscience at the University of Maryland School of Medicine, where he also received his BS in Zoology. Mr. Sekhri is currently a member of the Board of Directors of Veeva Systems Inc., Ipsen S.A., Chairman of the Board of Supervisory Directors of Pharming N.V. and Topas Therapeutics GmbH, and Chairman of the Board of Petra Pharma. Additionally, Mr. Sekhri is on the Board of Directors of the TB Alliance, and, as an avid classical music enthusiast, is on the Boards of The Metropolitan Opera, The Knights and the English Concert in America. Mr. Sekhri is also an active member of the Patrons Council of Carnegie Hall.

Anat Cohen-Dayag, Ph.D. joined Compugen's Board of Directors in February 2014. Dr. Cohen-Dayag joined Compugen in 2002 and held various positions. In November 2008, Dr. Cohen-Dayag was appointed as Vice President, Research and Development. In June 2009, Dr. Cohen-Dayag was appointed as co-Chief Executive Officer of Compugen and in March 2010 Dr. Cohen-Dayag was appointed as Compugen's President and CEO. Prior to joining Compugen, Dr. Cohen-Dayag was head of research and development and member of the Executive Management at Mindsense Biosystems Ltd. Prior to Mindsense Biosystems Ltd., Dr. Cohen-Dayag served as a scientist at the R&D department of Orgenics Ltd. Dr. Cohen-Dayag holds a B.Sc. in Biology from the Ben-Gurion University, Israel, and an M.Sc. in Chemical Immunology and a Ph.D. in Cellular Biology, both from the Weizmann Institute of Science, Israel. Additionally, Dr. Cohen-Dayag is a director of Ramot at Tel-Aviv University Ltd., and a director of the IATI (Israeli Advanced Technologies Industries).

Prof. Yair Aharonowitz joined Compugen's Board of Directors as an external director in July 2007 and was reappointed as an external director in April 2010, 2013 and 2016. In accordance with our decision to opt out of the requirement to elect external directors, he was due to terminate his service as our director on April 19, 2019. On March 19, 2019, our Board of Directors appointed Prof. Aharonowitz to continue to serve as a non-executive director until the end of the 2019 annual general meeting of shareholders. He is a Professor (Emeritus) of Microbiology and Biotechnology at Tel Aviv University (TAU). He was a visiting scientist at Oxford University, an Alberta Heritage Fellow at the University of Alberta, Edmonton, and a visiting professor at the Karolinska Institute and at the University of British Columbia. Professor Aharonowitz's research interests include the molecular genetics and biosynthesis of antibiotics, molecular biology of microbial pathogens and the development of new targets for new antibiotics. He served as TAU Vice President and Dean for R&D (1997-2001), Chairman of the Department of Microbiology and Biotechnology and Chairman of the Institute of Biotechnology and served as a member of the TAU Executive Council. He served as the Chairman of Ramot Fund for Applied Research, as a member of TAU committee for strategic planning, on the TAU patent committee and was a member of the National Committee for Biotechnology. He is a Fellow of the American Academy of Microbiology.

Dr. Jean-Pierre Bizzari joined Compugen's Board of Directors in September 2018. Dr. Bizzari is a world-renowned oncology expert who brings to Compugen over 35 years of broad experience in oncology drug development. Dr. Bizzari served as Executive Vice President and Global Head of Oncology at Celgene Corporation, responsible for Celgene's clinical development and operations-statistics teams across the United States, Europe and Asia/Japan where he oversaw the development and approval of leading oncology products, including REVLIMID® (lenalidomide), VIDAZA® (azacitidine), ISTODAX® (romidepsin) and ABRAXANE® (nab-paclitaxel). In addition, he was chairman of Celgene's hematology oncology development committee and a member of the company's management committee. Prior to Celgene, Dr. Bizzari was the Vice President, Clinical Oncology Development for Sanofi-Aventis (formerly Rhône-Poulenc, Rhône-Poulenc Rorer and Aventis) where he oversaw the approval of Eloxatin® (oxaliplatin), Taxotere® (docetaxel) and Elitek® (rasburicase). Dr. Bizzari joined the pharmaceutical industry in 1983 as Head of Oncology at the Institut de Recherches Internationales SERVIER (France). Dr. Bizzari is a member of the Scientific Advisory Board of the French National Cancer Institute, and the European Organization of Research and Treatment of Cancer and Chairman of the New Drug Advisory Committee. He also serves on the boards of Halozyne Therapeutics, Onxeo, Oxford BioTherapeutics, Pieris Pharmaceuticals, Nordic Nanovector and Transgene. Dr. Bizzari received his medical degree from the Nice Medical School and has trained at the Pitié-Salpêtrière Hospital in Paris, The Ontario Institute for Cancer Research, and The McGill Rosalind and Morris Goodman Cancer Research Centre (formerly the McGill Cancer Center) in Montreal, Canada.

Gilead Halevy joined Compugen's Board of Directors in June 2018 to serve as a director of the Company. Mr. Halevy serves as a general partner of Kedma Capital Partners, a leading Israeli private equity fund, of which he is also a founding member, since 2006. Prior to establishing Kedma, Mr. Halevy served as a Director at Giza Venture Capital from 2001 to 2006, where he led investments in communication and information technology companies, and directed Giza's European business activities. From 1998 to 2001, Mr. Halevy practiced law at White & Case LLP. Mr. Halevy was also a founding member of the White & Case Israel practice group during that time. Mr. Halevy currently serves as chairman of Brand Industries Ltd. (TASE), Carmor Integrated Solutions Ltd., Carmel Wineries; Continuity Software Ltd. and SAL Holdings. Mr. Halevy holds a B.A. in Humanities (multidisciplinary program for exceptional students) and an LL.B. (Magna Cum Laude) both from the Hebrew University of Jerusalem.

Kinneret Livnat Savitzky joined Compugen's Board of Directors in June 2018 to serve as a director of the Company. Since October 2017, Dr. Livnat Savitzky served as the Interim CEO, since January 2018 as a board member, and since May 2018 also as CEO of FutuRx Ltd., an Israeli biotechnology accelerator established by OrbiMed Israel Partners, Johnson & Johnson Innovation and Takeda Ventures Inc. (the venture group of Takeda Pharmaceutical Company) Dr. Livnat Savitzky also serves on the boards of the following biotechnology or healthcare companies: as an active chairperson in KAHN Medical and as a director in Hadasit Medical Research and Development and DreaMed Diabetes. In addition, Dr. Livnat Savitzky serves as a consultant to other pharmaceutical development companies and related funds. From 2010 to 2016, Dr. Livnat Savitzky served as CEO of BioLineRX Ltd., a Nasdaq-listed drug development company focused on oncology and immunology. During her tenure, BioLineRX signed a strategic collaboration with Novartis as well as licensing agreements with Merck (MSD), Genentech and others. Prior to being appointed CEO of BioLineRX, Dr. Livnat Savitzky held various R&D management positions at BioLineRX and Compugen. Dr. Livnat Savitzky holds a B.Sc. in Biology from The Hebrew University of Jerusalem, and an M.Sc. and Ph.D with distinction in Human Genetics from Tel Aviv University.

Arie Ovadia, Ph.D. joined Compugen's Board of Directors as an external director in July 2007 and was reappointed as an external director in April 2010, 2013 and 2016. In accordance with our decision to opt out of the requirement to elect external directors, he was due to terminate his service as our director on April 19, 2019. On March 19, 2019, our Board of Directors appointed Dr. Ovadia to continue to serve as a non-executive director until the end of the 2019 annual general meeting of shareholders. Mr. Ovadia advises major Israeli companies on finance, accounting and valuations, and is a member of the Board of Directors of several corporations, including Strauss Ltd., Israel Petrochemical Industries Ltd., Bazan Ltd., Maxtech Technologies Ltd., and Elron Electronic Industries Ltd. He has taught at New York University, Temple University and, in Israel, at Tel Aviv and Bradford Universities and The College of Management. Dr. Ovadia served as a member of the Israeli Accounting Board, and is a 14-year member of the Israel Securities Authority. Dr. Ovadia holds an undergraduate degree and an MBA from Tel Aviv University, and earned his Ph.D. in economics from the Wharton School at the University of Pennsylvania.

Sanford (Sandy) Zweifach joined Compugen's Board of Directors in June 2018 to serve as a director of the Company. Mr. Zweifach is the Founder and Chief Executive Officer of Nuvelution Pharma, Inc. since 2015. From 2010 to 2015, Mr. Zweifach served as CEO of Ascendancy Healthcare, Inc., which he also founded. He has also been a Partner at Reedland Capital Partners, a boutique investment bank, from 2005 to 2010, where he headed its life sciences M&A and advisory efforts. From 2003 to 2005, he was CEO of Pathways Diagnostics, a biomarker development company. Mr. Zweifach was a Managing Director/CFO of Bay City Capital, a venture capital/merchant banking firm, specializing in the biotech and the life science industry, where he was responsible for oversight of the firm's finance department, as well as President of the firm's M&A and financing division. Prior to this, he was President and CFO of Epoch Biosciences, which was acquired by Nanogen in 2004. Currently, he is a Chairman of Lyric Pharmaceuticals Inc., a director of Realm Therapeutics, Inc., and Chairman of IMIDomics, S.L. Earlier in his career, Mr. Zweifach was a Certified Public Accountant (US) for Coopers & Lybrand and held various investment banking positions focusing on biotech. He received his B.A. in Biology from UC San Diego and an M.S. in Human Physiology from UC Davis.

Ari Krashin was appointed Chief Financial Officer of Compugen in September 2014. Beginning March 1, 2016, Mr. Krashin also served as Chief Operating Officer, being additionally responsible for the Company's administrative, operational and IT activities. Mr. Krashin has over 20 years of experience in capital markets, finance and business development. He served as a chief financial officer for both public and private companies the most recent being AnyClip Media and Spacenet Inc. From 2000 to 2013, Mr. Krashin also served in various financial positions at Gilat Satellite Networks (Nasdaq: GILT), including his last position as chief financial officer, where he led the company's global finance and related operations, including business development, M&A activities, investor relations and administration. Mr. Krashin is a certified public accountant and began his professional career with Kesselman and Kesselman, PWC, Israel.

Kirk Christoffersen joined Compugen as Senior Vice President, Corporate and Business Development in December 2016. Prior to joining Compugen, Mr. Christoffersen was President of Apollo BioConsulting, a boutique life science consulting firm. From 2004 -2015, he led corporate development at GlobeImmune, Inc., initially as Senior Director and then as Vice President, Corporate Development. Prior to GlobeImmune, Mr. Christoffersen held leadership positions in corporate development and marketing at three biotechnology companies, including OSI pharmaceuticals, Gilead Sciences and NeXstar Pharmaceuticals. Mr. Christoffersen earned an undergraduate degree from the University of Michigan, and an M.B.A. from the Daniels College of Business at the University of Denver.

Dr. Henry Adewoye joined Compugen in March 2018 as Chief Medical Officer, bringing to Compugen over 20 years of extensive experience in leading multiple clinical trials in Oncology and Hematology in both the biopharmaceutical industry and academia. Before Compugen, Dr. Adewoye was with Gilead Sciences Inc., as Clinical Director in Oncology Clinical Research and was on the Oncology Leadership Team. He most recently served as Project Team and Clinical Lead for Idelalisib (first-in-class PI3K delta inhibitor approved for the treatment of relapsed CLL, FL/SLL) and Andecaliximab (MMP9 mAb inhibitor). Previously, he was Clinical Research Medical Director in Oncology at Amgen Inc. Dr. Adewoye was the Global Medical Monitor for the initial registrational trial of the bispecific antibody blinatumomab (Blincyto®) and several Phase 2 and 3 studies evaluating VEGF inhibitors (Motesanib, Trebananib) in patients with solid tumors. Dr. Adewoye completed his Fellowship in Hematology/Oncology at Boston Medical Center and completed his residency in Internal Medicine at Meharry Medical College. Dr. Adewoye received his medical degree at the University of Jos, Nigeria and Fellowship training in Hematology and Laboratory medicine at the University College Hospital Ibadan, Nigeria. Dr. Adewoye is Board Certified by the American Board of Internal Medicine in Medical Oncology, Hematology and Internal Medicine.

John Hunter, Ph.D joined Compugen in 2012 as Site Head at our U.S. subsidiary, Compugen USA, Inc., and VP Antibody Research and Development. In October 2018, he was appointed Chief Scientific Officer. Dr. Hunter has worked for over 20 years on different aspects of oncology drug development. Following graduation from UCSF, from 1996 to 2003, Dr. Hunter worked for Millennium Pharmaceuticals Inc., where he employed genomic approaches to identify novel drug targets in lung cancer. As a founding member of Millennium's Translational Medicine group, he worked to develop clinical biomarkers for their Aurora kinase small molecule inhibitors. Following Dr. Hunter's employment at Millennium, Dr. Hunter joined Xenogen Corp., where he worked as Senior Scientist in Oncology from 2004 to 2005. Dr. Hunter later joined XOMA Ltd., where from 2005 to 2012 he managed early stage antibody discovery for multiple therapeutic programs in oncology and inflammation. Dr. Hunter currently leads research and development efforts for Compugen's portfolio of novel oncology targets.

Zurit Levine, Ph.D. joined Compugen in 1999 and currently serves as Senior Vice President, Technology Innovation. Dr. Levine held several positions in Compugen's Research & Development department. In 2004, she was appointed Director of Therapeutic Selection & Validation, which position she held until 2007 when she was appointed Director of Therapeutic Discovery. In 2009, she was appointed Executive Director of Research & Development. From January 2010 to August 2011, she held the position of Vice President, Research and Development. In August 2011 she was appointed Vice President, Research and Discovery. Dr. Levine holds a B.Sc. in Biology, a M.Sc. in Biochemistry and a Ph.D. in Biochemistry, all from the Tel Aviv University, Israel.

Riki Schwartz, Ph.D. joined Compugen in October 2018 as Vice President Research and Discovery, responsible for the Company's computational discovery and research & validation groups. Dr. Schwartz has over 15 years of leadership experience in the pharmaceutical industry. Prior to joining Compugen, she served from 2017 to 2018 as CEO of BARcure LTD. an early-stage drug development company and as a drug development advisor to startup companies. Prior to that, from 2002 to 2015, Dr. Schwartz spent 13 years at Teva Pharmaceutical Industries serving in various management positions, with overall responsibility for drug development programs ranging from the concept stage and up to Phase III and registration and leading multidisciplinary global teams across different professional areas (including clinical, pharmacology, regulatory affairs, non-clinical safety and CMC). Dr. Schwartz holds a B.Sc. in Biology from Tel Aviv University and an M.Sc. and Ph.D. in Immunology from the Sackler Faculty of Medicine, Tel-Aviv University.

Arrangements Involving Directors and Senior Management

There are no arrangements or understandings of which we are aware relating to the election of our directors or the appointment of executive officers in our Company. In addition, there are no family relationships among any of the individuals listed in this Item 6.A.

B. COMPENSATION

Aggregate Executive Compensation -

During 2018, the aggregate compensation paid or accrued by us to all persons listed in Item 6.A above (Directors and Senior Management), as well as to four directors and a member of Senior Management who served in 2018 but have each since ceased to so serve was approximately \$4.4 million. This amount includes approximately \$0.5 million set aside or accrued to provide pension, severance, retirement or similar benefits, but excludes expenses (including business travel, professional and business association dues and expenses) reimbursed to our executives and other fringe benefits commonly reimbursed or paid by companies in Israel.

During 2018, we granted to our Directors and Senior Management a total of 835,000 options to purchase ordinary shares. These options are exercisable at an average exercise price of \$3.29 per share, and generally expire ten years after their respective dates of grant. As of December 31, 2018, there were a total of 4,211,790 outstanding options to purchase ordinary shares that were held by our Directors and Senior Management.

Individual Compensation of Covered Office Holders

The table below outlines the compensation granted to our five most highly compensated Office Holders (as such term is defined in the Companies Law – see below under “– Approval Required for Directors' and Officers' Compensation”) with respect to the year ended December 31, 2018. All amounts reported in the table reflect the cost to the Company, as recognized in our financial statements for the year ended December 31, 2018. We refer to the five individuals for whom disclosure is provided herein as our “Covered Office Holders”.

Information Regarding the Covered Office Holders	Compensation for Services⁽²⁾			
	Base Salary(\$)	Benefits and Perquisites (\$)⁽³⁾	Stock-Based Compensation(\$)⁽⁴⁾	Total(\$)
Name and Principal Position⁽¹⁾				
Dr. Anat Cohen-Dayag President & CEO	391,330	281,059	181,614	854,003
Kirk Christoffersen Senior VP – Corporate and Business Development	300,000	249,343	90,044	639,387
John Hunter Chief Scientific Officer	300,000	196,031	106,761	602,792
Ari Krashin Chief Financial and Operating Officer	232,235	129,226	214,275	575,736
Henry Adewoye Chief Medical Officer	269,129	241,739	48,038	558,906

- 1) All Covered Office Holders listed in the table are full-time employees of the Company.
- 2) Cash compensation amounts denominated in currencies other than the U.S. dollar were converted into U.S. dollars at an exchange rate of NIS 3.5949 = \$1.00, which reflects the average conversion rate for 2018 ("Representative Rate").
- 3) Amounts reported in this column include benefits and perquisites, including those mandated by applicable law. Such benefits and perquisites may include, to the extent applicable to the Covered Office Holders, bonuses, payments, contributions and/or allocations for savings funds, pension, severance, vacation, car or car allowance, medical insurances and benefits, risk insurance (e.g., life, disability, accident), phone, convalescence pay, payments for social security, tax gross-up payments and other benefits and perquisites consistent with the Company's policies.
- 4) Amounts reported in this column represent the expense recorded in our financial statements for the year ended December 31, 2018 with respect to options to purchase our ordinary shares granted to our Covered Office Holders. Assumptions and key variables used in the calculation of such amounts are discussed in Note 2o to our 2018 consolidated financial statements set forth elsewhere in this report.

Approval Required for Directors' and Officers' Compensation

As required by the Companies Law ("Amendment 20"), our shareholders, following the approval of the Board of Directors and the recommendation of the Audit Committee (sitting as a compensation committee), approved and adopted an amended compensation policy (the "Compensation Policy") at the 2017 Special General Meeting of Shareholders, which sets forth the Company's policy regarding the Terms of Office and Employment (as defined below) of our Office Holders (as defined below). The Compensation Policy provides our Compensation Committee and our Board of Directors with adequate measures and flexibility to tailor each of our Office Holder's compensation package based, among other matters, on geography, tasks, role, seniority and capability. Moreover, the Compensation Policy is intended to motivate our Office Holders to achieve ongoing targeted results in addition to a high level business performance in the long term, all, without encouraging excessive risk taking. The Company draws upon a pool of talent that is highly sought after by large and established global pharmaceutical and biotechnology companies as well as by other development-stage life science companies which operate both within and outside of the Company's geographic areas, most notably in the United States. The Company believes that it therefore must offer compensation terms, both to its executives and to its directors that are competitive with the compensation standards that exist in the companies with whom it competes for such talents.

The term "Office Holder" as defined in the Companies Law includes a director, the chief executive officer, an executive vice president, a vice president, any other person fulfilling or assuming any of the foregoing positions without regard to such person's title, and any manager who is directly subordinated to the chief executive officer. In addition to each person listed in the table under "Item 6. Directors, Senior Management and Employees – A. Directors and Senior Management", two other individuals have been Office Holders as of December 31, 2018. "Terms of Office and Employment" means the terms of office and employment of our Office Holders, including exemption and release of the Office Holder from liability for breach of his or her duty of care to the Company, an undertaking to indemnify the Office Holder, post factum indemnification or insurance; any grant, payment, remuneration, compensation, or other benefit provided in connection with termination of service; and any benefit, other payment or undertaking to provide any payment as aforesaid.

Pursuant to the Companies Law, arrangements with respect to the Terms of Office and Employment of Office Holders who are not directors must generally be approved by the compensation committee and the board of directors, and be consistent with the compensation policy (amendment of Terms of Office and Employment of such Office Holders requires the approval of the compensation committee only, if the committee determines that the amendment is not material). However, under certain circumstances and conditions, the compensation committee and board of directors may approve an arrangement that deviates from the compensation policy, provided that such arrangement is approved by the company's shareholders by a simple majority, and provided that (i) such majority includes a majority of the votes cast by shareholders who are present and voting (abstentions are disregarded) and are not controlling shareholders and who do not have a personal interest in the matter, or (ii) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter who were present and voted against the policy, constitute two percent or less of the voting power of the company (such majority determined in accordance with clause (i) or (ii), the "Compensation Majority").

Furthermore, in special circumstances, to the extent the Terms of Office and Employment of Office Holders who are not directors are not approved by the shareholders (where such approval is required), the compensation committee and the board of directors may subsequently override the resolution of the shareholders following a new discussion of the matter and for specified reasons.

Compensation for Office Holders who are Directors or Chief Executive Officers. The Terms of Office and Employment of directors, other than directors who serve as chief executive officers and/or who possess a controlling interest in a company, require the approval of the compensation committee, board of directors and shareholders by a simple majority. With respect to our President and Chief Executive Officer, who is also a director, or with respect to any chief executive officer who is not a director (to the extent applicable in the future), further approval of the shareholders by the Compensation Majority is required. However: (i) under certain circumstances, and to the extent that the proposed Terms of Office and Employment are in compliance with the compensation policy, a company may be exempt from receiving shareholder approval with respect to the Terms of Office and Employment of a candidate for the position of chief executive officer; and (ii) a company's compensation committee and board of directors are permitted to approve Terms of Office and Employment of a chief executive officer or of a director, without convening a general meeting of shareholders, provided that such terms: (a) are not more beneficial than the former terms, or are essentially the same in their effect; (b) are in line with the compensation policy; and (iii) are brought for shareholder approval at the next general meeting of shareholders.

Variable Compensation and Annual Cash Bonuses of Office Holders. The Companies Law requires that all variable compensation of directors and chief executive officers be based on measurable criteria, with the exception of a non-substantial portion of up to 3 monthly salaries. With respect to Office Holders who are not directors or chief executive officers, the Companies law allows that 100% of the variable compensation be based on non-measurable criteria. Our Compensation Policy allows for a non-substantial portion of up to 20% of the bonus objectives for each year to be based on non-measurable criteria, provided, however, that with respect to our Office Holders who are not directors or our Chief Executive Officer, our Compensation Committee and Board of Directors may increase the portion of targets based on non-measurable criteria above the rate of 20%, up to 50%. Further, the annual cash bonus of each of our Office Holders who are not directors is determined according to a formula that is consistent with the Compensation Policy and that links the bonus payment score to measurable and qualitative objectives relating to both the Company's performance and to the performance by each such Office Holder of his responsibilities. The measurable criteria include a financial target which is uniform with respect to all of our Office Holders, including our Chief Executive Officer. In the case of our Office Holders other than the Chief Executive Officer, assuming that the bonus terms conform to the Compensation Policy, the annual bonus objectives and subsequent payment scores are determined by the Compensation Committee and Board of Directors, while the bonus terms for our Chief Executive Officer generally require the additional approval by our shareholders. For each fiscal year, our Board of Directors determines the maximum target bonus for each of our Office Holders, including our Chief Executive Officer.

Compensation to our Non-Executive Directors (other than Mr. Paul Sekhri)

On August 6, 2018, our shareholders approved, following previous resolutions made by our Audit Committee (sitting as a compensation committee) and the Board of Directors, and consistent with our Compensation Policy, to compensate each of our non-executive directors whether currently in office or appointed in the future, excluding the Chairman of the Board (each a “non-executive director”) as follows:

Cash Fees:

- (i) an annual fee of \$45,000 (the “**Annual Base Fee**”); and
- (ii) an additional annual amount to be paid to non-executive directors for service as members on each of the Company’s committees, as follows (the “**Additional Annual Fee**”):
 - (a) Audit Committee - \$2,500 for a member, or \$5,000 for the chairman;
 - (b) Compensation Committee - \$2,000 for a member, or \$4,000 for the chairman; and
 - (c) Nomination and Governance Committee - \$1,000 for a member, or \$3,000 for the chairman.

No additional compensation shall be paid for attendance at a board or committee meeting.

VAT is added to the above compensation in accordance with applicable law.

Equity

In addition to the cash compensation detailed above, each non-executive director shall be entitled to a yearly grant of options to purchase the Company’s Ordinary Shares, so that in the first year of service as a director, each non-executive director shall be entitled to a one-time grant of 35,000 options (the “**Initial Option Grant**”) and, in addition, to a yearly grant of 10,000 options in each of the following years of service (the “**Annual Option Grant**”), as detailed below.

The grant date of each Initial Option Grant shall be the date of appointment for service as director, whether initially appointed by the Board or by the general meeting of shareholders, with an exercise price equal to the closing price of the Company’s Ordinary Shares on the Nasdaq on the last trading day prior to the date of their initial appointment to serve on the Board. The grant date of each Annual Option Grant shall be such date in each year on which the Board approves the annual option grants to other executive Office Holders (provided that the service as director continues at the time of each grant), with an exercise price equal to the closing price of the Company’s Ordinary Shares on the Nasdaq on the last trading day prior to such Board approval.

Mr. Zweifach, a non-executive director, was granted 40,000 options to purchase the Company’s Ordinary Shares in February 2018 while serving as a consultant to the Company, which service was terminated upon his appointment as a director by the Board. Mr. Zweifach therefore waived his right to receive the Initial Option Grant and is entitled only to future Annual Option Grants.

Both the Initial and the Annual Option Grants shall be subject (other than as described herein) to the terms and conditions of the Company’s 2010 Share Incentive Plan (the “**2010 Plan**”) or any other equity-based incentive plan the Company may adopt in the future and pursuant to which these equity awards would be granted. All such grants shall vest over a four-year period as follows: twenty five percent (25%) will vest on the first day of the quarter one calendar year immediately following the quarter in which the options were granted; and an additional 6.25% will vest each quarter thereafter for the next 36 months.

Notwithstanding the terms of the relevant plan, all options granted to non-executive directors shall be fully vested immediately upon the completion of one or more of the following events, whether by way of a consolidation, merger or reorganization of the Company or otherwise: (a) a sale of all or substantially all of Company’s issued share capital or assets to any other company, entity, person or a group of persons, or (b) the acquisition of more than 50% of the Company’s equity or voting power by any shareholder or group of shareholders (a “**Corporate Transaction**”). Further, notwithstanding the terms of the relevant plan, all options granted which shall be vested as of the date of final termination of office as a non-executive director of the Company may be exercised within one year following such termination of office. To the extent legally available and applicable, such options will be granted to the non-executive directors through a trustee under Section 102 of the Israel Income Tax Ordinance [New Version], 5721-1961 (the “**Tax Ordinance**”), under the capital gains route.

Compensation to the Company's Chairman of the Board of Directors, a Non-Executive Director

On October 17, 2017, our shareholders approved, following previous resolutions made by our Audit Committee (sitting as a compensation committee) and the Board of Directors, and consistent with our Compensation Policy, the following compensation for our non-executive Chairman of the Board, Mr. Paul Sekhri:

Cash Fees: An annual cash fee in the amount of \$150,000. No meeting fees will be paid in addition to such annual cash fee.

Grant of Options to Purchase Ordinary Shares: a one-time initial grant of options to purchase 500,000 Ordinary Shares. These options are subject to the terms and conditions applicable to options granted under the Company's 2010 Option Plan. Such grant vests over a four-year period as follows: twenty five percent (25%) vested on the first day of the quarter one calendar year immediately following the quarter in which the options were granted; and an additional 6.25% will vest each quarter thereafter for the next 36 months. These options will expire ten years after the grant date, unless they expire earlier in accordance with the terms of the Company's 2010 Option Plan. In their respective resolutions, our Audit Committee (sitting as a compensation committee) and Board took into consideration the fact that such grant of options to Mr. Sekhri is exceptional and is significantly higher than the usual annual grants provided by the Company to its Office Holders, and as such, approved it as a one-time exception that is made for an initial grant, and not intended to be provided to Mr. Sekhri on a yearly basis. Despite the fact that such grant of options to Mr. Sekhri exceeded the applicable cap for annual equity grants under the Compensation Policy (which is set at 300% of a non-executive director's total annual cash compensation), our Audit Committee (sitting as a compensation committee) and Board of Directors deemed such deviation merited under the circumstances and in the best interests of the Company. The acceleration provisions applicable to options granted to other non-executive directors also apply to the options granted to Mr. Sekhri.

Compensation to our President and Chief Executive Officer

Pursuant to Dr. Anat Cohen-Dayag's employment agreement, as the President and Chief Executive Officer of the Company she is entitled to a gross monthly salary of NIS 118,800 (approximately \$33,047 according to the Representative Rate), adjusted from time to time in accordance with changes in the Israeli Consumer Price Index, which shall be reviewed annually. Dr. Cohen-Dayag is also entitled to certain benefits and perquisites customary in Israel, including those mandated by applicable law. In addition, Dr. Anat Cohen-Dayag is eligible for an annual grant of equity-based compensation and to an annual cash bonus based upon achievement of objectives determined by the Company, both subject to receipt of all approvals required by applicable law and to the terms of our Compensation Policy.

On August 6, 2018, our shareholders approved that Dr. Cohen-Dayag shall be eligible to receive an annual cash bonus of up to nine monthly salaries for each of the calendar years 2018, 2019 and 2020, without the need for further shareholder approval, subject to meeting the specific performance criteria determined by the Compensation Committee and Board with respect to each such year, in accordance with the objectives and terms thereof and the continuous employment of Dr. Cohen-Dayag as the Company's President and Chief Executive Officer through the last day of the calendar year with respect to which the annual cash bonus is proposed to be paid. Additionally, on August 6, 2018, our shareholders approved an annual equity grant plan for Dr. Cohen-Dayag for each of the calendar years 2018, 2019 and 2020, according to which Dr. Cohen-Dayag shall be granted options to purchase up to 150,000 Ordinary Shares in each of 2018, 2019 and 2020, as shall be determined by the Compensation Committee and Board of Directors with respect to each such year. In order to align such grants (including the exercise price and vesting period) with the annual grant of options to other executive Office Holders (for whom shareholder approval is not required), our shareholders resolved that the annual grant to Dr. Cohen-Dayag will be made on such date in 2018, 2019 and 2020 on which the Board of Directors approves the respective year's annual option grants to executive Office Holders in such year; accordingly, the 2018 annual equity grant for Dr. Cohen-Dayag included 120,000 options, with an exercise price of \$3.15, granted on July 31, 2018.

The options granted in each respective year shall be subject to the terms and conditions applicable to options granted under the 2010 Plan. Each annual option grant will vest over a four-year period as follows: twenty five percent (25%) will vest on the first day of the quarter one calendar year immediately following the quarter in which the options are granted; and an additional 6.25% will vest each quarter thereafter for the next 36 months. These options will have an exercise price equal to the closing price of the Company's Ordinary Shares on Nasdaq on the last trading day prior to the approval of each year's grant by the Board. These options will expire ten years after the grant date, unless they expire earlier in accordance with the terms of the 2010 Plan or the terms of the option agreement to be entered into between the Company and Dr. Cohen-Dayag. The options will be granted through a trustee under Section 102 of the Tax Ordinance and, in accordance with the Company's previous election in this regard, be subject to the capital gains route for tax purposes.

Dr. Cohen-Dayag's employment agreement may generally be terminated by either party by providing six (6) months advance written notice, provided that in the event of termination by the Company for "justifiable cause" (as such term is defined in her employment agreement as shall be in effect from time to time) the Company may terminate Dr. Cohen-Dayag's employment without advance notice and that Dr. Cohen-Dayag may resign with advance notice of only two (2) months in the event of resignation for "good reason" (as such term is defined in her employment agreement as shall be in effect from time to time). Upon termination, Dr. Anat Cohen-Dayag will be entitled to receive certain payments associated with termination.

In the event that Dr. Cohen-Dayag's employment is: (a) terminated by the Company, other than for "justifiable cause"; or (b) terminated by Dr. Cohen-Dayag for "good reason" (hereinafter, (a) and (b) shall be referred to together as "Dismissal"), Dr. Cohen-Dayag will also be entitled to an additional one-time payment equal to six (6) monthly salaries (the "Termination Payment") and upon Dismissal within one year following certain "change of control" events (as defined in her employment agreement as shall be in effect from time to time), Dr. Cohen-Dayag will be entitled to a special termination payment (in addition to the Termination Payment) in an amount equal to six (6) monthly salaries.

In addition, upon Dismissal, or in the event of a "change of control", all outstanding unvested options granted to Dr. Cohen-Dayag as of such time will be accelerated and become immediately exercisable as of the effective date of such Dismissal/change of control. Upon acceleration due to an event of a Dismissal, Dr. Cohen-Dayag will also be entitled to exercise all outstanding vested options for a period of one (1) year from the date of such Dismissal, provided that such period does not extend beyond ten (10) years from the date of grant. Upon acceleration due to an event of change of control, following which Dr. Cohen-Dayag's employment is, within 12 months of the closing of such an event: (a) terminated by the Company, other than for "justifiable cause"; or (b) terminated by Dr. Cohen-Dayag for any reason, Dr. Cohen-Dayag will be entitled to exercise all outstanding vested options (including those vested as a result of such accelerated vesting) for a period of one (1) year from the date of termination of her employment, provided that such period does not extend beyond ten (10) years from the date of grant.

Dr. Cohen-Dayag is not entitled to any compensation (including in connection with her role as a director) in addition to that being paid to her as the President and Chief Executive Officer of the Company. However, in the event of termination of Dr. Cohen-Dayag employment agreement, she will be entitled to receive such compensation to the extent and for as long as she will serve as a non-executive director of the Company.

As of December 31, 2018, Dr. Cohen-Dayag held options to purchase a total of 1,235,000 ordinary shares, of which options to purchase 120,000 ordinary shares were granted during 2018. Out of the options to purchase 1,235,000 ordinary shares: (i) options to purchase 965,000 ordinary shares, with a weighted average exercise price of \$4.89 per share, were exercisable as of December 31, 2018; and (ii) options to purchase 270,000 ordinary shares, with a weighted average exercise price of \$4.03 per share, had not vested as of December 31, 2018. Of the unvested options at December 31, 2018, options to purchase 105,000 ordinary shares are expected to vest during 2019, options to purchase 80,000 ordinary shares are expected to vest during 2020 and options to purchase the remaining 85,000 ordinary shares are expected to vest during the period between January 1, 2021 and October 1, 2022. These unvested options were granted under the Company's 2010 Plan. For additional information on Dr. Cohen-Dayag's holdings see "Item 6. Directors, Senior Management and Employee – E. Share Ownership – Share Ownership by Directors and Other Executive Officers."

Insurance, Indemnification and Exemption

Pursuant to the Companies Law and the Israeli Securities Law, the Israeli Securities Authority is authorized to impose administrative sanctions, including monetary fines, against companies like ours and their officers and directors for certain violations of the Israeli Securities Law or the Companies Law (for further details see "*Administrative Enforcement*" below); and the Companies Law provides that companies like ours may indemnify their officers and directors, purchase an insurance policy to cover certain liabilities and exempt them in advance from liability to the company for a breach of their duty of care, if provisions for that purpose are included in their articles of association.

Our Office Holders' Insurance. Our Articles provide that, subject to the provisions of the Companies Law, we may enter into contracts to insure the liabilities of our Office Holders for any liabilities or expenses incurred by or imposed upon them as a result of any act (or omission) carried out by them as our Office Holders, including with respect to any of the following:

a breach of duty of care to us or to another person;

a breach of duty of loyalty to us, provided that the Office Holder acted in good faith and had reasonable grounds to assume that such act would not prejudice our interests; and

monetary liabilities or obligations imposed upon him or her in favor of another person.

Without derogating from the above, subject to the provisions of the Companies Law and the Israeli Securities Law, we may also enter into a contract to insure an office holder, in respect of expenses, including reasonable litigation expenses and legal fees, incurred by an Office Holder in relation to an administrative proceeding instituted against him or her, or payment required to be made to an injured party, pursuant to certain provisions of the Israeli Securities Law.

Under the Companies Law, exemption and indemnification of, and procurement of insurance coverage for, our Office Holders, must be approved by our Audit Committee, (sitting as a compensation committee) and our Board of Directors and, with respect to an Office Holder who is the CEO or a director, also by our shareholders. However, according to regulations promulgated under the Companies Law, shareholders' and Board approvals for the procurement of such insurance are not required if the insurance policy is approved by our Audit Committee, (sitting as a compensation committee) and: (i) the terms of such policy are within the framework for insurance coverage as approved by our shareholders and set forth in our Compensation Policy; (ii) the premium paid under the insurance policy is at fair market value; and (iii) the insurance policy does not and may not have a substantial effect on the Company's profitability, assets or obligations.

In accordance with our Compensation Policy, we are currently entitled to hold directors' and officers' liability insurance policy for the benefit of our Office Holders with insurance coverage of up to \$50 million and with an annual premium of up to \$350,000.

Our Office Holder's Indemnification. Our Articles provide that, subject to the provisions of the Companies Law, we may indemnify any of our Office Holders for all liabilities and expenses incurred by them arising from or as a result of any act (or omission) carried out by them as Office Holders of the Company, including as follows:

a financial liability imposed on him or her in favor of another person by any court judgment, including a settlement or an arbitration award approved by a court;

reasonable litigation expenses, including attorney's fees, incurred by the Office Holder as a result of an investigation or proceeding instituted against him or her by a competent authority which concluded without the filing of an indictment and without the imposition of any financial liability in lieu of criminal proceedings, or which concluded without the filing of an indictment but with the imposition of a financial liability in lieu of criminal proceedings concerning a criminal offense that does not require proof of criminal intent or in connection with a financial sanction;

reasonable litigation expenses, including attorneys' fees, expended by an Office Holder or charged to the Office Holder by a court, in a proceeding instituted against him or her by the Company or on its behalf or by another person, or in a criminal charge from which the Office Holder was acquitted, or in a criminal proceeding in which the Office Holder was convicted of an offense that does not require proof of criminal intent; and

expenses, including reasonable litigation expenses and legal fees, incurred by an Office Holder in relation to an administrative proceeding instituted against him or her, or payment required to be made to an injured party, pursuant to certain provisions of the Israeli Securities Law.

The Company may undertake to indemnify an office holder as mentioned above: (a) prospectively, provided that with respect of the first act (financial liability) the undertaking is limited to events which in the opinion of the Board are foreseeable in light of the Company's actual operations when the undertaking to indemnify is given, and to an amount or criteria set by the Board as reasonable under the circumstances, and further provided that such events and amount or criteria are set forth in the undertaking to indemnify, and (b) retroactively.

Indemnification letters, covering indemnification of those liabilities discussed above, were granted to each of our present Office Holders and were approved for any future Office Holders. Hence, we indemnify our Office Holders to the fullest extent permitted under the Companies Law.

Our Office Holder's Exemption. Our Articles provide that, subject to the provisions of the Companies Law, we may exempt and release our Office Holders, including in advance, from all or part of such Office Holder's liability for monetary or other damages due to a breach of their duty of care to the Company. Our directors are released and exempt from all liability as aforesaid to the fullest extent permitted by law with respect to any such breach, which has been or may be committed.

Limitations on Insurance, Indemnification and Exemption. The Companies Law provides that a company may not insure, exempt or indemnify an office holder for any breach of his or her liability arising from any of the following:

- a breach by the office holder of his or her duty of loyalty, except that the company may enter into an insurance contract or indemnify an office holder if the office holder acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach by the office holder of his or her duty of care if such breach was intentional or reckless, but unless such breach was solely negligent;
- any act or omission done with the intent to derive an illegal personal benefit; or
- any fine, civil fine, financial sanction or monetary settlement in lieu of criminal proceedings imposed on such office holder.

Administrative Enforcement

The Israeli Securities Law includes an administrative enforcement procedure that may be used by the Israeli Securities Authority, to enhance the efficacy of enforcement in the securities market in Israel. This administrative enforcement procedure may be applied to any company or person (including director, officer or shareholder of a company) performing any of the actions specifically designated as breaches of law under the Israeli Securities Law. Furthermore, the Israeli Securities Law requires that the CEO of a company supervise and take all reasonable measures to prevent the company or any of its employees from breaching the Israeli Securities Law. The CEO is presumed to have fulfilled such supervisory duty if the company adopts internal enforcement procedures designed to prevent such breaches, appoints a representative to supervise the implementation of such procedures and takes measures to correct the breach and prevent its reoccurrence.

As detailed above, under the Israeli Securities Law, a company cannot obtain insurance against or indemnify a third-party (including its officers and/or employees) for any administrative procedure and/or monetary fine (other than for payment of damages to an injured party). The Israeli Securities Law permits insurance and/or indemnification for expenses related to an administrative procedure, such as reasonable legal fees, provided that it is permitted under the company's articles of association.

We have adopted and implemented an internal enforcement plan to reduce our exposure to potential breaches of sections in the Companies Law and the Israeli Securities Law, applicable to us. Our Articles and letters of indemnification permit, among others, insurance and/or indemnification as contemplated under the Israeli Securities Law (see "*Insurance, Indemnification and exemption*" above).

C. BOARD PRACTICES

We are incorporated in Israel, and, therefore, are generally subject to various corporate governance practices under Israeli law such as with respect to external directors, independent directors, audit committee, compensation committee, an internal auditor and approvals of interested party transactions. These matters are in addition to the requirements of the Nasdaq Global Market and other relevant provisions of U.S. securities laws applicable to us. Under the Nasdaq Listing Rules, a foreign private issuer may generally follow its home country practices for corporate governance in lieu of the comparable Nasdaq Global Market requirements, except for certain matters such as composition and responsibilities of the audit committee and the SEC-mandated standards for the independence of its members. We currently comply with all the above-mentioned requirements. See "Item 3. Key Information – D. Risk Factors – Risks related to operations in Israel – Being a foreign private issuer exempts us from certain SEC and Nasdaq requirements". For information regarding home country practices followed by us see "Item 16G - Corporate Governance".

Board of Directors

Our Board of Directors consists of eight members. Other than two of our directors who were elected as external directors under the provisions of the Companies Law (discussed below), our directors are elected for a term of approximately one year, ending at the annual general meeting immediately following the annual general meeting at which they were elected or upon earlier termination in circumstances referred to under the Companies Law or our Articles. Our Articles provide that we may have no less than five nor more than fourteen directors.

None of our directors is party to a service contract with us that provides for any severance or similar benefits upon termination of his or her service other than our President and Chief Executive Officer, Dr. Anat Cohen-Dayag, with whom we entered into an employment agreement. For additional information on the employment agreement entered into with Dr. Cohen-Dayag, please see “Item 6 – Directors, Senior Management and Employees – B. Compensation – Compensation to our President and Chief Executive Officer.”

Directors under the Companies Law - General

A nominee for service as a director in a public company may not be elected without submitting a declaration to the company, prior to his or her election, specifying that he or she has the requisite qualifications to serve as a director, an external director or an independent director, as applicable, and the ability to devote the appropriate time to performing his or her duties as such.

A director, including an external director or an independent director, who ceases to meet the statutory requirements to serve as a director, external director or independent director, as applicable, must notify the company to that effect immediately and his or her service as a director will expire upon submission of such notice.

External Directors and Independent Directors under the Companies Law

Under the Companies Law, Israeli public companies are generally required to have on their board of directors at least two external directors meeting certain independence criteria, provided under Israeli law. We, as an Israeli public company with no controlling shareholder (within the meaning of the Companies Law), whose shares are listed on the Nasdaq Global Market, may exempt ourselves from the requirement of having external directors on our Board of Directors and related requirements concerning the composition of the audit and compensation committees of the board of directors, provided that we continue to comply with applicable U.S. securities laws and Nasdaq Listing Rules. As currently we do not have a controlling shareholder and as we comply with the Nasdaq majority board independence requirement, and with the Nasdaq and SEC audit and compensation committee composition requirements, on June 7, 2018, our Board determined to opt out of the requirement to elect external directors. In accordance with this decision, and the requirements under these regulations, our two former external directors, Prof. Yair Aharonowitz and Dr. Arie Ovadia, remained on our Board and serve as non-executive directors until the expiry of their current three-year term of service on April 19, 2019. On March 19, 2019, our Board of Directors appointed Prof. Yair Aharonowitz and Dr. Ovadia to continue to serve as non-executive directors until the end of the 2019 Annual General Meeting of Shareholders.

The term controlling shareholder, as used in the Companies Law for purposes of all matters related to external directors and for certain other purposes, means a shareholder that has the ability to direct the activities of the company, other than by virtue of being an office holder. For purposes of all matters related to external directors, a shareholder is presumed to be a controlling shareholder if the shareholder holds 50% or more of the voting rights in the company or has the right to appoint the majority of the directors of the company or its chief executive officer.

Pursuant to the Companies Law an external director is required to have either accounting and financial expertise or professional qualifications according to criteria set forth under the Companies Law and regulations promulgated there under, and at least one of the external directors is required to have accounting and financial expertise. The board of directors must make the determinations as to the financial and accounting expertise, and as to the professional qualifications, of a director taking into consideration those criteria and matters set forth in the regulations. In addition, the boards of directors of publicly traded companies are required to make a determination as to the minimum number of directors who must have financial and accounting expertise as aforesaid based, among other things, on the type of company, its size, the volume and complexity of the company's activities and the number of directors. Our Board of Directors has determined that the minimum number of directors with financial and accounting expertise is one and that Dr. Arie Ovadia qualifies as such.

Under the Companies Law, an 'independent director' is either an external director or a director appointed or classified as such who meets the same non-affiliation criteria as an external director, as determined by the company's audit committee, and who has not served as a director of the company for more than nine consecutive years. For these purposes, ceasing to serve as a director for a period of two years or less would not be deemed to sever the consecutive nature of such director's service. However, as our shares are listed on the Nasdaq Global Market, we may also classify directors who qualify as independent directors under the relevant non-Israeli rules, as 'independent directors' under the Companies Law even if they serve for a period longer than 9 consecutive years. Each of our directors, other than Dr. Anat Cohen-Dayag, who also serves as our Chief Executive Officer, meets the 'independent directors' criteria under the Companies Law.

Independent Directors under the Nasdaq Listing Rules

In addition to the requirements of the Companies Law as described above, since our shares are listed on the Nasdaq Global Market, pursuant to the Nasdaq Listing Rules, a majority of our directors must be independent (as defined under the Nasdaq Listing Rules). We comply with such Nasdaq independence requirement, as each of our directors, other than Dr. Anat Cohen-Dayag, who also serves as our Chief Executive Officer, has been determined by our Board of Directors to meet the Nasdaq independence requirements.

Board Committees

Audit Committee

The Companies Law requires public companies such as ours to appoint an audit committee, the responsibilities of which include, among other things: (i) identifying flaws in the management of the Company's business and making recommendations to the Board of Directors as to how to correct them, and providing for arrangements regarding employee complaints with respect thereto, (ii) reviewing and considering certain related party transactions and certain actions involving conflicts of interest (as well as deciding whether certain actions specified in the Companies Law are considered material or non-material and whether certain transactions are considered exceptional or ordinary), (iii) reviewing the internal auditor's work program performance and examining the company's internal control structure and processes, (iv) examining the external auditor's scope of work as well as the external auditor's fees and providing its recommendations to the appropriate corporate organ and (v) overseeing the accounting and financial reporting processes of the Company.

Under the Nasdaq Listing Rules, we are required to maintain an audit committee that operates under a formal written charter and has certain responsibilities and authority, including being directly responsible for the appointment, compensation, retention and oversight of the work of our independent auditors. However, under Israeli law and our Articles, the appointment of independent auditors requires the approval of the shareholders and their compensation requires the approval of our Board of Directors. In addition, as described above, pursuant to the Companies Law, the Audit Committee is required to examine the independent auditors' scope of work as well as the external auditors' fees and to provide its recommendations with respect thereto to the appropriate corporate organ. Accordingly, the appointment of our independent auditors is approved by our shareholders at the Audit Committee's recommendation and their compensation for audit and non-audit services is approved by the Board of Directors following the Audit Committee's recommendation.

We have adopted a charter for the Audit Committee, which sets forth the purpose and responsibilities of such committee.

In carrying out its duties, the Audit Committee meets with management at least once in each fiscal quarter at which time, among other things, it reviews, and either approves or disapproves, the financial results of the Company for the immediately preceding fiscal quarter and conveys its conclusions in this regard to the Board of Directors. The Audit Committee also generally monitors the services provided by the Company's external auditors to ensure their independence, and reviews all audit and non-audit services provided by them. The Company's external and internal auditors also report regularly to the Audit Committee at its meetings and the Audit Committee discusses with our external auditors the quality, not just the acceptability, of the accounting principles, the reasonableness of significant judgments and the clarity of disclosures in our financial statements, as and when it deems it appropriate to do so.

Under the Nasdaq Listing Rules, the audit committee is required to consist of at least three independent directors, each of whom is financially literate and at least one of whom has accounting or related financial management expertise.

We have an Audit Committee consisting of four directors, Dr. Arie Ovadia, who serves as the chairman of our Audit Committee, Prof. Yair Aharonowitz, Mr. Gilead Halevy and Mr. Sanford (Sandy) Zweifach, all of whom are financially literate under the applicable rules and regulations of the SEC and Nasdaq Listing Rules and one of whom, Dr. Arie Ovadia, is an audit committee financial expert as defined by the SEC rules, and has the requisite financial experience required under the Nasdaq Listing Rules. Each of the members of the audit committee is “independent” as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, which is different from the general test for independence of board and committee members under the Nasdaq Listing Rules.

The Audit Committee composition requirements referred to under Section 115 of the Companies Law are not applicable to the Company as the Board of Directors, as part of its decision to opt out of the requirement to elect external directors, also adopted relief from such composition requirements on the basis that the Company complies, and will continue to comply, with the U.S. Securities Law and Nasdaq Listing Rules described above.

Compensation Committee

The Companies Law generally provides that public companies such as the Company must appoint a compensation committee, the responsibilities of which include, among others: (i) reviewing and making recommendations to the Board of Directors with respect to our Compensation Policy, (ii) reviewing and considering arrangements with respect to the Terms of Office and Employment of Office Holders, and (iii) overseeing, subject to applicable law, the administration of the Company’s various compensation plans and arrangements, including, incentive compensation and equity based plans. Under the Companies Law, the Compensation Committee may need to seek the approval of the Board of Directors and the shareholders for certain compensation-related decisions, (see “Item 6 - Directors, Senior Management and Employees – B. Compensation - Approval Required for Directors’ and Officers’ Compensation”).

We have adopted a charter for the Compensation Committee, which sets forth the purpose and responsibilities of such committee.

Under the Nasdaq Listing Rules, we are required to maintain a compensation committee consisting of at least two independent directors (as defined under the Nasdaq Listing Rules). Each compensation committee member must also be deemed by our Board of Directors to meet the enhanced independence requirements for members of the compensation committee under the Nasdaq Listing Rules, which requires, among other things, that our Board consider the source of each such committee member’s compensation in considering whether he or she is independent.

The Compensation Committee composition requirements referred to under Section 118A of the Companies Law are not applicable to the Company as the Board of Directors, as part of its decision to opt out of the requirement to elect external directors, also adopted relief from such composition requirements on the basis that the Company complies, and will continue to comply, with the Nasdaq majority board independence requirement and with US Securities Law and Nasdaq Listing Rules concerning the composition of the compensation committee.

We have a Compensation Committee consisting of three directors, Mr. Sanford (Sandy) Zweifach, who serves as the chairman of our Compensation Committee, Dr. Kinneret Livnat Savitzky and Dr. Arie Ovadia. Each member of our Compensation Committee is an ‘independent director’ in accordance with the Nasdaq listing standards.

Nomination and Corporate Governance Committee

The Nasdaq Listing Rules require that director nominees be selected or recommended for the board’s selection either by a nomination committee composed solely of independent directors, or by a majority of independent directors, in a vote in which only independent directors participate, subject to certain exceptions. Mr. Paul Sekhri, who serves as the chairman of our Nomination and Corporate Governance Committee, Dr. Kinneret Livnat Savitzky and Mr. Sanford (Sandy) Zweifach, each an independent director, are the members of our Nomination and Corporate Governance Committee, which, among other responsibilities, recommends director nominees for our board’s approval.

Internal Auditor

Under the Companies Law, the board of directors must appoint an internal auditor, recommended by the audit committee. The role of the internal auditor is to examine, among other matters, whether the company's actions comply with the law and orderly business procedures. Under the Companies Law, an interested party or an Office Holder of a company, or a relative of an interested party or of an Office Holder of a company, as well as the company's independent auditors or any one on behalf of the independent auditors may not serve as a company's internal auditor. The internal auditor's tenure cannot be terminated without his or her consent, nor can he or she be suspended from such position unless the board of directors has so resolved after hearing the opinion of the audit committee and after providing the internal auditor with the opportunity to present his or her position to the board of directors and to the audit committee. An interested party is defined in the Companies Law as a holder of 5% or more of the company's outstanding shares or voting rights, any person or entity who has the right to designate one or more directors or the chief executive officer of the company or any person who serves as a director or as a chief executive officer of the company.

Ms. Hila Barr of Brightman Almagor Zohar & Co., a member firm of Deloitte Touche Tohmatsu, serves as our internal auditor since 2010. Ms. Hila Barr is not an employee, affiliate or Office Holder of the Company, or affiliated with the Company's independent auditors.

Fiduciary Duties and Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Office Holders

The Companies Law codifies the fiduciary duties that office holders owe to a company. All but one person listed in the table under "Item 6. Directors, Senior Management and Employees – A. Directors and Senior Management" are Office Holders. In addition to those persons listed in the table under Item 6.A, two other individuals were Office Holders as of December 31, 2018.

An Office Holders' fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an Office Holder to act with the standard of skills with which a reasonable Office Holder in the same position would have acted under the same circumstances. The duty of care includes a duty to use reasonable means to obtain:

- information regarding the business advisability of a given action brought for the Office Holder's approval or performed by the Office Holder by virtue of his or her position; and
- all other information of importance pertaining to the aforesaid actions.

The duty of loyalty requires an Office Holder to act in good faith and for the benefit of the company and includes the duty to:

- refrain from any act involving a conflict of interest between the fulfillment of his or her position in the company and the fulfillment of any other position or his or her personal affairs;
- refrain from any act that is competitive with the business of the company;
- refrain from exploiting any business opportunity of the company with the aim of obtaining a personal gain for himself or herself or for others; and
- disclose to the company all relevant information and provide it with all documents relating to the company's affairs which the Office Holder obtained due to his or her position in the company.

Disclosure of Personal Interests of Office Holders and Approval of Certain Transactions

The Companies Law requires that an Office Holder promptly disclose to the company any personal interest that the Office Holder may have and all related material information known to him or her, in connection with any existing or proposed transaction by the company. In addition, if the transaction is an extraordinary transaction, as defined under Israeli law, the Office Holder must also disclose any personal interest held by the Office Holder's spouse, siblings, parents, grandparents, descendants, spouse's descendants and the spouses of any of the foregoing (a "Relative"). In addition, the Office Holder must also disclose any interest held by any corporation in which the Office Holder: (i) holds at least 5% of the company's outstanding share capital or voting rights; (ii) is a director or general manager; or (iii) has the right to appoint at least one director or the general manager. An extraordinary transaction is defined as a transaction which is either not in the ordinary course of business, not on market terms, or likely to have a material impact on the company's profitability, assets or liabilities.

Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction in which an Office Holder has a personal interest and which is not an extraordinary transaction, requires Board approval, after the Office Holder complies with the above disclosure requirement and provided the transaction is not adverse to the company's interest. Our Articles do not provide for a different method of approval. Furthermore, if the transaction is an extraordinary transaction, then, in addition to any approval stipulated by the articles of association, it also must be approved by the company's audit committee and then by the board of directors, and, under certain circumstances, by the shareholders of the company.

A person with a personal interest in any matter may not generally be present at any audit committee, compensation committee or board of directors meeting where such matter is being considered, and if he or she is a member of the committee or a director, he or she may not generally vote on such matter at the applicable meeting.

Disclosure of Personal Interest of Controlling Shareholders and Approval of certain Transactions

The Companies Law extends the disclosure requirements applicable to an Office Holder to a 'controlling shareholder' in a public company. For this purpose, a 'controlling shareholder' is a shareholder who has the ability to direct the activities of a company, including a shareholder or a group of shareholders who together own 25% or more of the voting rights if no other shareholder holds more than 50% of the voting rights.

Extraordinary transactions of a public company with a controlling shareholder or in which a controlling shareholder has a personal interest, as well as any engagement by a public company of a controlling shareholder or of such controlling shareholder's Relative, directly or indirectly, with respect to the provision of services to the company, and, if such person is also an Office Holder of such company, with respect to such person's Terms of Office and Employment as an Office Holder, and if such person is an employee of the company but not an Office Holder, with respect to such person's employment by the company, generally require the approval of each of the audit committee (or with respect to Terms of Office and Employment the compensation committee), the board of directors and the shareholders of the company, in that order. The shareholder approval must fulfill one of the following requirements: (i) it received the positive vote of at least a majority of the voting rights in the company who are present and voting in the meeting and held by shareholders who do not have a personal interest in the transaction; (abstentions are disregarded) or (ii) the voting rights held by shareholders who have no personal interest in the transaction and who have voted against the transaction, do not exceed two percent of the voting rights in the company.

Any extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest with a term of more than three years generally need to be brought for re-approval in accordance with the above procedure every three years, unless the audit committee determined that the duration of the transaction is reasonable given the circumstances related thereto and has been approved by the shareholders for such longer duration.

Pursuant to regulations promulgated under the Companies Law, certain transactions with a controlling shareholder or his or her Relative, or with directors, that would otherwise require approval of a company's shareholders may be exempt from shareholder approval upon certain determinations of the audit committee or the compensation committee and board of directors.

For information concerning the direct and indirect personal interests of certain of our Office Holders and principal shareholders in certain transactions with us, see "Item 7. Major Shareholders and Related Party Transactions – B. Related Party Transactions."

Shareholders Duties

Pursuant to the Companies Law, a shareholder has a duty to: (i) act in good faith in fulfilling his obligations towards the company and the other shareholders; and (ii) refrain from abusing his or her power with respect to the company, including, when voting at a general meeting with respect to the following matters: (a) an amendment to the company's articles of association; (b) an increase of the company's authorized share capital; (c) a merger; or (d) interested party transactions that require shareholders' approval.

In addition, any controlling shareholder, any shareholder who knows that it possesses power to determine the outcome of a shareholder vote and any shareholder who, pursuant to the provisions of a company's articles of association has the power to appoint or prevent the appointment of an office holder in the company is under a duty of fairness towards the company. The Companies Law does not describe the substance of such duty of fairness but states that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty of fairness, taking into account such shareholder's position.

Approval of Significant Private Placement

Under the Companies Law, a significant private placement of securities requires approval by the board of directors and the shareholders by a simple majority. A private placement is considered a significant private placement if it results in a person becoming a controlling shareholder, or if all of the following conditions are met: the securities issued amount to 20% or more of the company's outstanding voting rights before the issuance; some or all of the consideration is other than cash or listed securities or the transaction is not on market terms; and the transaction will increase the relative holdings of a shareholder who holds 5% or more of the company's outstanding share capital or voting rights or will cause any person to become, as a result of the issuance, a holder of more than 5% of the company's outstanding share capital or voting rights.

D. EMPLOYEES

The following table sets out the number of our full-time employees engaged in specified activities, at the end of the fiscal years 2018, 2017 and 2016 (the numbers include employees of our wholly owned U.S. subsidiary Compugen USA, Inc.):

	December 31, 2018	December 31, 2017	December 31, 2016
Research & Development	66	78	74
Administration, Accounting and Operations	21	20	21
Marketing and Business Development	2	3	3
Total	89	101	98

In addition to the headquarters in Holon, Israel, we maintain a subsidiary in South San Francisco, California where our mAb research and development operation was located until the 2019 Restructuring, when we announced that the research and development activities are being consolidated in one location in Israel. For the year ended December 31, 2016, 66 of our employees were located in Israel and 32 were located in the U.S. and for the year ended December 31, 2017, 71 of our employees were located in Israel and 30 were located in the U.S. and for the year ended December 31, 2018, 61 of our employees were located in Israel and 28 were located in the U.S.

We consider our relations with our employees to be satisfactory and we have not experienced a significant labor dispute or strike. We are not a party to any collective bargaining agreement with respect to our Israeli employees. However, we are subject to certain labor related statutes and to certain provisions of collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordinating Bureau of Economic Organizations and/or the Industrialists' Association, which are applicable to our Israeli employees by virtue of expansion orders of the Israeli Minister of the Economy. These statutes and provisions cover a wide range of subjects and provide certain minimum employment standards, including the length of the work day and work week, minimum wages, travel expenses, contributions to a pension fund, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay, annual and other vacations, sick pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimum. An additional provision applicable to all employees in Israel under collective bargaining agreements and expansion orders is the automatic adjustment of wages in relation to increases in the Israeli CPI. The amount and frequency of these adjustments are modified from time to time; however, no such adjustments have been made in recent years pursuant to expansion orders.

Our severance pay liability to our Israeli employees, based upon the number of years of service and the latest monthly salary, is in the large part covered by regular deposits with recognized pension funds, deposits with severance pay funds and purchases of insurance policies. Pursuant to Section 14 of the Israeli Severance Pay Law 5723-1963, certain of our liabilities for employee severance rights upon termination are covered by regular contributions to defined contribution plans so that upon termination of employment of the relevant employees, we are only required to release the payments made by us to such funds on account of severance and by doing so are deemed to have complied with all of our severance payment obligations relating to the service of applicable employees with respect to the period during which the provisions of such section apply. For information concerning our liability for severance pay, see Note 2m to our 2018 consolidated financial statements.

Our employees are not represented by a labor union. We have written employment contracts (including signed offers of employment) with each of our employees.

E. SHARE OWNERSHIP

Share Ownership by Directors and Other Executive Officers

All of the persons listed above under the caption “Directors and Senior Management” own ordinary shares of the Company and/or options to purchase ordinary shares of the Company. Except as set forth in the table below, none of the directors or executive officers beneficially owns ordinary shares and/or ordinary shares underlying options amounting to 1% or more of the outstanding ordinary shares. The following table sets forth certain information as of March 1, 2019, regarding the beneficial ownership by our directors and senior management. All numbers quoted in the table are inclusive of options to purchase shares that are exercisable within 60 days after March 1, 2019. The shares that may be issued under these options are deemed to be outstanding for the purpose of computing the percentage of ownership of such individual or group but are not deemed to be outstanding for the purpose of computing the percentage of ownership of the other individual or group shown in the table. The information in this table is based on 59,902,172 ordinary shares outstanding as of March 1, 2019.

Beneficial Owner	Amount Owned	Percent of Class
Anat Cohen-Dayag ⁽¹⁾	1,098,622	1.80%
All directors and executive officers as a group (14 persons) ⁽²⁾	2,542,753	4.08%

⁽¹⁾ Includes (i) 96,122 shares held by Dr. Cohen-Dayag and (ii) 1,002,500 shares subject to options that are exercisable within 60 days after March 1, 2019 with a weighted average exercise price of \$4.91 per share, and which expire between July 2019 and August 2027.

⁽²⁾ See Note 1 above. Also includes (i) a total of 2,422,831 shares subject to options that are beneficially owned by directors and executive officers that are exercisable within 60 days after March 1, 2019 with a weighted average exercise price of \$5.09 per share and which expire between July 2019 and October 2027 and (ii) a total of 119,922 ordinary shares held by directors and executive officers.

Share Option Plans

We maintain one active share option plan, plus one additional share option plan under which prior grants remain outstanding, for our employees, directors and consultants. In addition to the discussion below, see Note 7 to our 2018 consolidated financial statements.

Our Board of Directors administered our share option plans until February 2014 and as of such date our Compensation Committee administers our share option plans and has the authority to designate terms of the options granted under our plans including the grantees, exercise prices, grant dates, vesting schedules and expiration dates, which may be no more than ten years after the grant date. Options may not be granted with an exercise price of less than the fair market value of our ordinary shares on the date of grant, unless otherwise determined by our Board of Directors. The administration of our share option plans by the Compensation Committee is subject to applicable law (including with respect to the required approval procedure of compensation to Office Holders under the Companies Law (for additional information on the approval procedure of compensation to Office Holders, see “Item 6. Directors, Senior Management and Employees – B. Approval Required for Directors’ and Officers’ Compensation”).

Compugen Share Option Plan (2000)

The Compugen Share Option Plan (2000), or the “2000 Option Plan,” enabled granting options for up to an aggregate of 10,191,511 ordinary shares of the Company to our and our subsidiaries’ employees, directors and consultants. No further options are being granted under this plan following a July 25, 2010 decision of our Board of Directors which resolved to cancel the 2000 Option Plan. As of December 31, 2018, options to purchase 753,249 ordinary shares at a weighted average exercise price of approximately \$3.87 per share were outstanding (i.e., were granted but not canceled, expired or exercised) under the 2000 Option Plan. Options to purchase 6,775,775 ordinary shares under the 2000 Option Plan have previously been exercised at a weighted average exercise price of approximately \$2.58.

Compugen 2010 Share Incentive Plan

On July 25, 2010, our Board of Directors adopted the Compugen 2010 Share Incentive Plan or the “2010 Plan”. The adoption of the 2010 Plan was approved by our shareholders on May 12, 2011. In addition, the Board of Directors and shareholders resolved that the options available for grants under the 2000 Option Plan, at such time, as well as any options that may return to such pool in connection with terminated options, will be made available for future grants under the 2010 Plan. 10,133,931 shares are reserved for grant under the 2010 Plan. In keeping with our Board of Directors’ and shareholders’ resolutions any shares subject to options granted under the 2000 Option Plan prior to the adoption of the 2010 Plan which terminate unexercised, will also be made available for future grants under the 2010 Plan. Subject to applicable law, our Board of Directors may amend the 2010 Plan, provided that any action by our Board of Directors which will alter or impair the rights or obligations of an option holder requires the prior consent of that option holder. Our Board of Directors last amended the 2010 Plan in August 2017, to increase the number of shares available thereunder. See “Item 16G. Corporate Governance.”

If a grantee leaves his or her employment or other relationship with us, or if his or her relationship with us is terminated without cause (and other than by reason of death or disability, as defined in the 2010 Plan), the term of his or her unexercised options will generally expire in 90 days, unless determined otherwise by our Board of Directors. As of December 31, 2018, options to purchase 8,217,189 ordinary shares at a weighted average exercise price of approximately \$4.85 per share were outstanding (i.e., were granted but not canceled, expired or exercised) under the 2010 Plan. Options to purchase 840,209 ordinary shares under the 2010 Plan have previously been exercised at a weighted average exercise price of approximately \$4.58. Options to purchase 1,076,533 ordinary shares remain available for future grant as of December 31, 2018.

Administration of our Share Options Plans

Our Board of Directors has elected the “Capital Gains Track” (as defined in Section 102(b) (2) of the Tax Ordinance) for the grant of options to Israeli grantees.

Pursuant to Section 102 of the Tax Ordinance, and pursuant to an election made by the Company thereunder, gains derived by employees (which term includes directors) in Israel arising from the sale of shares acquired pursuant to the exercise of options granted to them through a trustee under Section 102 of the Tax Ordinance after January 1, 2003, will generally be subject to a flat capital gains tax rate of 25%, although these gains, or part of them, may under certain circumstances also be considered part of an employee’s regular salary and subject to such employee’s regular tax rate applicable to such salary. As a result of this election under Section 102, the Company will not, in the case of equity awards made on or after January 1, 2003, be allowed to claim as an expense for tax purposes in Israel the amounts credited to the employee as capital gains, although it will generally be entitled to do so in respect of the salary income component (if any) of such awards when the related tax is paid by the employee.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. MAJOR SHAREHOLDERS

The following table sets forth share ownership information as of March 1, 2019 (unless otherwise noted below) with respect to each person who is known by us to be the beneficial owner of more than 5% of our outstanding ordinary shares. The information contained in the table below has been obtained from the Company's records or from information furnished by an individual or entity to the Company or disclosed in public filings with the SEC. Except where otherwise indicated, and except pursuant to community property laws, we believe, based on information furnished by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares. As of March 1, 2019, there were a total of 44 holders of record of our ordinary shares, of which 29 were registered with addresses in the United States. Such United States holders were, as of such date, the holders of record of approximately 99.9% of the outstanding ordinary shares. Our ordinary shares are traded on the Nasdaq Global Market in the United States and on the TASE in Israel. A significant portion of our shares are held in street name, therefore we cannot determine who our shareholders are, their geographical location or how many shares a particular shareholder owns.

Total "Number of Ordinary Shares Beneficially Owned" in the table below include shares that may be acquired by an individual or group upon the exercise of options that are either currently exercisable or will become exercisable within 60 days of March 1, 2019.

The shareholders listed below do not have any different voting rights from any of our other shareholders.

Beneficial Owner	Number of Ordinary Shares Beneficially Owned	Percent of Ordinary Shares Beneficially Owned ⁽¹⁾
ARK Investment Management LLC ⁽²⁾	7,105,958	11.86%

(1) Based upon 59,902,172 ordinary shares issued and outstanding as of March 1, 2019.

(2) Based upon information provided by the shareholder in its Form 13G filed with the SEC on February 14, 2019. With respect to the ordinary shares reported in the Schedule 13G, ARK Investment Management LLC (ARK) is indicated as having (i) sole voting and dispositive power with respect to 6,906,103 ordinary shares, (ii) shared voting power with respect to 56,726 ordinary shares and (iii) shared dispositive power with respect to 199,855 ordinary shares. Furthermore, in such filing ARK indicated aggregate beneficial ownership of 7,105,958 ordinary shares. The address of the principal business office of ARK Investment Management LLC is 3 East 28th Street, 7th Floor, New York, NY 10016.

B. RELATED PARTY TRANSACTIONS

Other than as set forth below and transactions related to compensation of our executive officers and directors as described under "Item 6. Directors, Senior Management and Employees — B. Compensation," since January 1, 2019, we have not entered into any related party transactions.

Indemnification Agreements

Our Articles permit us to exculpate, indemnify and insure our Office Holders to the fullest extent permitted by the Companies Law. Accordingly, we release our Office Holders from liability and indemnify them to the fullest extent permitted by law, and provide them with letters of indemnification and exemption and release for this purpose, in the form approved at a Special General Meeting of the shareholders which took place in September 2013. Under the letters of indemnification and exemption and release, (i) Compugen's undertaking to indemnify each Office Holder for monetary liabilities or obligations imposed by a court judgment (including a settlement or an arbitrator's award approved by a court) shall be limited to matters that result from or are connected to those events or circumstances set forth therein, and (ii) the indemnification that the Company undertakes towards all persons whom it resolved to indemnify for the matters and circumstances described therein, jointly and in the aggregate, shall not exceed \$5 million.

Our Office Holders are also covered by directors' and officers' liability insurance. For more information see "Item 6. Directors, Senior Management and Employees — B. Compensation – Insurance, Indemnification and Exemption."

C. INTERESTS OF EXPERTS AND COUNSEL

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

Consolidated Financial Statements

Our consolidated financial statements are included beginning on page F-1 of this annual report. See also "Item 18. Financial Statements."

Legal Proceedings

Currently, we are not a party to any legal or arbitration proceedings, including governmental proceedings that are pending or known to be contemplated, that our management believes, individually or in the aggregate, may have, or have had in the recent past, a significant effect on our financial position or profitability, nor are we party to any material proceeding in which any director, member of our senior management or affiliate is a party adverse to us or our subsidiaries or has a material interest adverse to us or our subsidiaries.

Dividend Distribution Policy

We have never paid any cash dividends on our ordinary shares, and we do not intend to pay cash dividends on our ordinary shares in the foreseeable future. Our current policy is to retain earnings for use in our business.

In the event that we decide to pay a cash dividend from income that is tax exempt under our Approved Enterprises and/or Benefiting Enterprises programs, we would be required to pay the applicable corporate tax that would otherwise have been payable on such income which would be in addition to the tax payable by the dividend payee. See Note 8 to our 2018 consolidated financial statements and "Item 10. Additional Information – E. Taxation."

B. SIGNIFICANT CHANGES

Not applicable.

ITEM 9. THE OFFER AND LISTING**A. OFFER AND LISTING DETAILS**

Our ordinary shares were listed on The Nasdaq Global Market through June 16, 2009. On June 17, 2009, we transferred the listing of our ordinary shares from The Nasdaq Global Market to The Nasdaq Capital Market, and on January 27, 2014 we transferred the listing of our ordinary shares from The Nasdaq Capital Market back to The Nasdaq Global Market. The high and low sales prices per share of our ordinary shares for the periods indicated are set forth below:

<u>Year Ended</u>	<u>High</u>	<u>Low</u>
December 31, 2014	\$ 14.32	\$ 6.27
December 31, 2015	\$ 9.65	\$ 4.64
December 31, 2016	\$ 7.57	\$ 4.32
December 31, 2017	\$ 5.40	\$ 2.25
December 31, 2018	\$ 5.00	\$ 2.00
<u>Quarter Ended</u>		
March 31, 2017	\$ 5.40	\$ 4.20
June 30, 2017	\$ 5.40	\$ 3.50
September 30, 2017	\$ 4.25	\$ 2.60
December 31, 2017	\$ 4.15	\$ 2.25
March 31, 2018	\$ 4.73	\$ 2.43
June 30, 2018	\$ 5.00	\$ 3.10
September 30, 2018	\$ 4.10	\$ 3.00
December 31, 2018	\$ 4.00	\$ 2.00
<u>Month Ended</u>		
September 30, 2018	\$ 4.10	\$ 3.65
October 31, 2018	\$ 4.00	\$ 2.76
November 30, 2018	\$ 3.59	\$ 2.90
December 31, 2018	\$ 3.59	\$ 2.00
January 31, 2019	\$ 3.68	\$ 2.17
February 28, 2019	\$ 3.86	\$ 2.95

The high and low sales prices per share of our ordinary shares on the Tel Aviv Stock Exchange for the periods indicated are set forth below. The currency in which our shares are traded on the Tel Aviv Stock Exchange is the New Israeli Shekel, or NIS. The below dollar amounts represent a conversion from NIS to dollar amounts in accordance with the dollar NIS conversion rate as of the relevant date.

<u>Year Ended</u>	<u>High*</u>	<u>Low*</u>
December 31, 2014	\$ 13.48	\$ 6.40
December 31, 2015	\$ 9.66	\$ 4.59
December 31, 2016	\$ 7.38	\$ 4.31
December 31, 2017	\$ 5.32	\$ 2.36
December 31, 2018	\$ 4.66	\$ 2.12

<u>Quarter Ended</u>		
March 31, 2017	\$ 5.32	\$ 4.18
June 30, 2017	\$ 5.37	\$ 3.52
September 30, 2017	\$ 3.99	\$ 2.76
December 31, 2017	\$ 3.95	\$ 2.36
March 31, 2018	\$ 4.66	\$ 2.41
June 30, 2018	\$ 4.55	\$ 3.13
September 30, 2018	\$ 4.07	\$ 3.03
December 31, 2018	\$ 4.07	\$ 2.12

<u>Month Ended</u>		
September 30, 2018	\$ 4.07	\$ 3.64
October 31, 2018	\$ 4.07	\$ 2.93
November 30, 2018	\$ 3.51	\$ 3.03
December 31, 2018	\$ 3.56	\$ 2.12
January 31, 2019	\$ 3.67	\$ 2.17
February 28, 2019	\$ 3.86	\$ 3.14

B. PLAN OF DISTRIBUTION

Not applicable

C. MARKETS

Our ordinary shares are traded in the United States on The Nasdaq Global Market and in Israel on the Tel Aviv Stock Exchange (TASE).

D. SELLING SHAREHOLDERS

Not applicable

E. DILUTION

Not applicable

F. EXPENSES OF THE ISSUE

Not applicable

ITEM 10. ADDITIONAL INFORMATION

A. SHARE CAPITAL

Not applicable

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

Set forth below is a summary of certain provisions of our Memorandum of Association (“Memorandum”) and our Articles. This description does not purport to be complete and is qualified in its entirety by reference to the full text of our Memorandum and Articles.

Objects and Purposes

We are incorporated under the Companies Law under the name Compugen Ltd. Our Memorandum was registered in 1993, and was amended by our shareholders at our 2014 Annual General Meeting. At our 2017 Annual General Meeting, the shareholders adopted and restated the Articles. The purpose of the Company as stated in our incorporation documents is to engage in any lawful act or activity for which companies may be organized under the Companies Law.

Rights Attached To Our Shares

Our authorized share capital is NIS 1,000,000 divided into 100,000,000 ordinary shares of nominal (par) value NIS 0.01 each.

Subject to our Articles, fully paid ordinary shares of the Company confer on the holders thereof rights to attend and to vote at general meetings of the shareholders. Subject to the rights of holders of shares with limited or preferred rights which may be issued in the future, the ordinary shares of the Company confer upon the holders thereof equal rights to receive dividends and to participate in the distribution of the assets of the Company upon its winding-up, in proportion to the amount paid up or credited as paid up on account of the nominal value of the shares held by them respectively and in respect of which such dividends are being paid or such distribution is being made, without regard to any premium paid in excess of the nominal value, if any. No preferred shares are currently authorized. All outstanding ordinary shares are validly issued and fully paid.

Voting Rights

Subject to the provisions of our Articles, holders of ordinary shares have one vote for each ordinary share held by such shareholder of record, on all matters submitted to a vote of shareholders. Shareholders may vote in person, by proxy or by proxy card. Alternatively, shareholders who hold shares through members of the Tel Aviv Stock Exchange may vote electronically via the electronic voting system of the Israel Securities Authority ("Electronic Vote"). These voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future. As our ordinary shares do not have cumulative voting rights in the election of directors, the holders of the majority of the shares present and voting at a shareholders meeting generally have the power to elect all of our directors, except the external directors whose election requires a special majority.

Transfer of Shares

Our ordinary shares which have been fully paid-up are transferable by submission of a proper instrument of transfer together with the certificate of the shares to be transferred and such other evidence of title, as the Board of Directors may require, unless such transfer is prohibited by another instrument or by applicable securities laws.

Dividends

Under the Companies law, dividends may be distributed only out of profits available for dividends as determined by the Companies Law, provided that there is no reasonable concern that the distribution will prevent the Company from being able to meet its existing and anticipated obligations when they become due. If the company does not meet the profit requirement, a court may nevertheless allow the company to distribute a dividend, as long as the court is convinced that there is no reasonable concern that such distribution will prevent the company from being able to meet its existing and anticipated obligations when they become due. Pursuant to our Articles, no dividend shall be paid otherwise than out of the profits of the Company. Generally, under the Companies Law, the decision to distribute dividends and the amount to be distributed is made by a company's board of directors.

Our Articles provide that our Board of Directors, may, subject to the Companies Law, from time to time, declare and cause the Company to pay such dividends as may appear to the Board of Directors to be justified by the profits of our Company. Subject to the rights of the holders of shares with preferential, special or deferred rights that may be authorized in the future, our profits which shall be declared as dividends shall be distributed according to the proportion of the nominal (par) value paid up or credited as paid up on account of the shares held at the date so appointed by the Company and in respect of which such dividend is being paid, without regard to the premium paid in excess of the nominal (par) value, if any. The declaration of dividends does not require shareholders' approval.

To date, we have not declared or distributed any dividend and we do not intend to pay cash dividends on our ordinary shares in the foreseeable future.

Liquidation Rights

In the event of our winding up on liquidation or dissolution, subject to applicable law, our assets available for distribution among the shareholders shall be distributed to the holders of ordinary shares in proportion to the amount paid up or credited as paid up on account of the nominal value of the shares held by them respectively and in respect of which such distribution is being made, without regard to any premium paid in excess of the nominal value, if any. This liquidation right may be affected by the grant of limited or preferential rights as to liquidation to the holders of a class of shares that may be authorized in the future.

Redemption Provisions

We may, subject to applicable law and to our Articles, issue redeemable shares and redeem the same upon such terms and conditions as determined by our Board of Directors.

Capital Calls

Under our Articles, the liability of each shareholder for the Company's obligations is limited to the unpaid sum, if any, owing to the Company in consideration for the issuance of the shares held by such shareholder.

Modification of Class Rights

Our Memorandum provides that we may amend the Memorandum in order to increase, consolidate or divide or otherwise amend our share capital by a simple majority of the voting power present at a shareholders meeting as currently provided in our Articles or by such other majority as shall be set forth in our Articles from time to time.

Pursuant to our Articles, if at any time our share capital is divided into different classes of shares, the rights attached to any class, unless otherwise provided by our Articles, may be modified or abrogated by the Company, subject to the consent in writing of, or sanction of a resolution passed by, the holders of a majority of the issued shares of such class at a separate general meeting of the holders of the shares of such class.

Limitations on the Rights to Own Securities

Our Articles and Israeli law do not restrict the ownership or voting of ordinary shares by non-residents or persons who are not citizens of Israel, except with respect to subjects of nations which are in a state of war with Israel.

Changes in Capital

Our Articles enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by a simple majority of our shareholders at a general meeting by voting on such change in the capital.

Shareholders Meetings and Resolutions

Our Articles provide that our annual general meeting shall be held once in every calendar year at such time (within a period of not more than fifteen months after the last preceding annual general meeting), and place determined by our Board of Directors. Our Board of Directors may, in its discretion, convene additional special shareholders meetings and, pursuant to the Companies Law, must convene a meeting upon the demand of: (a) two directors or one quarter of the directors in office; or (b) the holder or holders of (i) 5% or more of the Company's issued share capital and one percent or more of its voting rights; or (ii) 5% or more of the Company's voting rights. All demands for shareholders meetings must set forth the items to be considered at that meeting.

The chairman of the Board of Directors, or any other director or office holder of the Company which may be designated for this purpose by the Board of Directors, shall preside as chairman at each of our general meetings. If there is no such chairman, or if the appointed chairman is unwilling to take the chair, or if he shall have indicated in advance that he will not be attending, or if at any meeting such chairman is not present within thirty (30) minutes after the time fixed for holding the meeting, then those present at the meeting shall choose someone present to be chairman of the meeting. The office of chairman shall not, by itself, entitle the holder thereof to vote at any general meeting nor shall it entitle a second or casting vote.

According to regulations promulgated pursuant to the Companies Law and governing the terms of notice and publication of shareholder meetings of public companies (the “General Meeting Regulations”), holder(s) of one percent or more of the Company’s voting rights may propose any matter appropriate for deliberation at a shareholder meeting to be included on the agenda of a shareholder meeting, generally by submitting a proposal within seven days of publicizing the convening of a shareholder meeting, or, if the Company publishes a preliminary notice at least 21 days prior to publicizing the convening of a meeting, stating its intention to convene such meeting and the agenda thereof, within fourteen days of such preliminary notice. Any such proposal must further comply with the information requirements under applicable law and the Articles. The agenda for a shareholder meeting is determined by the Board of Directors and must include matters in respect of which the convening of a shareholder meeting was demanded and any matter requested to be included by holder(s) of one percent of the Company’s voting rights, as detailed above.

Pursuant to the Companies Law and the General Meeting Regulations shareholder meetings generally require prior notice of not less than 21 days, and not less than 35 days in certain cases. Pursuant to the Articles, we are not required to deliver or serve notice of a general meeting or of any adjournments thereof to any shareholder. However, subject to applicable law and stock exchange rules and regulations, we will publicize the convening of a general meeting in any manner reasonably determined by us, and any such publication shall be deemed duly made, given and delivered to all shareholders on the date on which it is first made, posted, filed or published in the manner so determined by us in our sole discretion.

The function of the annual general meeting is to elect directors, receive and consider the profit and loss account, the balance sheet and the ordinary reports and accounts of the directors and auditors, appoint auditors and transact any other business which under our Articles or applicable law may be transacted by the shareholders of the Company in a general meeting.

Pursuant to our Articles, the quorum required for a meeting of shareholders consists of at least two shareholders, present in person, by proxy, by proxy card or by electronic voting, and holding shares conferring in the aggregate twenty-five percent (25%) or more of the voting power of the Company. If within half an hour from the time appointed for the meeting a quorum is not present, the meeting, shall stand adjourned to the same day in the following week at the same time and place or to such other later day, time and place as the Board of Directors may determine. At the adjourned meeting, any number of participants will constitute a quorum present, in person, by proxy, by proxy card or by electronic voting; provided, however, that Special General Meeting which was convened by the Board upon the demand of shareholders or Directors then in office, or directly by such shareholders or Directors, in accordance the terms of the Companies Law, shall be cancelled.

Generally, under the Companies Law and our Articles, shareholder resolutions are deemed adopted if approved by the holders of a simple majority of the voting rights represented at the meeting, in person, by proxy, by proxy card or by electronic voting, and voting on the matter, unless a different majority is required by law or pursuant to the Articles such as a resolution for the voluntary winding up of our Company which requires the approval of holders of 75% of the voting power presented and voting at the meeting.

Change of Control

Merger

Under the Companies Law, a merger is generally required to be approved by the shareholders and board of directors of each of the merging companies. If the share capital of the company that will not be the surviving company is divided into different classes of shares, the approval of each class is also required, unless determined otherwise by the court. Similarly, unless an Israeli court determines otherwise, a merger will not be approved if it is objected to by shareholders holding a majority of the voting rights participating and voting at the meeting (abstentions are disregarded), after excluding the shares held by the other party to the merger, by any person who holds 25% or more of the other party to the merger or by anyone on their behalf, including by the relatives of, or corporations controlled by, these persons.

In approving a merger, the board of directors of both merging companies must determine that there is no reasonable concern that, as a result of the merger, the surviving company will not be able to satisfy its obligations to its creditors. Similarly, upon the request of a creditor of either party to the proposed merger, an Israeli court may prevent or delay the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will not be able to satisfy the obligations of the merging parties. A court may also issue other instructions for the protection of the creditors’ rights in connection with a merger. Further, a merger may not be completed unless at least (i) 50 days have passed from the time that the requisite proposals for the approval of the merger were filed with the Israeli registrar of companies; and (ii) 30 days have passed since the merger was approved by the shareholders of each party.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This rule does not apply if there is already another holder of 25% or more of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company. These requirements do not apply if the acquisition (i) occurs in the context of a private placement by the company that received shareholder approval, (ii) was from a shareholder holding 25% or more of the voting rights in the company and resulted in the acquirer becoming a holder of 25% or more of the voting rights in the company, or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered in the offer exceeds the number of shares whose holders objected to the offer (excluding controlling shareholders, holders of 25% or more of the voting rights in the company and any person having a personal interest in the acceptance of the tender offer).

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer, or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention. An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer is accepted, then shareholders who did not respond to or that had objected the offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Full Tender Offer

Under the Companies Law, a person may not acquire shares in a public company if, after the acquisition, the acquirer will hold more than 90% of the shares or more than 90% of any class of shares of that company, unless a tender offer is made to purchase all of the shares or all of the shares of the particular class. The Companies Law also generally provides that as long as a shareholder in a public company holds more than 90% of the company's shares or of a class of shares, that shareholder shall be precluded from purchasing any additional shares. In order for all of the shares that the purchaser offered to purchase be transferred to him by operation of law, one of the following needs to have occurred: (i) the shareholders who declined or do not respond to the tender offer hold less than 5% of the company's outstanding share capital or of the relevant class of shares and the majority of offerees who do not have a personal interest in accepting the tender offer accepted the offer, or (ii) the shareholders who declined or do not respond to the tender offer hold less than 2% of the company's outstanding share capital or of the relevant class of shares.

A shareholder that had his or her shares so transferred, whether he or she accepted the tender offer or not, has the right, within six months from the date of acceptance of the tender offer, to petition the court to determine that the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, the purchaser may provide in its offer that shareholders who accept the tender offer will not be entitled to such rights.

If the conditions set forth above are not met, the purchaser may not acquire additional shares of the company from shareholders who accepted the tender offer to the extent that following such acquisition, the purchaser would own more than 90% of the company's issued and outstanding share capital. The above restrictions apply, in addition to the acquisition of shares, to the acquisition of voting power.

C. MATERIAL CONTRACTS

Please see "Item 4. Information on the Company — B. Business Overview — Business Strategy and Partnerships — Bayer Collaboration, — Bristol-Myers Collaboration, — MedImmune License" and "Item 5. Operating and Financial Review and Prospects Finance – B. Liquidity and Capital Resources" for a discussion of our material contracts.

D. EXCHANGE CONTROLS

There are currently no exchange controls in effect in Israel that restrict the repatriation by non-residents of Israel in non-Israeli currency of any dividends, if any are declared and paid, and liquidation distributions or the Company's ability to import and export capital.

E. TAXATION

The following is a brief summary of certain material tax consequences concerning the ownership and disposition of our ordinary shares by purchasers or holders of our ordinary shares. Because parts of this discussion are based on new or existing tax or other legislation that has not been subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will be accepted by the tax or other authorities in question. The summary below does not address all of the tax consequences that may be relevant to all purchasers or holders of our ordinary shares in light of each purchaser's or holder's particular circumstances and specific tax treatment. For example, the summary below does not address the tax treatment of residents of Israel and traders in securities who are subject to specific tax regimes. As individual circumstances may differ, holders of our ordinary shares should consult their own tax advisors as to United States, Israeli or other tax consequences of the purchase, ownership and disposition of our ordinary shares. This discussion is not intended, nor should it be construed, as legal or professional tax advice and it is not exhaustive of all possible tax considerations. Each individual should consult his or her own tax or legal advisor.

Israeli Taxation

Taxation of Capital Gains Applicable to Non-Israeli Shareholders

Israeli law generally imposes a capital gains tax on the sale of securities of an Israeli company traded on the TASE, on an authorized stock exchange outside Israel or on a regulated market (which includes a system through which securities are traded pursuant to rules prescribed by the competent authority in the relevant jurisdiction) in or outside Israel (a "Recognized Exchange"). Pursuant to amendments to the Tax Ordinance, effective as of January 1, 2012, the capital gains tax rate applicable to individuals upon the sale of such securities is such individual's marginal tax rate but not more than 25%, or 30% with respect to an individual who meets the definition of a 'Substantial Shareholder' on the date of the sale of the securities or at any time during the 12 months preceding such date. A 'Substantial Shareholder' is defined as a person who, either alone or together with any other person, holds, directly or indirectly, at least 10% of any of the means of control of a company (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company's liquidation proceeds and the right to appoint a director).

With respect to corporate investors, capital gain tax equal to the corporate tax rate (23% in 2018) will be imposed on the sale of our traded shares.

In addition, if our ordinary shares are traded on a Recognized Exchange gains on the sale of our ordinary shares held by non-Israeli tax resident investors will generally be exempt from Israeli capital gains tax so long as the shares were not held through a permanent establishment that the non-Israeli tax resident investor maintains in Israel. Notwithstanding the foregoing, dealers in securities in Israel are taxed at regular tax rates applicable to business income.

In addition, persons paying consideration for shares, including purchasers of shares, Israeli securities dealers effecting a transaction, or a financial institution through which securities being sold are held, are required, subject to any applicable exemptions and the demonstration by the selling shareholder of its non-Israeli residency and other requirements, to withhold tax upon the sale of publicly traded securities at a rate of 25% for individuals and at the corporate tax rate (23% in 2018) for corporations.

Israeli law also generally exempts non-Israeli residents from capital gains tax on the sale of securities of Israeli companies that are not traded on stock exchange in Israel, provided that the securities were acquired on or after January 1, 2009 and that (i) such gains are not generated through a permanent establishment that the non- Israeli resident maintains in Israel; (ii) the shares were not purchased from a relative; (iii) the sale if shares is not subject to real estate tax.

Income Taxes on Dividend Distribution to Non-Israeli Shareholders

In principle, non-Israeli residents (whether individuals or corporations) are generally subject to Israeli income tax on the receipt of dividends paid for publicly traded at the rate of 25% so long as the shares are registered with a Nominee Company which is a company incorporated to be a holder of record and distribution agent of publicly traded or other securities in accordance with the Israeli Securities Law, and at the rate of 30% on dividends paid to Substantial Shareholders whose shares are not registered with a Nominee Company , unless a different rate is provided under an applicable tax treaty. The distribution of dividends to non-Israeli residents (either individuals or corporations) from income derived from the Company's Approved Enterprises or Benefiting Enterprises during the applicable benefits period is subject to withholding tax at a rate of 20% unless a different tax rate is provided under an applicable tax treaty.

A non-resident of Israel who has dividend income derived from or accrued in Israel, from which the full amount of tax was withheld, is generally exempt from the duty to file tax returns in Israel in respect of such income, provided that: (i) such income was not derived from a business conducted in Israel by the taxpayer; and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Residents of the United States generally will have withholding tax in Israel deducted at source. As discussed below, they may be entitled to a credit or deduction for U.S. federal income tax purposes for all or part of the amount of the taxes withheld, subject to detailed rules contained in U.S. tax legislation.

U.S. Israel Tax Treaty

The Convention between the Government of the State of Israel and the Government of the United States of America With Respect to Taxes on Income (the "Treaty") is generally effective as of January 1, 1995. Under the Treaty, the maximum Israeli withholding tax on dividends paid to a holder of our ordinary shares who is a Treaty U.S. Resident (as defined below) is generally 25%. However, pursuant to the Investment Law, dividends distributed by an Israeli company and derived from income eligible for benefits under the Investment Law will generally be subject to a reduced dividend withholding tax rate, subject to the conditions specified in the Treaty. The Treaty further provides that a 15% or a 12.5% Israeli dividend withholding tax will apply to dividends paid to a U.S. corporation owning 10% or more of an Israeli company's voting shares during, in general, the current and preceding tax year of the Israeli company. The 15% rate applies to dividends distributed from income derived from an Approved Enterprise or, presumably, from a Benefiting Enterprise, in each case within the applicable period or, presumably, from a Preferred Enterprise, and the lower 12.5% rate applies to dividends distributed from income derived from other sources. However, these provisions do not apply if the company has certain amounts of passive income.

Pursuant to the Treaty, the sale, exchange or disposition of our ordinary shares by a person who qualifies as a resident of the United States within the meaning of the Treaty and who is entitled to claim the benefits afforded to such residents under the Treaty (a "Treaty U.S. Resident") generally will not be subject to the Israeli capital gains tax unless such Treaty U.S. Resident holds, directly or indirectly, shares representing 10% or more of the voting power of the Company during any part of the 12-month period preceding such sale, exchange or disposition subject to certain conditions. A sale, exchange or disposition of our ordinary shares by a Treaty U.S. Resident who holds, directly or indirectly, shares representing 10% or more of the voting power of the Company at any time during such preceding 12-month period would not be exempt under the Treaty from such Israeli tax; however, under the Treaty, such Treaty U.S. Resident would be permitted to claim a credit for such taxes against U.S. federal income tax imposed on any gain from such sale, exchange or disposition, under the circumstances and subject to the limitations specified in the Treaty and U.S. domestic law. As mentioned above, gains on the sale of ordinary shares held by non-Israeli tax resident investors will generally be exempt from Israeli capital gains tax if the ordinary shares are traded on a Recognized Exchange. This exemption would generally apply notwithstanding the Treaty.

Surcharge Tax

Furthermore, beginning on January 1, 2013, an additional tax liability at the rate of 3% (as of 2017) was added to the applicable tax rate on the annual taxable income of the individuals (whether any such individual is an Israeli resident or non-Israeli resident) exceeding NIS 641,880 in 2018 and NIS 649,560 in 2019.

Israeli Transfer Pricing Regulations

On November 29, 2006, Income Tax Regulations (Determination of Market Terms), 2006, promulgated under Section 85A of the Tax Ordinance, came into effect (the “TP Regulations”). Section 85A of the Tax Ordinance and the TP Regulations generally require that all cross-border transactions carried out between related parties be conducted on an arm’s length principle basis and will be taxed accordingly. The TP Regulations have not had a material effect on the Company.

Certain Material U.S. Federal Income Tax Considerations

General

The following is a summary of certain material U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning, and disposing of our ordinary shares. For this purpose, a U.S. holder is, in each case as defined for U.S. federal income tax purposes: (a) an individual who is a citizen or resident of the United States; (b) a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia; (c) an estate the income of which is subject to U.S. federal income tax regardless of its source; or (d) a trust that is subject to the primary supervision of a court over its administration and one or more U.S. persons control all substantial decisions, or a trust that has validly elected to be treated as a domestic trust under applicable Treasury Regulations. This summary does not address any tax consequences to persons other than U.S. holders.

This discussion is a general summary and does not address all aspects of U.S. federal income taxation that may be relevant to particular U.S. holders based on their particular investment or tax circumstances. Except where noted, this summary deals only with ordinary shares held as capital assets (generally, property held for investment). It does not address any tax consequences to certain types of U.S. holders that are subject to special treatment under the U.S. federal income tax laws, such as insurance companies, tax-exempt organizations, financial institutions, broker-dealers, dealers in securities or currencies, traders in securities that elect to use the mark-to-market method of accounting for their securities, persons subject to Section 451(b) of the Internal Revenue Code of 1986, as amended (or, the “Code”), partnerships or other pass-through entities (or arrangements treated as a partnership) for U.S. federal tax purposes, regulated investment companies, real estate investment trusts, expatriates, persons liable for alternative minimum tax, persons owning, directly or by attribution, 10% or more, by voting power or value, of our ordinary shares, persons whose “functional currency” is not the U.S. dollar, persons holding ordinary shares as part of a hedging, constructive sale or conversion, straddle, or other risk-reducing transaction, or persons acquiring an interest in our ordinary shares in exchange for services.

This summary relates only to U.S. federal income taxes. It does not address any other tax, including but not limited to, state, local, or foreign taxes, or any other U.S. federal taxes other than income taxes.

If a partnership (including an entity or arrangement classified as a partnership for U.S. federal income tax purposes) holds our ordinary shares, the tax treatment of a partner (including a person classified as a partner for U.S. federal income tax purposes) will generally depend upon the status of the partner and the activities of the partnership. A partner of a partnership holding our ordinary shares should consult its tax advisors.

The statements in this summary are based on the current U.S. federal income tax laws as contained in the Code, Treasury Regulations, and relevant judicial decisions and administrative guidance, all as of the date hereof, and such authorities may be replaced, revoked or modified so as to result in U.S. federal income tax consequences different from those discussed below. The U.S. federal tax laws are subject to change, and any such change may materially affect the U.S. federal income tax consequences of purchasing, owning, or disposing of our ordinary shares. We cannot assure you that new laws, interpretations of law or court decisions, any of which may take effect retroactively, will not cause any statement in this summary to be inaccurate. No ruling or opinions of counsel will be sought in connection with the matters discussed herein. There can be no assurance that the positions we take on our tax returns will be accepted by the U.S. Internal Revenue Service, or IRS.

This summary is not a substitute for careful tax planning. Prospective investors are urged to consult their own tax advisors regarding the specific U.S. federal, state, foreign and other tax consequences to them, in light of their own particular circumstances, of the purchase, ownership and disposition of our ordinary shares and the effect of potential changes in applicable tax laws.

Dividends

Subject to the discussion under “Item 10. Additional Information – E. Taxation – Certain Material U.S. Federal Income Tax Considerations – Passive Foreign Investment Company” below, the gross amount of any distributions with respect to our ordinary shares (including any amounts withheld to reflect Israeli withholding taxes) will be taxable as dividends, to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Such income (including any withheld taxes) will be includable in a U.S. holder’s gross income as ordinary income on the day actually or constructively received. The dividends received deduction will not be available to a U.S. holder that is taxed as a corporation.

With respect to non-corporate U.S. holders, certain dividends received from a “qualified foreign corporation” may be subject to reduced rates of taxation. A qualified foreign corporation includes a foreign corporation that is eligible for the benefits of a comprehensive income tax treaty with the United States which the United States Treasury Department determines to be satisfactory for these purposes and which includes an exchange of information provision. The United States Treasury Department has determined that the Treaty meets these requirements. A foreign corporation is also treated as a qualified foreign corporation with respect to dividends paid by that corporation on shares that are readily tradable on an established securities market in the United States. Our ordinary shares will generally be considered to be readily tradeable on an established securities market in the United States if they are listed on Nasdaq, which we intend them to be; however, there can be no assurance that our ordinary shares will be considered readily tradable on an established securities market in any year. If we are a qualified foreign corporation, and we are not classified as a passive foreign investment company (a “PFIC”) for the taxable year in which a dividend is paid or the or the preceding taxable year (as discussed below under “Item 10. Additional Information – E. Taxation – Certain Material U.S. Federal Income Tax Considerations – Passive Foreign Investment Company”), dividend income will generally qualified as “qualified dividend income” in the hands of individual U.S. holders, which is generally taxed at the lower applicable long term capital gains rates, provided certain holding period and other requirements for treatment of such dividends as “qualified dividend income” are satisfied. U.S. holders should consult their own tax advisors regarding the availability of the lower rate for dividends paid with respect to our ordinary shares.

Although, to the extent we pay dividends in the future, we intend to pay dividends to U.S. holders in U.S. dollars, the amount of any dividend paid in Israeli currency will equal its U.S. dollar value for U.S. federal income tax purposes, calculated by reference to the exchange rate in effect on the date the dividend is received by the U.S. holder, regardless of whether the Israeli currency is converted into U.S. dollars. If the Israeli currency received as a dividend are converted into United States dollars on the date they are received, the U.S. holder generally will not be required to recognize foreign currency gain or loss in respect of the dividend income. If the Israeli currency is not converted into U.S. dollars on the date of receipt, the U.S. holder will have a basis in the Israeli currency equal to its U.S. dollar value on the date of receipt. Any subsequent gain or loss upon the conversion or other disposition of the Israeli currency will be treated as ordinary income or loss, and generally will, for U.S. federal income tax purposes, be treated as income or loss from U.S. sources.

Certain U.S. holders generally may claim any Israeli taxes withheld from distributions either as a deduction from gross income or as a credit against U.S. federal income tax liability. However, the foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. U.S. holders should consult their own tax advisors regarding the foreign tax credit rules.

To the extent that the amount of any distribution (including amounts withheld to reflect Israeli withholding taxes) exceeds our current and accumulated earnings and profits for a taxable year, as determined under U.S. federal income tax principles, the distribution will first be treated as a tax-free return of capital, causing a reduction in the U.S. holder’s adjusted basis of the shares, and the balance in excess of adjusted basis will be treated as capital gain from a taxable disposition of ordinary shares. We do not expect to determine earnings and profits in accordance with U.S. federal income tax principles. Therefore, U.S. holders should expect that a distribution will generally be treated as a dividend.

Disposition of Ordinary Shares

In general, subject to the discussion under – “Item 10. Additional Information – E. Taxation – Certain Material U.S. Federal Income Tax Considerations – Passive Foreign Investment Company”, a U.S. holder will recognize U.S.-source capital gain or loss upon a taxable disposition of an ordinary share equal to the difference between the sum of the fair market value of any property and the amount of cash received in such disposition (including the amount of any foreign taxes withheld therefrom) and the U.S. holder’s adjusted tax basis in such share. A U.S. holder’s adjusted tax basis generally will equal the U.S. holder’s acquisition cost less any return of capital. Such capital gain or loss will be long-term capital gain or loss if a U.S. holder’s holding period in the ordinary share is more than one year at the time of the taxable disposition. Subject to certain exceptions (including but not limited to those described under “Item 10. Additional Information – E. Taxation – Certain Material U.S. Federal Income Tax Considerations – Passive Foreign Investment Company” below), long-term capital gain realized by a non-corporate U.S. holder generally will be eligible for reduced rates of tax. The deduction of capital losses may be subject to limitation. U.S. holders should consult their own independent tax advisors regarding the foreign tax credit rules with respect to any foreign taxes withheld from a taxable disposition of ordinary shares, as well as regarding any foreign currency gain or loss in connection with such a disposition.

Passive Foreign Investment Company

In general, we will be a PFIC for any taxable year in which:

at least 75% of our gross income is passive income, or

on average, at least 50% of the value (determined on a quarterly basis) of our assets is attributable to assets that produce or are held for the production of passive income.

For this purpose, passive income generally includes dividends, interest, royalties and rents (other than royalties and rents derived in the active conduct of a trade or business and not derived from a related person). Assets that produce or are held for the production of passive income may include cash (even if held as working capital or raised in a public offering), marketable securities and other assets that may produce passive income. The 50% passive asset test described above is generally based on the fair market value of each asset, with the value of goodwill and going concern value determined in large part by reference to the market value of our ordinary shares, which may be volatile. If we own at least 25% (by value) of the stock of another corporation, we will be treated, for purposes of the PFIC tests, as owning our proportionate share of the other corporation’s assets and receiving our proportionate share of the other corporation’s income.

Based on our financial statements and the projected composition of our income and valuation of our assets, including goodwill, we believe that we were not classified as a passive foreign investment company, or PFIC, for our taxable year that ended on December 31, 2018. However, our status as a PFIC is a fact-intensive determination made on an annual basis, and cannot be definitively determined until the close of the year in question. Accordingly, we cannot provide any assurances regarding our PFIC status for the current or future taxable years. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. If we are a PFIC for any taxable year during which a U.S. holder holds our ordinary shares, such U.S. holder will be subject to special tax rules discussed below and could suffer adverse tax consequences.

If we are classified as a PFIC in any taxable year during a U.S. holder’s holding period of our ordinary shares, such U.S. holder could be liable for additional taxes and interest charges upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. holder’s holding period for the ordinary shares, and (2) any gain recognized on a sale, exchange or other taxable disposition, including a pledge, of the ordinary shares, whether or not we continue to be a PFIC. In these circumstances, the tax will be determined by allocating such distribution or gain ratably over the U.S. holder’s holding period for the ordinary shares. The amount allocated to the current taxable year (i.e., the year in which the distribution occurs or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax. If we are a PFIC for any year during which a U.S. holder holds the ordinary shares, we must generally continue to be treated as a PFIC by that holder for all succeeding years during which the U.S. holder holds the ordinary shares, unless we cease to meet the requirements for PFIC status and the U.S. holder makes a “deemed sale” election with respect to the ordinary shares. If such election is made, the U.S. holder will be deemed to have sold the ordinary shares it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described above. After the deemed sale election, the U.S. holder’s ordinary shares with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently again become a PFIC.

If a U.S. holder has made a QEF election covering all taxable years during which the holder holds ordinary shares and in which we are a PFIC, distributions and gains will not be taxed as described above. Instead, a U.S. holder that makes a QEF election is required for each taxable year to include in income the holder's pro rata share of the ordinary earnings of the QEF as ordinary income and a pro rata share of the net capital gain of the QEF as capital gain, regardless of whether such earnings or gain have in fact been distributed. A separate election may be made for undistributed income to defer payment of taxes. If deferred, the taxes will be subject to an interest charge. Where earnings and profits that were included in income under this rule are later distributed, the distribution is not a dividend. The basis of a U.S. shareholder's shares in a QEF is increased by amounts that are included in income, and decreased by amounts distributed but not taxed as dividends. In addition, if a U.S. holder makes a timely QEF election, our ordinary shares will not be considered shares in a PFIC in years in which we are not a PFIC, even if the U.S. holder had held ordinary shares in prior years in which we were a PFIC.

In order to comply with the requirements of a QEF election, a U.S. holder must receive certain information from us. The QEF election is made on a shareholder-by-shareholder basis and can be revoked only with the consent of the IRS. A shareholder makes a QEF election by attaching a completed IRS Form 8621, including the information provided in the PFIC annual information statement, to a timely filed U.S. federal income tax return and by filing a copy of the form with the IRS. There is no assurance that we will provide such information as the IRS may require in order to enable U.S. holders to make the QEF election. Moreover, there is no assurance that we will have timely knowledge of our status as a PFIC in the future.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a timely and valid "mark-to-market" election is made by a U.S. holder for the ordinary shares held by such U.S. holder. An electing U.S. holder would generally take into account as ordinary income or loss each year an amount equal to the difference between the U.S. holder's adjusted tax basis in such ordinary shares and their fair market value; however, losses would be allowed only to the extent of the excess of amounts previously included in income over ordinary losses deducted in prior years as a result of the mark-to-market election. The adjusted tax basis of a U.S. holder's ordinary shares is increased by the amount included in gross income under the mark-to-market regime, or is decreased by the amount of the deduction allowed under the regime. Any gain from a sale, exchange or other taxable disposition of the ordinary shares in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other taxable disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If a U.S. holder makes a mark-to-market election it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election.

A mark-to-market election is available to a U.S. holder only for "marketable stock." Generally, stock will be considered marketable stock if it is "regularly traded" on a "qualified exchange" within the meaning of applicable Treasury Regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. The ordinary shares will be marketable stock as long as they remain listed on a qualified exchange, such as Nasdaq, and are regularly traded. A mark-to-market election will not apply to the ordinary shares for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. U.S. holders are urged to consult their tax advisor about the availability of the mark-to-market election, and whether making the election would be advisable in such holder's particular circumstances.

If we are a PFIC and, at any time, have a non-U.S. subsidiary that is classified as a PFIC, U.S. holders of our ordinary shares generally would be deemed to own, and also would be subject to the PFIC rules with respect to, their indirect ownership interests in that lower-tier PFIC. If we are a PFIC and a U.S. holder of our ordinary shares does not make a QEF election in respect of a lower-tier PFIC, the U.S. holder could incur liability for the deferred tax and interest charge described above if either (1) we receive a distribution from, or dispose of all or part of our interest in, the lower-tier PFIC or (2) the U.S. holder disposes of all or part of its ordinary shares. There is no assurance that any lower-tier PFIC will provide to a U.S. holder the information that may be required to make a QEF election with respect to the lower-tier PFIC. A mark-to-market election under the PFIC rules with respect to our ordinary shares would not apply to a lower-tier PFIC, and a U.S. holder would not be able to make such a mark-to-market election in respect of its indirect ownership interest in that lower-tier PFIC. Consequently, U.S. holders of our ordinary shares could be subject to the PFIC rules with respect to income of the lower-tier PFIC the value of which already had been taken into account indirectly via mark-to-market adjustments. U.S. holders are urged to consult their own tax advisors regarding the issues raised by lower-tier PFICs.

Each U.S. holder who is a shareholder of a PFIC must file an annual information report on IRS Form 8621 containing such information as the U.S. Treasury Department may require. The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

THE RULES DEALING WITH PFICS AND WITH THE QEF AND MARK-TO-MARKET ELECTIONS ARE VERY COMPLEX AND ARE AFFECTED BY VARIOUS FACTORS IN ADDITION TO THOSE DESCRIBED ABOVE, INCLUDING OUR OWNERSHIP OF ANY NON-U.S. SUBSIDIARIES. AS A RESULT, U.S. HOLDERS OF ORDINARY SHARES ARE STRONGLY ENCOURAGED TO CONSULT THEIR TAX ADVISORS ABOUT THE PFIC RULES IN CONNECTION WITH THEIR PURCHASING, HOLDING OR DISPOSING OF ORDINARY SHARES.

Backup Withholding and Information Reporting

In general, information reporting will apply to dividends in respect of our ordinary shares and the proceeds from the sale, exchange or redemption of our ordinary shares that are paid to a U.S. holder within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient. A backup withholding tax generally would apply to such payments if the U.S. holder fails to provide a taxpayer identification number or certification of other exempt status or, in the case of dividend payments, fails to report in full dividend and interest income.

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is furnished to the Internal Revenue Service in a timely manner.

Individuals who own "specified foreign financial assets" with an aggregate value in excess of \$50,000 may be required to file an information report on IRS Form 8938, "Statement of Specified Foreign Financial Assets," with respect to such assets with their tax returns. "Specified foreign financial assets" include any financial accounts maintained by foreign financial institutions, as well as any of the following, but only if they are not held in accounts maintained by financial institutions: (i) stocks and securities issued by non-U.S. persons; (ii) financial instruments and contracts held for investment that have non-U.S. issuers or counterparties; and (iii) interests in foreign entities. U.S. holders that are individuals are urged to consult their tax advisors regarding the application of this legislation to their ownership of our ordinary shares.

Tax on Net Investment Income

Certain U.S. holders that are individuals, estates or trusts whose income exceeds certain thresholds will be required to pay an additional 3.8% tax on "net investment income", which includes, among other things, dividends and net gain from the sale or other disposition of property (other than property held in a trade or business), which may include our ordinary shares. U.S. holders should consult their own tax advisors regarding the application of the tax on net investment income to their particular circumstances.

F. DIVIDENDS AND PAYING AGENTS

Not applicable.

G. STATEMENT BY EXPERTS

Not applicable.

H. DOCUMENTS ON DISPLAY

We are required to file reports and other information with the SEC under the Securities Exchange Act of 1934 (the "Exchange Act") and the regulations thereunder applicable to foreign private issuers. As a "foreign private issuer" we are exempt from the rules and regulations under the Securities Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and "shortswing" profit recovery provisions contained in Section 16 of the Securities Exchange Act, with respect to their purchase and sale of our shares. In addition, we are not required to file reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Securities Exchange Act. Nasdaq rules generally require that companies send an annual report to shareholders prior to the annual general meeting, however we rely upon an exception under the Nasdaq Listing Rules and follow the generally accepted business practice for companies in Israel. Specifically, we file annual reports on Form 20-F, which contain financial statements audited by an independent accounting firm, electronically with the SEC and post a copy on our website. We also furnish to the SEC reports on Form 6-K containing unaudited financial information after the end of each of the first three quarters.

You may review a copy of our filings with the SEC, including any exhibits and schedules, at the offices of the Israel Securities Authority at 22 Kanfei Nesharim St., Jerusalem, Israel. As a foreign private issuer, we were only required to file through the SEC's EDGAR system as of November 2002. Our periodic filings are therefore available on the SEC's Website www.sec.gov from that date. You may read and copy any reports, statements or other information that we file with the SEC, through the SEC's EDGAR system available on the SEC's website. These SEC filings are also available to the public on the Israel Securities Authority's website at www.isa.gov.il and from commercial document retrieval services.

Any statement in this annual report about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to this annual report, the contract or document is deemed to modify the description contained in this annual report. We urge you to review the exhibits themselves for a complete description of the contract or document.

I. SUBSIDIARY INFORMATION

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to a variety of risks, including changes in interest rates and foreign currency exchange risk and inflation.

Interest Rate Risk

As of December 31, 2018, we had \$45.7 million in cash, cash equivalents, restricted cash and short-term bank deposits. We mostly invest our cash surplus in bank deposits. Since these investments typically carry fixed interest rate, financial income over the holding period is not sensitive to changes in interest rates. For more information, see Note 2 to our 2018 consolidated financial statements.

Foreign Currency Exchange Risk and Inflation

The cost of our Israel operations, as expressed in U.S. dollars, is influenced by the extent to which any increase in the rate of inflation in Israel is not offset (or is offset on a lagging basis) by a devaluation of the NIS in relation to the U.S. dollar. The inflation (deflation) rate in Israel was 0.8%, 0.4% and (0.2%) in 2018, 2017 and 2016, respectively. The appreciation (devaluation) of the NIS against the U.S. dollar amounted to (8.1%), 9.8% and 1.5% in 2018, 2017 and 2016, respectively. For 2017, assuming a 10% appreciation of the NIS against the U.S. dollar, we would experience exchange rate losses of approximately \$1.2 million, while assuming a 10% devaluation of the NIS against the U.S. dollar, we would experience an exchange rate gain of approximately \$1.0 million. A significant portion of our expenditures is employee compensation-related. Salaries for Israel-based employees are paid in NIS and may be adjusted for changes in the Israeli consumer price index, or CPI, through salary increases or adjustments. These upward adjustments increase salary expenses in U.S. dollar terms. The devaluation/appreciation of the NIS against the U.S. dollar decreases/increases employee compensation expenditures as expressed in dollars proportionally. Some of our other NIS-based expenses are either currently adjusted to U.S. dollars or are adjusted to the CPI. We currently have no foreign currency derivative contracts to hedge against currency exchange risk fluctuation but may consider entering into such contracts in the future. For more information, see Note 2 of our 2018 consolidated financial statements.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

A. DISCLOSURE CONTROLS AND PROCEDURES

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we are required to file are recorded, processed, summarized and reported on a timely basis. Under the supervision of our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) and 15d-15(e) promulgated under the Exchange Act. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this annual report.

B. MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management, with the involvement of our Board of Directors and Audit Committee, is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control system has been designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision of our Chief Executive Officer and Chief Financial Officer, our management conducted an evaluation of the effectiveness of our internal control over financial reporting, as such term is defined under Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act. In making this assessment, our management used the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our internal control over financial reporting was effective as of the end of the period covered by this annual report.

Notwithstanding the foregoing, all internal control systems no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm in Israel, which has audited our financial statements for the year ended December 31, 2018 that are included in this annual report, has issued an attestation report on our internal control over financial reporting as of December 31, 2018.

C. ATTESTATION REPORT OF THE REGISTERED PUBLIC ACCOUNTING FIRM

The attestation report of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm in Israel, on internal control over financial reporting as of December 31, 2018 is provided on page F-3, as included under Item 18 of this annual report.

D. CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

Based on the evaluation conducted by our management, with the participation of our Chief Executive Officer and Chief Financial Officer, pursuant to Rules 13a-15(d) and 15d-15(d) promulgated under the Exchange Act, our management (including such officers) have concluded that, there were no changes in our internal control over financial reporting that occurred during the period covered by this annual report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 16. RESERVED**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our Board of Directors has determined that Mr. Arie Ovadia, who serves on our Audit Committee and who meets the “independence” definition under the Nasdaq Listing Rules, qualifies as an “audit committee financial expert” as defined in the instructions to this Item 16A of Form 20-F.

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Business Conduct that applies to all of our employees, officers and directors as well as a Code of Ethics for Senior Financial Officers that applies to our chief executive officer, chief financial officer, director of finance, controller, assistant controller and persons performing similar functions at our subsidiary.

The Code of Ethics for Senior Financial Officers is available on our website, www.cgen.com. However, information contained on our website does not constitute a part of this annual report.

We intend to post on our website all disclosures that are required by law or by the Nasdaq Listing Rules concerning any amendments to, or waivers from, any provision of the Code of Business Conduct or the Code of Ethics.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table presents the fees billed or accrued to us by our principal accountant for professional services rendered in the years ended December 31, 2018 and 2017:

	2018	2017
Audit Fees	\$ 146,000	\$ 155,000
Audit Related Fees	\$ 90,000	\$ 15,000
Tax Fees	\$ 6,500	\$ 2,500
All Other Fees	\$ 2,500	\$ 2,500
Total	\$ 245,000	\$ 175,000

“Audit Fees” are fees for professional services rendered by our principal accountant in connection with the integrated audit (including review of internal control over financial reporting) of our consolidated annual financial statements and review of our unaudited interim financial statements;

“Audit Related Fees” are fees for professional services rendered by our principal accountant in connection with the audit and other assignments;

“Tax Fees” are fees for services rendered by our principal accountant in connection with tax compliance tax advice and tax planning which in year 2018 and 2017 were consultancy relating to withholding tax on payments to foreign suppliers and Annual Israeli tax reports; and

“All Other Fees” are fees for other consulting services rendered by our principal accountant to us including consultancy and consents with respect to an underwritten public offering and related prospectus supplements filed with the SEC.

Pre-Approval Policies for non-Audit Services

Our Audit Committee is in charge of a policy and procedures for approval of audit and non-audit services rendered by our independent auditors. This policy generally provides that we will not engage our independent registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our Audit Committee or the engagement is entered into pursuant to the pre-approval procedure described below. Annually, our Audit Committee pre-approves specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount. All of the fees listed in the table above were approved by our Audit Committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not Applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

The Nasdaq Listing Rules require companies with securities listed thereon to comply with its corporate governance standards. As a foreign private issuer whose shares are listed on Nasdaq, we are permitted to follow certain home country corporate governance practices instead of those followed by U.S. companies under the Nasdaq Listing Rules, including:

Shareholder Approval: Pursuant to Israeli law, we seek shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law, which are different from the requirements for seeking shareholder approval under Nasdaq Listing Rule 5635. For example, on December 19, 2016 our board of directors elected to follow Israel's practices in lieu of Nasdaq Listing Rule 5635(c) which requires that companies obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans. We seek shareholder approval in specified situations, including upon issuance of options to directors in their capacity as directors, as required by Israeli law.

Quorum at an Adjourned General Meeting of Shareholders: Consistent with Israeli law, generally, a quorum for an adjourned general meeting of shareholders of the Company is any two shareholders present in person, by proxy, by proxy card or by electronic vote at such meeting. As such, the Israeli quorum requirements for an adjourned meeting are different from the Nasdaq requirement that an issuer listed on Nasdaq have a quorum requirement that in no case be less than 33 1/3% of the outstanding shares of the company's common voting stock.

Distribution of Annual Reports: We have chosen to follow our home country practice in lieu of the requirements of Nasdaq Rule 5250(d)(1), relating to an issuer's furnishing of its annual report to shareholders. Specifically, we file annual reports on Form 20-F, which contain financial statements audited by an independent accounting firm, electronically with the SEC and post a copy on our website.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

See Item 18.

ITEM 18. FINANCIAL STATEMENTS

Our consolidated financial statements and related notes are included in this Annual Report beginning on page F-1.

ITEM 19. EXHIBITS

Index to Exhibits

<u>Exhibit Number</u>	<u>Description</u>
<u>1.1</u>	<u>Articles of Association of Compugen, as amended (incorporated by reference to Exhibit 1.1 to Compugen's annual report on Form 20-F for the year ended December 31, 2017, filed with the SEC on March 27, 2017 (File No. 000-30902)).</u>
<u>1.2</u>	<u>Memorandum of Association of Compugen, as amended (incorporated by reference to Exhibit 99.2 to Compugen's report on Form 6-K filed with the SEC on October 29, 2014 (File No. 000-30902)).</u>
4.1	Compugen Ltd. Share Option Plan (2000) (incorporated by reference to Exhibit 10.17 to Compugen's Registration Statement on Form F-1 filed on August 2, 2000 (File No. 333-12316)).
<u>4.2</u>	<u>Compugen Ltd. 2010 Share Incentive Plan (incorporated by reference to Exhibit 4.6 to Compugen's annual report on Form 20-F for the year ended December 31, 2014, filed with the SEC on March 12, 2015 (File No. 000-30902)).</u>
<u>4.3@</u>	<u>Research and Development Collaboration and License Agreement, dated August 5, 2013, by and between Compugen Ltd. and BayerPharma AG ("Bayer") (incorporated by reference to Exhibit 4.7 to Compugen's annual report on Form 20-F, filed with the SEC on February 18, 2014 (File No. 000-30902)).</u>
<u>4.4@</u>	<u>First Amendment to the Research and Development Collaboration and License Agreement, by and between Compugen Ltd and Bayer dated as of February 5, 2014 (incorporated by reference to Exhibit 10.1 to Compugen's 6-K, filed with the SEC on August 9, 2016 (File No. 000-30902)).</u>

<u>4.5@</u>	<u>Second Amendment to the Research and Development Collaboration and License Agreement, by and between Compugen Ltd and Bayer, dated as of July 27, 2015 (incorporated by reference to Exhibit 10.2 to Compugen's 6-K, filed with the SEC on August 9, 2016 (File No. 000-30902)).</u>
<u>4.6@</u>	<u>Third Amendment to Research and Development Collaboration and License Agreement, by and between Compugen Ltd and Bayer, dated as of April 17, 2016 (incorporated by reference to Exhibit 10.3 to Compugen's 6-K, filed with the SEC on August 9, 2016 (File No. 000-30902)).</u>
<u>4.7</u>	<u>Lease, dated December 12, 2013, by and between Britannia Pointe Grand Limited Partnership and Compugen USA, Inc. (incorporated by reference to Exhibit 4.8 to Compugen's annual report on Form 20-F for the year ended December 31, 2013, filed with the SEC on February 18, 2014 (File No. 000-30902))</u>
<u>4.8</u>	<u>Form of Indemnification Undertaking and Exemption and Release between Compugen Ltd. and its directors and office holders (incorporated by reference to Exhibit C to Exhibit 99.3 to Compugen's 6-K filed with the SEC on August 2, 2013 (File No. 000-30902)).</u>
<u>4.9</u>	<u>Office Lease Agreement ("Holon Lease"), dated March 2015, by and between Kanit Hashalom Investments Ltd and Compugen Ltd. (incorporated by reference to Exhibit 99.2 to Compugen's 6-K filed with the SEC on May 5, 2015 (File No. 000-30902))</u>
<u>4.10</u>	<u>Amendment to Holon Lease made and entered into on November 26, 2015 by and between Kanit Hashalom Investments Ltd and Compugen Ltd. (incorporated by reference to Exhibit 4.10 to Compugen's annual report on Form 20-F for the year ended December 31, 2015, filed with the SEC on March 7, 2016 (File No. 000-30902))</u>
<u>4.11@</u>	<u>License Agreement, between the Company and MedImmune Limited ("MedImmune"), entered into as of March 30, 2018 (incorporated by reference to Exhibit 10.1 to Compugen's 6-K, filed with the SEC on May 9, 2018 (File No. 000-30902)).</u>
<u>4.12@</u>	<u>Amendment No. 1 to the License Agreement, between the Company and MedImmune, dated May 9, 2018 (incorporated by reference to Exhibit 10.1 to Compugen's 6-K, filed with the SEC on August 1, 2018 (File No. 000-30902)).</u>
<u>4.13</u>	<u>Controlled Equity OfferingSM Sales Agreement between the Company and Cantor Fitzgerald & Co., dated May 25, 2018 (incorporated by reference to Exhibit 1.1 to Compugen's 6-K, filed with the SEC on May 25, 2018 (File No. 000-30902)).</u>
<u>4.14</u>	<u>Securities Purchase Agreement, dated as of June 14, 2018, by and among the Company and the purchasers named therein (incorporated by reference to Exhibit 1.1 to Compugen's 6-K, filed with the SEC on June 19, 2018 (File No. 000-30902)).</u>
<u>4.15</u>	<u>Form of Warrant to Purchase Ordinary Shares (incorporated by reference to Exhibit 4.1 to Compugen's 6-K, filed with the SEC on June 19, 2018 (File No. 000-30902)).</u>
<u>4.16@</u>	<u>Master Clinical Trial Collaboration Agreement, between the Company and Bristol-Myers Squibb Company, dated October 10, 2018 (incorporated by reference to Exhibit 10.1 to Compugen's 6-K, filed with the SEC on November 7, 2018 (File No. 000-30902)).</u>
<u>4.17</u>	<u>Securities Purchase Agreement, dated as of October 10, 2018, between the Company and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.2 to Compugen's 6-K, filed with the SEC on November 7, 2018 (File No. 000-30902)).</u>
<u>8.1*</u>	<u>Subsidiaries.</u>

<u>12.1*</u>	<u>Certification by Principal Executive Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) under the Exchange Act and Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>12.2*</u>	<u>Certification by Principal Financial and Accounting Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) under the Exchange Act and Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>13.1*</u>	<u>Certification by Principal Executive Officer and Principal Financial and Accounting Officer pursuant to Rule 13a-14(b)/Rule 15d-14(b) under the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
<u>15.1*</u>	<u>Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global.</u>
101*	The following financial information from Compugen Ltd.'s Annual Report on Form 20-F for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Statements of Operations for the years ended December 31, 2018, 2017 and 2016; (ii) Consolidated Balance Sheets at December 31, 2018 and 2017; (iii) Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2018, 2017 and 2016; (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016; and (v) Notes to Consolidated Financial Statements.

* Filed herewith.

@ Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

COMPUGEN LTD.

Signature: /s/ Dr. Anat Cohen-Dayag

Name: Dr. Anat Cohen-Dayag

Title: President and Chief Executive Officer, Director

Date: March 21, 2019

COMPUGEN LTD. AND ITS SUBSIDIARY
CONSOLIDATED FINANCIAL STATEMENTS
AS OF DECEMBER 31, 2018
U.S. DOLLARS IN THOUSANDS
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of COMPUGEN LTD.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Compugen Ltd. and its subsidiary (the "Company") as of December 31, 2018 and 2017 and the related consolidated statements of comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and 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 at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 21, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/S/KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company's auditor since 2002

Tel-Aviv, Israel
March 21, 2019



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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of COMPUGEN LTD.

Opinion on Internal Control over Financial Reporting

We have audited Compugen Ltd. and its subsidiary's (the "Company") internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017 and the related consolidated statements of comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018 and our report dated March 21, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures, as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/S/KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

Tel-Aviv, Israel
March 21, 2019

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

		December 31,	
	Note	2018	2017
ASSETS			
CURRENT ASSETS:			
Cash and cash equivalents		\$ 5,861	\$ 25,470
Restricted cash		605	1,050
Short-term bank deposits		39,209	3,918
Other accounts receivable and prepaid expenses	3	903	741
Total current assets		46,578	31,179
NON-CURRENT ASSETS:			
Long-term prepaid expenses		776	110
Severance pay fund		2,454	2,810
Property and equipment, net	4	3,372	4,647
Total non- current assets		6,602	7,567
Total assets		\$ 53,180	\$ 38,746

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

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands (except share and per share data)

	Note	December 31,	
		2018	2017
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES:			
Trade payables		\$ 2,946	\$ 3,445
Short term deferred participation in R&D expenses		1,089	-
Other accounts payable and accrued expenses	5	5,954	2,749
Total current liabilities		9,989	6,194
NON- CURRENT LIABILITIES:			
Long term deferred participation in R&D expenses		3,003	-
Accrued severance pay		2,945	3,255
Total non-current liabilities		5,948	3,255
COMMITMENTS AND CONTINGENT LIABILITIES	6		
SHAREHOLDERS' EQUITY:	7		
Share capital:			
Ordinary shares of NIS 0.01 par value: 100,000,000 shares authorized at December 31, 2018 and 2017; 59,849,784 and 51,293,070 shares issued and outstanding at December 31, 2018 and 2017, respectively			
		164	140
Additional paid-in capital		367,920	337,382
Accumulated other comprehensive income		-	17
Accumulated deficit		(330,841)	(308,242)
Total shareholders' equity		37,243	29,297
Total liabilities and shareholders' equity		\$ 53,180	\$ 38,746

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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

U.S. dollars in thousands (except share and per share data)

	Note	Year ended December 31,		
		2018	2017	2016
Revenue		\$ 17,800	\$ -	\$ 712
Cost of revenue		1,034	-	223
Gross profit		16,766	-	489
Operating expenses:				
Research and development expenses, net		30,318	28,583	24,549
Marketing and business development expenses		1,634	1,189	1,174
General and administrative expenses		8,041	7,633	7,349
Total operating expenses		39,993	37,405	33,072
Operating loss		(23,227)	(37,405)	(32,583)
Financial and other income, net	11	628	339	1,097
Loss before taxes on income		(22,599)	(37,066)	(31,486)
Taxes on income	8	-	-	(20)
Net loss		\$ (22,599)	\$ (37,066)	\$ (31,506)
Basic net loss per share		\$ (0.41)	\$ (0.72)	\$ (0.62)
Diluted net loss per share		\$ (0.41)	\$ (0.72)	\$ (0.62)
Other comprehensive loss:				
Realized gain arising during the period from marketable securities		\$ -	\$ -	\$ (440)
Unrealized gain arising during the period from foreign currency derivative contracts		\$ -	\$ 17	\$ 7
Realized loss (gain) arising during the period from foreign currency derivative contracts		\$ (17)	\$ (7)	\$ 19
Total comprehensive loss		\$ (22,616)	\$ (37,056)	\$ (31,920)
Weighted average number of ordinary shares used in computing basic net loss per share		55,277,428	51,179,694	50,855,908
Weighted average number of ordinary shares used in computing diluted net loss per share		55,277,428	51,179,694	50,855,908

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

STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

U.S. dollars in thousands (except share data)

	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive Income	Accumulated deficit	Total shareholders' equity
	Number	Amount				
Balance as of January 1, 2016	50,572,244	\$ 138	\$ 328,797	\$ 421	\$ (239,459)	\$ 89,897
Options exercised	559,290	2	2,456	-	-	2,458
Stock-based compensation relating to options issued to non-employees	-	-	152	-	-	152
Stock-based compensation relating to options issued to employees and directors	-	-	2,932	-	-	2,932
Changes in other comprehensive income from marketable securities	-	-	-	(440)	-	(440)
Changes in other comprehensive income (loss) from foreign currency derivative contracts	-	-	-	26	-	26
Net loss	-	-	-	-	(31,506)	(31,506)
Balance as of December 31, 2016	51,131,534	140	334,337	7	(270,965)	63,519
Options exercised	161,536	(*)	201	-	-	201
Stock-based compensation relating to options issued to non-employees	-	-	23	-	-	23
Stock-based compensation relating to options issued to employees and directors	-	-	2,610	-	-	2,610
Changes in other comprehensive income (loss) from foreign currency derivative contracts	-	-	-	10	-	10
Cumulative effect adjustment from adoption of ASU 2016-09, Note 2x	-	-	211	-	(211)	-
Net loss	-	-	-	-	(37,066)	(37,066)
Balance as of December 31, 2017	51,293,070	140	337,382	17	(308,242)	29,297
Options exercised	765,420	2	683	-	-	685
Issuance of shares and warrants, net	7,791,294	22	27,689	-	-	27,711
Stock-based compensation relating to options issued to non-employees	-	-	193	-	-	193
Stock-based compensation relating to options issued to employees and directors	-	-	1,973	-	-	1,973
Changes in other comprehensive income (loss) from foreign currency derivative contracts	-	-	-	(17)	-	(17)
Net loss	-	-	-	-	(22,599)	(22,599)
Balance as of December 31, 2018	59,849,784	\$ 164	\$ 367,920	\$ -	\$ (330,841)	\$ 37,243

(*) Representing amount lower than \$1.

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		
	2018	2017	2016
Cash flows from operating activities:			
Net loss	\$ (22,599)	\$ (37,066)	\$ (31,506)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	2,166	2,633	3,084
Depreciation	1,394	1,593	1,484
Increase (decrease) in Severance pay, net	46	(33)	101
Gain from sale of marketable securities	-	-	(383)
Loss from property and equipment sales and disposals	52	-	-
Decrease (increase) in interest receivables from short-term bank deposits	(288)	247	303
Decrease in trade receivable	-	-	7,800
Decrease (increase) in other accounts receivable and prepaid expenses	(179)	422	206
Decrease (increase) in long-term prepaid expenses	(666)	(18)	9
Increase (decrease) in trade payables and other accounts payable and accrued expenses	2,691	1,564	(605)
Increase in deferred participation in R&D expenses	4,092	-	-
Decrease in deferred revenues	-	-	(312)
Net cash used in operating activities	(13,291)	(30,658)	(19,819)
Cash flows from investing activities:			
Proceeds from maturity of short-term bank deposits	27,400	71,560	69,000
Investment in short-term and long-term bank deposits	(62,403)	(24,900)	(50,561)
Purchase of property and equipment	(158)	(385)	(2,599)
Proceeds from sale of property and equipment	2	-	-
Proceeds from sale of marketable securities	-	-	369
Net cash provided by (used in) investing activities	(35,159)	46,275	16,209

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		
	2018	2017	2016
<u>Cash flows from financing activities:</u>			
Proceeds from issuance of ordinary shares, net	27,711	-	-
Proceeds from exercise of options	685	201	2,458
Net cash provided by financing activities	28,396	201	2,458
Increase (decrease) in cash, cash equivalents and restricted cash	(20,054)	15,818	(1,152)
Cash, cash equivalents and restricted cash at the beginning of the year	26,520	10,702	11,854
Cash and cash equivalents and restricted cash at the end of the year	\$ 6,466	\$ 26,520	\$ 10,702
<u>Supplemental disclosure of non-cash investing and financing activities:</u>			
Change in receivables from foreign currency derivative contracts	\$ 17	\$ (10)	\$ 7
Changes in other accounts payable from foreign currency derivative contracts	\$ -	\$ -	\$ 19
Purchase of property and equipment	\$ 15	\$ 33	\$ 143
<u>Cash paid (received) during the year for:</u>			
Income taxes	\$ -	\$ -	\$ 20
Interest payments received from bank short-term deposits and cash equivalents	\$ 355	\$ 640	\$ (1,032)

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 1: - GENERAL

- a. Compugen ("The Company") a clinical-stage, therapeutic discovery and development company utilizing its proprietary computational discovery platforms to identify novel drug targets and develop first-in-class therapeutics in the field of cancer immunotherapy. The Company's therapeutic pipeline consists of immuno-oncology programs against novel drug targets it has discovered, including T cell immune checkpoints and other early-stage immuno-oncology programs focused largely on myeloid targets. The Company's business model is to enter into collaborations for its novel targets and related drug product candidates at various stages of research and development.
- b. The Company is headquartered in Holon, Israel. Its clinical development and business development activities operate from its United States subsidiary in South San Francisco, CA.
- c. The Company has incurred losses in the amount of \$ 22,599 during the year ended December 31, 2018, has an accumulated deficit of \$ 330,841 as of December 31, 2018 and has accumulated negative cash flow from operating activities amounted to \$ 13,291 for the year ended December 31, 2018. On February 26, 2019, the Company announced a corporate restructuring to reduce costs by consolidating and streamlining R&D operations. The restructuring includes reducing its workforce by 35%, consolidating R&D activities in one location in Israel and outsourcing certain preclinical activities to third-party service providers. The Company believes that its existing capital resources together with the anticipated cost reductions will be adequate to satisfy its expected liquidity requirements through mid-2020. Please also refer to Note 14.
- d. On August 5, 2013, the Company entered into a Research and Development Collaboration and License Agreement ("Bayer Agreement") with Bayer Pharma AG ("Bayer") for the research, development, and commercialization of antibody-based therapeutics for antibody-based therapeutics against two novel, Compugen-discovered immune checkpoint regulators.

Under the terms of the Bayer Agreement, the Company received an upfront payment of \$ 10,000, and, following the return of the CGEN 15022 program in 2017, is eligible to receive an aggregate of over \$ 250,000 in potential milestone payments for both programs, not including aggregate milestone payments of approximately \$ 23,000 received to date. Additionally, the Company is eligible to receive mid- to high single digit royalties on global net sales of any approved products under the collaboration.

Pursuant to the terms of Bayer Agreement, BAY 1905254 program (formerly CGEN-15001T) was transferred to Bayer's full control for further preclinical and clinical development activities, and worldwide commercialization under milestone and royalty bearing licenses from Compugen.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 1: - GENERAL (Cont.)

- e. Effective March 30, 2018, the Company entered into an exclusive license agreement with MedImmune Limited, the global biologics research and development arm of AstraZeneca ("AstraZeneca") to enable the development of bi-specific and multi-specific immuno-oncology antibody products. Under the terms of the agreement, Compugen provided an exclusive license to AstraZeneca for the development of bi-specific and multi-specific antibody products derived from a Compugen pipeline program. AstraZeneca has the right to create multiple products under this license and will be solely responsible for all research, development and commercial activities under the agreement. Compugen received a \$10,000 upfront payment and is eligible to receive up to \$ 200,000 in development, regulatory and commercial milestones for the first product as well as tiered royalties on future product sales. If additional products are developed, additional milestones and royalties would be due to Compugen for each product.
- f. On October 10, 2018, the Company entered into a Master Clinical Trial Collaboration Agreement (the "Agreement") with Bristol-Myers Squibb Company ("Bristol-Myers Squibb") to evaluate the safety and tolerability of Compugen's COM701 in combination with Bristol-Myers Squibb's programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo® (nivolumab), in patients with advanced solid tumors. Pursuant to the Agreement, Compugen is responsible for and will continue sponsoring the ongoing two-part Phase 1 trial, which includes the evaluation of the combination of COM701 and Opdivo®. The collaboration is also designed to address potential future combinations, including trials sponsored by Bristol-Myers Squibb to investigate combined inhibition of checkpoint mechanisms, such as PVRIG and TIGIT. Bristol-Myers Squibb and Compugen will each supply the other company with its own compound for the other party's study, and otherwise each party will be responsible for all costs associated with the study that it is conducting.

In conjunction with the signing of the Agreement, Bristol-Myers Squibb made a \$ 12,000 investment in Compugen, see Note 7b.

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP").

- a. Use of estimates:

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions. The Company's management believes that the estimates, judgments and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

b. Financial statements in U.S. dollars:

The reporting and functional currency of the Company is the U.S. dollar, as the Company's management believes that the U.S. dollar is the primary currency of the economic environment in which the Company and Compugen USA, Inc. have operated and expect to continue to operate in the foreseeable future.

Transactions and balances denominated in U.S. dollars are presented at their original amounts. Monetary accounts denominated in currencies other than the dollar are re-measured into dollars in accordance with ASC No. 830, "Foreign Currency Matters". All transaction gains and losses from the re-measurement of monetary balance sheet items are reflected in the consolidated statement of comprehensive loss as financial income or expenses, as appropriate.

c. Basis of consolidation:

The consolidated financial statements include the accounts of the Company and Compugen USA, Inc. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash equivalents:

Cash equivalents are short-term highly liquid investments that are readily convertible to cash with original maturities of three months or less at acquisition.

e. Restricted cash:

Restricted cash held in interest bearing saving accounts which are used as a security for the Company's Israeli facility leasehold bank guarantee, foreign currency derivative contracts, and credit card security for Compugen USA Inc.

f. Short-term bank deposits:

Bank deposits with maturities of more than three months but less than one year are included in short-term bank deposits. Such short-term bank deposits are stated at cost which approximates market values.

The short-term bank deposits as of December 31, 2018 and 2017 are in U.S. dollars and bear an annual average interest rate of 2.35% and 1.46%, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

g. Marketable securities:

The Company accounts for its investment in Evogene Ltd. ("Evogene") in accordance with ASC No. 320, "Investments - Debt and Equity Securities".

Management determines the appropriate classification of its investments at the time of purchase and reevaluates such determinations at each balance sheet date.

The Company classifies its investment in Evogene as available-for-sale securities which are carried at fair value, with the unrealized gains and losses, reported in "accumulated other comprehensive income (loss)" in shareholders' equity. Realized gains and losses on sale of investments are included in "financial and other income (loss), net" and are derived using the specific identification method for determining the cost of securities.

The Company recognizes an impairment charge when a decline in the fair value of its investments is below the cost basis of such securities and is judged to be other-than-temporary. Factors considered in making such a determination include the duration and severity of the impairment, the reason for the decline in value, the potential recovery period and the Company's intent to sell, including whether it is more likely than not that the Company will be required to sell the investment before recovery of cost basis. During the year 2016, no impairment losses have been identified.

As of December 31, 2016 the Company sold its entire holdings in its marketable securities.

h. Property and equipment, net:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following annual rates:

	%
Computers, software and related equipment	33
Laboratory equipment and office furniture	6 - 20 (mainly 20)
Leasehold improvements	Shorter of the term of the lease or useful life

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

i. Impairment of long-lived assets:

The long-lived assets of the Company and Compugen USA, Inc. are reviewed for impairment in accordance with ASC 360, "Property, Plant, and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset with the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During the years 2018, 2017 and 2016, no impairment losses have been identified.

j. Revenue recognition:

The Company generates revenues mainly from its collaborative and license agreements. The revenues are derived mainly from upfront license payments, research and development services and contingent payments related to milestone achievements.

The Company has adopted the new revenue standard, Topic 606 – "Revenue from Contracts with Customers", as of January 1, 2018, using a modified retrospective adoption transition to each prior reporting period presented. The adoption did not have an effect over the Consolidated Financial Statements on the adoption date and no adjustment to prior year consolidated financial statements was required.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 606. In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company performs the following steps:

- Identification of the contract, or contracts, with a customer
- Identification of the performance obligations in the contract - At contract inception, the Company assesses the goods or services promised in a contract with a customer and identifies those distinct goods and services that represent a performance obligation. A promised good or service may not be identified as a performance obligation if it is immaterial in the context of the contract with the customer, if it is not separately identifiable from other promises in the contract (either because it is not capable of being separated or because it is not separable in the context of the contract), or if the performance obligation does not provide the customer with a material right.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

j. Revenue recognition (Cont.):

- Determination of the transaction price - The Company considers the terms of the contract and its customary business practices to determine the transaction price. The transaction price is the amount of consideration to which the Company expects to be entitled in exchange for transferring promised goods or services to a customer. The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration will only be included in the transaction price when it is not considered constrained, which is when it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur.
- Allocation of the transaction price to the performance obligations in the contract - If it is determined that multiple performance obligations exist, the transaction price is allocated at the inception of the agreement to all identified performance obligations based on the relative standalone selling prices. The relative selling price for each deliverable is estimated using objective evidence if it is available. If objective evidence is not available, the Company uses its best estimate of the selling price for the deliverable.
- Recognition of revenue when, or as, the Company satisfies a performance obligation - Revenue is recognized when, or as, the Company satisfies a performance obligation by transferring a promised good or service to a customer. An asset is transferred when, or as, the customer obtains control of that asset, which for a service is considered to be as the services are received and used.

After contract inception, the transaction price is reassessed at every period end and updated for changes such as resolution of uncertain events. Any change in the transaction price is allocated to the performance obligations on the same basis as at contract inception.

The Company entered into an exclusive license agreement with AstraZeneca. Under the terms of the agreement, Compugen provided AstraZeneca with an exclusive license to intellectual property ("IP") rights of the Company for the development of bi-specific and multi-specific antibody products derived from a Compugen pipeline program. Compugen received a \$ 10,000 upfront nonrefundable payment and is eligible to receive up to \$ 200,000 in development, regulatory and commercial milestones for the first product as well as tiered royalties on future product sales.

Under ASC 606, the Company determined the license to the IP to be a functional IP that has significant standalone functionality. The Company is not required to continue to support, develop or maintain the intellectual property transferred and will not undertake any activities to change the standalone functionality of the IP. Therefore, the license to the IP is a distinct performance obligation and as such revenue is recognized at the point in time that control of the license is transferred to the customer.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

j. Revenue recognition (Cont.):

Future milestone payments are considered variable consideration and are subject to the variable consideration constraint (i.e. will be recognized once concluded that it is “probable” that a significant reversal of the cumulative revenues recognized under the contract will not occur in future periods when the uncertainty related to the variable consideration is resolved). Therefore, as the milestone payments are not probable, revenue was not recognized in respect to such milestone payments.

Sales- or usage-based royalties to be received in exchange for licenses of IP are recognized at the later of when (1) the subsequent sale or usage occurs or (2) the performance obligation to which some or all of the sales- or usage-based royalty has been allocated is satisfied (in whole or in part). As royalties are payable based on future Commercial Sales, as defined in the agreement, which did not occur as of the financial statements date, the Company did not recognize any revenues from royalties.

On April 17, 2016 the Company achieved the first substantive milestone with respect to the second licensed program, under the Bayer Agreement according to which the Company recognized revenues in total amount of \$ 400 in accordance with the criteria prescribed under ASC 605-28.

On September 20, 2018 the Company achieved the fourth substantive milestone with respect to the remaining licensed program, under the Bayer Agreement according to which the Company recognized revenues in total amount of \$ 7,800 in accordance with the criteria prescribed under ASC 606.

For information regarding disaggregated revenues, please refer to Note 10 below.

k. Cost of revenues:

Cost of revenues consist mainly of research and development expenses attributed to the Bayer Agreement, as well as certain royalties paid.

l. Research and development expenses, net:

Research and development costs are charged to the statement of comprehensive loss as incurred and are presented net of the amount of any grants the Company receive for research and development in the period in which the grant was received.

The portion of the Bristol-Myers Squibb \$ 12,000 investment over the fair market value of the shares issued in the amount of \$ 4,121 was considered as deferred participation of Bristol-Myers Squibb in R&D expenses which will be amortized over the period of the clinical trial based on the progress in the R&D, in accordance with ASC 808 “Collaborative Arrangements”, see Note 1f and Note 7b.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

m. Severance pay:

The Company's liability for severance pay for its Israeli employees is calculated pursuant to Israeli Severance Pay Law based on the most recent salary of the employees multiplied by the number of years of employment as of the balance sheet date, and is in large part covered by regular deposits with recognized pension funds, deposits with severance pay funds and purchases of insurance policies. The value of these deposits and policies is recorded as an asset in the Company's balance sheet. Pursuant to Section 14 of the Israeli Severance Pay Law, for Israeli employees under this section, the Company's contributions for severance pay have replaced its severance obligation. Upon contribution of the full amount of the employee's monthly salary for each year of service, no additional calculations are conducted between the parties regarding the matter of severance pay and no additional payments are made by the Company to the employee. Further, the related obligation and amounts deposited on behalf of the employee for such obligation are not stated on the balance sheet, as the Company is legally released from the obligation to employees once the deposit amounts have been paid.

Severance expenses for the years ended December 31, 2018, 2017 and 2016 amounted to approximately \$ 556, \$ 365 and \$ 486, respectively.

n. Stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation", ("ASC 718"), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The Company accounts for forfeitures as they occur. The value of the pro-rata portion of the award, assuming no forfeiture, is recognized in the Company's consolidated statement of comprehensive loss as an expense over the requisite service periods. Upon forfeiture the expense is adjusted so that expense is recognized for the portion of the award that actually vested.

The Company recognizes compensation expenses for the value of its awards granted based on the straight-line method over the requisite service period of each of the awards.

The Company selected the Black-Scholes-Merton ("Black-Scholes") option-pricing model as the most appropriate fair value method for its share-options awards. The option-pricing model requires a number of assumptions, of which the most significant are the expected share price volatility and the expected option term. Expected volatility was calculated based on actual historical share price movements over a term that is equivalent to the expected term of granted options. The expected term of options granted is based on historical experience and represents the period of time that options granted are expected to be outstanding.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

n. Stock-based compensation (Cont.):

The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

The Company used the following weighted-average assumptions for options granted to employees and directors:

	Year ended December 31,		
	2018	2017	2016
Volatility	53.21%	50.7%	50.7%
Risk-free interest rate	2.9%	1.86%	1.17%
Dividend yield	0%	0%	0%
Expected life (years)	4.9	4.8	4.7

The Company applies ASC 505-50, "Equity-Based Payments to Non-Employees" ("ASC 505") with respect to options and warrants issued to non-employees which requires the use of option valuation models to measure the fair value of the options and warrants at the measurement date.

o. Concentration of credit risks:

Financial instruments that potentially subject the Company and Compugen USA, Inc. to concentration of credit risk consist principally of cash and cash equivalents, restricted cash, short-term bank deposits and foreign currency derivative contracts.

Cash, cash equivalents, restricted cash and short-term bank deposits are invested in major banks in Israel and in the U.S. Generally, these deposits may be redeemed upon demand and bear minimal risk.

The Company entered into forward contracts to hedge against the risk of overall changes in future cash flow from payments of payroll and related expenses as well as other expenses denominated in NIS. The derivative instruments hedge a portion of the Company's non-dollar currency exposure. Counterparty to the Company's derivative instruments is major financial institution.

p. Basic and diluted loss per share:

Basic loss per share is calculated based on the weighted average number of ordinary shares outstanding during each year. Diluted net loss per share is calculated based on the weighted average number of ordinary shares outstanding during each year, plus dilutive potential in accordance with ASC 260, "Earnings per Share."

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2: - SIGNIFICANT ACCOUNTING POLICIES (Cont.)

p. Basic and diluted loss per share (cont.):

All outstanding share options and warrants for the years ended December 31, 2018, 2017 and 2016 have been excluded from the calculation of the diluted net loss per share because all such securities are anti-dilutive for all periods presented. As of December 31, 2018, 2017 and 2016 the total weighted average number of shares related to outstanding options excluded from the calculations of diluted net loss per share were 8,780,532, 8,774,219 and 7,943,914, respectively.

q. Income taxes:

The Company accounts for income taxes in accordance with ASC No. 740, "Income Taxes", ("ASC 740") which prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value. As of December 31, 2018, and 2017, a full valuation allowance was provided by the Company.

ASC 740 contains a two-step approach to recognizing and measuring a liability for uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. The Company believes that its income tax filing positions and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded pursuant to ASC 740-10.

r. Fair value of financial instruments:

The Company applies ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"), pursuant to which fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputting that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company.

Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

r. Fair value of financial instruments (Cont.):

The hierarchy is broken down into three levels based on the inputs as follows:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company can access at the measurement date.

Level 2 - Valuations based on one or more quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The carrying amounts of cash and cash equivalents, restricted cash, short-term bank deposits, other accounts receivable and prepaid expenses, trade payable and other accounts payable and accrued expenses approximate their fair values due to the short-term maturities of such instruments.

The Company measures its investment in foreign currency derivative contracts at fair value (see also Note 9).

s. Derivative instruments:

The Company accounts for derivatives and hedging based on ASC 815, "Derivatives and Hedging". ASC 815 requires the Company to recognize all derivatives on the balance sheet at fair value. The accounting for changes in the fair value (i.e., gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must designate the hedging instrument, based upon the exposure being hedged, as a fair value hedge, cash flow hedge, or a hedge of a net investment in a foreign operation.

If the derivatives meet the definition of a hedge and are so designated, depending on the nature of the hedge, changes in the fair value of such derivatives will either be offset against the change in fair value of the hedged assets, liabilities, or firm commitments through earnings, or recognized in other comprehensive income until the hedged item is recognized in earnings. The ineffective portion of a derivative's change in fair value is recognized in earnings.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

s. Derivative instruments (Cont.):

The Company entered into forward contracts to hedge against the risk of overall changes in future cash flow from payments of payroll and related expenses as well as other expenses denominated in NIS. As of December 31, 2018 and 2017, the Company had outstanding forward contracts in the notional amount of \$ 0 and \$ 177, respectively. The contracts as of December 31, 2017, were for a period of half a month ended January 12, 2018. The Company measured the fair value of the contracts in accordance with ASC 820 (classified as level 2).

These contracts met the requirement for cash flow hedge accounting and as such during 2018, 2017 and 2016 total gains in the amounts of \$ 20, \$ 422 and \$ 75, respectively, were recognized and were classified to operating expenses as effective hedge. As of December 31, 2018, 2017 and 2016 an unrealized gain in the amount of \$ 0, \$ 17 and \$ 7, respectively, were recognized under other comprehensive income (loss). The fair value of the Company's outstanding forward contracts at December 31, 2018 and 2017 amounted to unrealized gain of \$ 0 and \$ 17, respectively.

t. Comprehensive income (loss):

The Company accounts for comprehensive income (loss) in accordance with ASC 220, "Comprehensive Income". This statement establishes standards for the reporting and display of comprehensive income (loss) and its components in a full set of general-purpose financial statements. Comprehensive income (loss) generally represents all changes in shareholders' equity during the period except those resulting from investments by, or distributions to, shareholders. The Company elected to present the comprehensive income (loss) in a single continuous statement.

The Company determined that its items of other comprehensive income (loss) relate to unrealized gains (losses) on foreign currency derivative contracts and unrealized gains (losses) on available-for-sale marketable securities.

u. Recently adopted Accounting Standards:

The Company adopted Topic 606 – "Revenue from Contracts with Customers" with a date of initial application of January 1, 2018. Please refer to Note 2j.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

- u. Recently adopted Accounting Standards (Cont.):

Recently issued accounting standards, not yet adopted.

In February 2016, the FASB issued ASU 2016-02, "Leases", on the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). ASC 842 supersedes the previous leases standard, ASC 840, "Leases". The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use ("ROU") asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. The company may elect, as a practical expedient, to account for leases with a term of 12 months or less in a manner similar to the accounting under existing guidance for operating leases today. In July 2018, the FASB issued amendments in ASU 2018-11, which provide another transition method in addition to the existing transition method, by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption, and to not apply the new guidance in the comparative periods they present in the financial statements. The guidance is effective for the interim and annual periods beginning on or after December 15, 2018, and the Company has elected to apply the standard retrospectively at the beginning of the period of adoption through a cumulative-effect adjustment. The Company also elected the available practical expedients on adoption. To adopt this new standard, the Company has implemented changes to its existing systems and processes in conjunction with a review of existing vendor agreements. The Company expects adoption of the standard to have a material impact on its consolidated balance sheets which will result in the recognition of ROU asset and lease liability of approximately \$ 5,000 to \$ 5,500 at January 1, 2019.

The most significant impact from recognition of ROU assets and lease liabilities relates to the Company's office spaces. However, the Company does not anticipate that the adoption of this standard will have a material impact on the operating expenses in its consolidated statements of comprehensive loss since the expense recognition under this new standard will be similar to current practice. The Company's financial income (expenses), net will be impacted by the revaluation of the lease liabilities in non-USD denominated currencies.

In June 2018, the FASB issued ASU 2018-07, "Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." This ASU supersedes ASC 505-50, "Equity—Equity Based Payments to Non-Employees," and expands the scope of ASC 718, "Compensation – Stock Compensation," to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. For public companies that file with the SEC, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606, "Revenue from Contracts with Customers." The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 3: - OTHER ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2018	2017
Prepaid expenses	\$ 736	\$ 690
Government authorities	109	34
Receivables from foreign currency derivative contracts	-	17
Other	58	-
	<u>\$ 903</u>	<u>\$ 741</u>

NOTE 4: - PROPERTY AND EQUIPMENT, NET

	December 31,	
	2018	2017
Cost:		
Computers, software and related equipment	\$ 1,371	\$ 1,346
Laboratory equipment and office furniture	5,808	5,752
Leasehold improvements	2,536	2,531
	<u>9,715</u>	<u>9,629</u>
Accumulated depreciation:		
Computers, software and related equipment	1,166	958
Laboratory equipment and office furniture	4,247	3,369
Leasehold improvements	930	655
	<u>6,343</u>	<u>4,982</u>
Depreciated cost	<u>\$ 3,372</u>	<u>\$ 4,647</u>

During 2018 and 2017 total cost of \$ 87 and \$ 12, respectively and total accumulated depreciation of \$ 33 and \$ 12, respectively related to certain nonfunctional Lab and computer equipment were disposed from the consolidated balance sheets.

For the years ended December 31, 2018, 2017 and 2016, depreciation expenses were approximately \$ 1,394, \$ 1,593 and \$ 1,484, respectively.

NOTE 5:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2018	2017
Employees and related accruals	\$ 2,504	\$ 1,673
Royalties payments related to Milestone payments from Bayer	234	-
Accrued expenses	3,216	1,076
	<u>\$ 5,954</u>	<u>\$ 2,749</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 6: - COMMITMENTS AND CONTINGENCIES

- a. The Company and Compugen USA, Inc. lease their facilities and motor vehicles under various operating lease agreements that expire on various dates.

Annual minimum future rental commitments under operating leases are approximately as follows:

December 31,

2019	\$	1,489
2020		1,447
2021		865
2022		608
2023		607
2024 and after		1,342
	\$	<u>6,358</u>

Operating lease expenses for the Company and Compugen USA, Inc. were approximately \$ 1,680, \$ 1,379 and \$ 1,337 in the years ended December 31, 2018, 2017 and 2016, respectively.

The above annual minimum future rental commitments include a first option to extend the lease of the Company facility for additional five-year period and exclude a second option to extend the lease of the Company facility for additional five-year period, following expiration of the current lease period.

- b. The Company provided bank guarantees in the amount of \$ 612 in favor of its offices' lessor in Israel, foreign currency derivative contracts and credit card security for its U.S. subsidiary.
- c. Under the Office of the Israel Innovation Authority of the Israeli Ministry of Industry, Trade and Labor, formerly known as the Office of the Chief Scientist, (the "IIA"), the Company is not obligated to repay any amounts received from the IIA if it does not generate any income from the results of the funded research program(s). If income is generated from a funded research program, the Company is committed to pay royalties at a rate of between 3% to 5% of future revenue arising from such research program (s), and up to a maximum of 100% of the amount received, linked to the U.S. dollar (for grants received under programs approved subsequent to January 1, 1999, the maximum to be repaid is 100% plus interest at LIBOR). For the years ended December 31, 2018, 2017 and 2016, the Company has an aggregate of paid and accrued royalties to the IIA, recorded as cost of revenue in the consolidated statement of comprehensive loss, in the amount of \$ 534, \$ 0 and \$ 25, respectively.

As of December 31, 2018, the Company's aggregate contingent obligations for payments to IIA, based on royalty-bearing participation received or accrued, net of royalties paid or accrued, totaled approximately to \$ 9,098.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 6:- COMMITMENTS AND CONTINGENCIES (Cont.)

- d. On June 25, 2012 the Company entered into an Antibodies Discovery Collaboration Agreement (the "Antibodies Discovery Agreement") with a U.S. antibody technology company ("mAb Technology Company"), providing an established source for fully human mAbs. Under the Antibodies Discovery Agreement, the mAb Technology Company will be entitled to certain royalties that could be eliminated, upon payment of certain one-time fees (all payments referred together as "Contingent Fees"). For the years ended December 31, 2018, 2017 and 2016, the Company incurred such Contingent Fees in the amounts of \$ 500, \$ 0 and \$ 0.
- e. On May 9, 2012, the Company entered into agreement (the "May 2012 Agreement") with a U.S. Business Development Strategic Advisor ("Advisor") for the purpose of entering into transactions with Pharma companies related to selected Pipeline Program Candidates. Under the agreement the Advisor shall be entitled to 4% of the cash considerations that may be received under such transactions. In 2014, the May 2012 Agreement was terminated except for certain payments arising from the Bayer Agreement which survive termination until August 5, 2025.

For the years ended December 31, 2018, 2017 and 2016, the Company has an aggregate of paid and accrued payments recorded as marketing and business development expenses in the consolidated statement of comprehensive loss in the amount of \$ 312, \$ 0 and \$ 0, respectively.

- f. Effective as of January 5, 2018, the Company entered into a Commercial License Agreement (CLA) with a European cell line development company. Under the agreement the Company is required to pay an annual maintenance fee, certain amounts upon the occurrence of specified milestones events, and 1% royalties on annual net sales with respect to each commercialized product manufactured using the company's cell line. Royalties due under the CLA are creditable against the annual maintenance fee. In addition, the Company may at any time prior to the occurrence of a specific milestone event buy-out the royalty payment obligations in a single fixed amount.

NOTE 7:- SHAREHOLDERS' EQUITY

- a. Ordinary shares:

The ordinary shares confer upon their holders the right to attend and vote at general meetings of the shareholders. Subject to the rights of holders of shares with limited or preferred rights which may be issued in the future, the ordinary shares of the Company confer upon the holders thereof equal rights to receive dividends, and to participate in the distribution of the assets of the Company upon its winding-up, in proportion to the amount paid up or credited as paid up on account of the nominal value of the shares held by them respectively and in respect of which such dividends are being paid or such distribution is being made, without regard to any premium paid in excess of the nominal value, if any.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

b. Issuance of shares:

On May 25, 2018, the Company entered into a Controlled Equity OfferingSM sales agreement with Cantor Fitzgerald & Co. ("Cantor"), as sales agent, pursuant to which the Company may offer and sell, from time to time through Cantor, ordinary shares, par value NIS 0.01 per share, of the Company (the "Ordinary Shares"), under an "at-the-market" ("ATM") offering, having an aggregate offering price of up to \$ 25,000 (the "ATM Shares"). Any ATM Shares offered and sold will be issued pursuant to the Company's shelf registration statement on Form F-3 (Registration No. 333-213007) and the related prospectus previously declared effective by the Securities and Exchange Commission (the "SEC") on October 11, 2016 (the "Registration Statement"), as supplemented by a prospectus supplement, dated May 25, 2018. As of December 31, 2018, 50,594 shares were issued and sold under the ATM, with proceeds of approximately \$ 156 (net of \$ 45 issuance expenses).

On June 14, 2018, the Company entered into securities purchase agreement with certain institutional investors and a placement agency agreement with JMP Securities LLC in connection with a registered direct offering (the "Offering") of an aggregate of 5,316,457 Ordinary Shares (the "RD Shares") of the Company at a purchase price of \$ 3.95 per RD Share. In connection with the issuance of the RD Shares, the Company also issued warrants to purchase an aggregate of up to 4,253,165 additional ordinary shares. The Warrants is exercisable at a price of \$ 4.74 per Ordinary Share and have a term of five years from the date of issuance. The Offering was made pursuant to the Company's Registration Statement. Proceeds from the Offering were \$ 19,767 (net of \$ 1,233 issuance expenses).

On October 10, 2018, the Company entered into a Master Clinical Trial Collaboration Agreement (the "Master Clinical Agreement") with Bristol-Myers Squibb to evaluate the safety and tolerability of the Company's COM701 in combination with Bristol-Myers Squibb's programmed death-1 (PD-1) immune checkpoint inhibitor Opdivo® (nivolumab), in patients with advanced solid tumors. In conjunction with the Master Clinical Agreement, Bristol-Myers Squibb made a \$ 12,000 equity investment in the Company. Under the terms of the securities purchase agreement, Bristol-Myers Squibb purchased 2,424,243 ordinary shares of the Company at a purchase price of \$ 4.95 per share. The share price represents a 33% premium over the average closing price of Compugen's ordinary shares for twenty (20) Nasdaq trading days prior to the execution of the securities purchase agreement. The investment closed on October 12, 2018.

The premium over the fair market value in the amount of \$ 4,121 represents the relative fair value of deferred participation of Bristol-Myers Squibb in R&D expenses which will be amortized over the period of the clinical trial based on the progress in the R&D, in accordance with ASC 808 "Collaborative Arrangements" and \$ 7,788 (net of \$ 91 issuance expenses were considered equity investment).

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

c. Share option plans:

Under the Company's 2000 and 2010 Share Option Plans as amended (together "the Plan"), options may be granted to employees, directors and non-employees of the Company and Compugen USA Inc.

Under the 2010 Share Option Plan the Company reserved for issuance up to an aggregate of 10,133,931 ordinary shares. The Company's Board of Directors last amended the Plan in August 2017, to increase the number of shares available under the 2010 Plan. As of December 31, 2018, an aggregate of 1,076,533 options under the 2010 Share Option Plan of the Company are still available for future grant.

In general, options granted under the Plan vest over a four-year period and expire 10 years from the date of grant and are granted at an exercise price of not less than the fair market value of the Company's ordinary shares on the date of grant, unless otherwise determined by the Company's board of directors. The exercise price of the options granted under the plans may not be less than the nominal value of the shares into which such options are exercised and the expiration date may not be later than 10 years from the date of grant. If a grantee leaves his or her employment or other relationship with the Company, or if his or her relationship with the Company is terminated without cause (and other than by reason of death or disability, as defined in the Plan), the term of his or her unexercised options will generally expire in 90 days, unless determined otherwise by the Company's board of directors.

Any options that are cancelled or forfeited before expiration become available for future grants.

Transactions related to the grant of options to employees and directors under the above plans during the year ended December 31, 2018, were as follows:

	Number of options	Weighted average exercise price \$	Weighted average remaining contractual life Years	Aggregate intrinsic value \$
Options outstanding at beginning of year	8,648,583	4.72	6.03	1,364
Options granted	1,593,400	3.23		
Options exercised	(765,420)	0.89		
Options forfeited	(1,274,125)	5.32		
Options expired	-			
Options outstanding at end of year	8,202,438	4.69	5.97	-
Exercisable at end of year	4,791,683	5.38	3.96	-

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

Weighted average fair value of options granted to employees and directors during the years 2018, 2017 and 2016 was \$ 1.55, \$ 1.66 and \$ 2.79 per share, respectively.

Aggregate intrinsic value of exercised options by employees and directors during the years 2018, 2017 and 2016 was \$ 1,521, \$ 351 and \$ 941, respectively. The Aggregate intrinsic value of the exercised options represents the total intrinsic value (the difference between the sale price of the Company's share at the date of exercise, and the exercise price) multiplied by the number of options exercised.

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing share price on the last trading day of calendar 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2018. This amount is impacted by the changes in the fair market value of the Company's shares.

d. Options to non-employees:

	Number of options	Weighted average exercise price \$	Weighted average remaining contractual life Years	Aggregate intrinsic value \$
Options outstanding at beginning of year	793,000	5.80	4.39	-
Options granted	75,000	3.09		
Options exercised	-			
Options forfeited	(100,000)	5.52		
Options expired	-			
Options outstanding at end of year	768,000	5.57	3.65	-
Exercisable at end of year	450,500	6.25	3.30	-

The unvested options are re-measured using a Black-Scholes option-pricing model at their then-current fair value at the last date of each reporting period and compensation cost is adjusted for the changes for those fair values. The Company recognized the compensation cost using the straight-line method.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 7:- SHAREHOLDERS' EQUITY (Cont.)

The Company used the following weighted-average assumptions for general options granted to non-employees:

	Year ended December 31,		
	2018	2017	2016
Volatility	55.15%	52.09%	49.92%
Risk-free interest rate	2.54%	2.21%	1.98%
Dividend yield	0%	0%	0%
Expected life (years)	5.85	5.23	5.29

- e. As of December 31, 2018, the total unrecognized estimated compensation cost related to non-vested share options granted prior to that date was \$ 5,222 which is expected to be recognized over a weighted average period of approximately 2.87 years.

The stock-based compensation expenses are included as follows in the expense categories:

	Year ended December 31,		
	2018	2017	2016
Cost of revenue	\$ -	\$ -	\$ 23
Research and development expenses	948	1,331	1,522
Marketing and business development expenses	215	187	147
General and administrative expenses	1,003	1,115	1,392
	<u>\$ 2,166</u>	<u>\$ 2,633</u>	<u>\$ 3,084</u>

NOTE 8:- INCOME TAXES

- a. Israeli taxation

1. Tax rates applicable to the income of the Company.

Taxable income of the Company is subject to a corporate tax rate as follow: 2016 – 25%, 2017- 24% and 23% in 2018.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

The deferred tax balances as of December 31, 2018 and 2017 have been calculated based on the revised tax rates.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Cont.)

2. Measurement of taxable income in US dollars:

The Company has elected to measure its taxable income and file its tax return under the Israeli Income Tax Regulations (Principles Regarding the Management of Books of Account of Foreign Invested Companies and Certain Partnerships and the Determination of Their Taxable Income), 1986. Accordingly, results for tax purposes are measured in terms of earnings in dollars.

3. Tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959 (the "Investment Law"):

The Company's production facilities in Israel have been granted the status of an "Approved Enterprise" in accordance with the Investment Law under five separate investment programs. According to the provisions of the Investment Law, the Company has been granted the "Alternative Benefit Plan", under which the main benefits are tax exemptions and reduced tax rates.

Therefore, the Company's income derived from the "Approved Enterprise" will be entitled to a tax exemption for a period of two years from the first year of taxable income and to an additional period of five to eight years of reduced tax rates of 10% - 25% (based on the percentage of foreign ownership). The duration of tax benefits of reduced tax rates is subject to a limitation of the earlier of 12 years from commencement of production, or 14 years from the approval date.

Tax-exempt income attributable to the "Approved Enterprise" cannot be distributed to shareholders without subjecting the Company to taxes except upon complete liquidation of the Company. If such retained tax-exempt income is distributed in a manner other than upon the complete liquidation of the Company, it would be taxed (grossed up to reflect such pre-tax income that it would have had to earn in order to distribute the dividend) at the reduced corporate tax rate between 10%-25%, applicable to such profits as if the Company had not been tax-exempted under the alternative tax benefits.

The entitlement to the above benefits is conditional upon the Company fulfilling the conditions stipulated by the Investment Law, regulations published thereunder and the certificate of approval for the specific investments in "Approved Enterprises". In the event of failure to comply with these conditions, the benefits may be canceled and the Company may be required to refund the amount of the benefits, in whole or in part, including interest. As of December 31, 2018, management believes that the Company is in compliance with all of the aforementioned conditions.

Income from sources other than the "Approved Enterprise" during the benefit period will be subject to tax at the regular tax rate prevailing at that time.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Cont.)

On April 1, 2005, an amendment to the Investment Law came into effect (the "Amendment 60") that significantly changed the provisions of the Investment Law. The Amendment 60 limits the scope of enterprises that may be approved by the Investment Center by setting criteria for the approval of a facility as a "Beneficiary Enterprise" including a provision generally requiring that at least 25% of the Beneficiary Enterprise's income will be derived from export.

Another condition for receiving the benefits under the alternative track in respect of expansion programs pursuant to Amendment 60 is a minimum qualifying investment. The Company was eligible under the terms of minimum qualifying investment and elected 2008, and 2012 as its "years of election".

Additionally, the Amendment 60 enacted major changes in the manner in which tax benefits are awarded under the Investment Law so that companies no longer require Investment Center approval in order to qualify for tax benefits. However, the Investment Law provides that terms and benefits included in any certificate of approval already granted will remain subject to the provisions of the Investment Law as they were on the date of such approval.

As of December 31, 2018, there was no taxable income attributable to the Beneficiary Enterprise.

In January 2011, another amendment to the Investment Law came into effect ("the 2011 Amendment"). According to the 2011 Amendment, the benefit tracks in the Investment Law were modified and a flat tax rate applies to the Company's entire income subject to this amendment (the "Preferred Income").

Once an election is made, the Company's income will be subject to the amended tax rate of 16% from 2015 and thereafter (or 9% a preferred enterprise located in development area A).

Commencing from the 2011 tax year, the Company can elect (without possibility of reversal) to apply the Amendment in a certain tax year and from that year and thereafter, it will be subject to the amended tax rates.

The Company does not currently intend to adopt the 2011 Amendment and intends to continue to comply with the Investment Law as in effect prior to enactment of the 2011 Amendment. Accordingly, the Company did not adjust its deferred tax balances as of December 31, 2018. The Company's position may change in the future.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Cont.)

In December 2016, the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2016 and 2017 Budget Years), 2016 which includes Amendment 73 to the Law ("Amendment 73") was published. According to Amendment 73, a preferred enterprise located in development area A will be subject to a tax rate of 7.5% instead of 9% effective from January 1, 2016 and thereafter (the tax rate applicable to preferred enterprises located in other areas remains at 16%).

Amendment 73 also prescribes special tax tracks for technological enterprises, which are subject to rules that were issued by the Minister of Finance by May 2017. The new tax tracks under the Amendment are as follows:

Preferred Technological Enterprise ("PTE") - an enterprise for which total consolidated revenues of its parent company and all subsidiaries are less than NIS 10 billion in a tax year. A PTE, as defined in the Law, which is located in the center of Israel will be subject to tax at a rate of 12% on profits deriving from intellectual property (in development area A - a tax rate of 7.5%).

The above changes in the tax rates relating to PTE tax track were not taken into account in the computation of deferred taxes as of December 31, 2018 and 2017, since the Company estimates that it will not implement the PTE tax track.

4. Tax benefits under the law for the Encouragement of Industry (taxes), 1969 (the "Encouragement Law"):

The Encouragement Law provides several tax benefits for industrial companies. An industrial company is defined as a company resident in Israel, at least 90% of the income of which in a given tax year exclusive of income from specified Government loans, capital gains, interest and dividends, is derived from an industrial enterprise owned by it. An industrial enterprise is defined as an enterprise whose major activity in a given tax year is industrial production activity.

Management believes that the Company is currently qualified as an "industrial company" under the Encouragement Law and, as such, is entitled to tax benefits, including: (1) deduction of purchase of know-how and patents and/or right to use a patent over an eight-year period; (2) the right to elect, under specified conditions, to file a consolidated tax return with additional related Israeli industrial companies and an industrial holding company; (3) accelerated depreciation rates on equipment and buildings; and (4) expenses related to a public offering on the Tel-Aviv Stock exchange and on recognized stock markets outside of Israel, are deductible in equal amounts over three years.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Cont.)

Eligibility for benefits under the Encouragement Law is not subject to receipt of prior approval from any Governmental authority. No assurance can be given that the Israeli tax authorities will agree that the Company qualifies, or, that the Company will continue to qualify as an industrial company or that the benefits described above will be available to the Company in the future

5. Net operating losses carryforward and capital loss:

As of December 31, 2018, Compugen Ltd.'s net operating losses carryforward for tax purposes in Israel amounted to approximately \$ 244,800. These net operating losses may be carried forward indefinitely and may be offset against future taxable income.

b. Non-Israeli subsidiary, Compugen USA, Inc.:

On December 22, 2017, the United States enacted the Tax Cuts and Jobs Act (the "U.S. Tax Reform" or "TCJA"); a comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include several key tax provisions that might impact the Company, among others: (i) a permanent reduction to the statutory federal corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017; (ii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain new rules designed to prevent erosion of the U.S. income tax base - "BEAT"); (iii) establishing immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits; and (iv) providing a permanent deduction to corporations generating revenues from non-US markets (known as a deduction for foreign derived intangible income - "FDII").

In December 2017, the Securities and Exchange Commission staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to provide guidance for companies that had not completed their accounting measurement for the income tax effects of the TCJA. Due to the complexities involved in accounting for the enactment of the TCJA, SAB 118 allowed for a provisional estimate of the impacts of the TCJA in the Company's earnings for the year ended December 31, 2017, as well as up to a one year measurement period that ended on December 22, 2018, for any subsequent adjustments to such provisional estimate.

The Company has concluded that a reasonable estimate could be developed for the effects of the tax reform. However, due to the short time frame between the enactment of the reform and the year end, its fundamental changes, the accounting complexity, and the expected ongoing guidance and accounting interpretations over the next 12 months, the Company considers the accounting of the deferred tax remeasurement and other items to be incomplete.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Cont.)

These effects have been included in the consolidated financial statements for the year ended December 31, 2017 as provisional amounts, which had no effect on the benefit from taxes on income due to the valuation allowance. No changes were required to be made in the provisional amounts during the measurement period.

There were no adjustments to the provisional amounts during the measurement period.

As of December 31, 2018, Compugen USA, Inc. has net operating loss carryforwards for federal income tax purposes of approximately \$ 6,000 which expires in the years 2021 to 2032. Utilization of the U.S. net operating losses may be subject to substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization.

Neither Israeli income taxes, foreign withholding taxes nor deferred income taxes were provided in relation to undistributed earnings of the Company's foreign subsidiary. This is because the Company has the intent and ability to reinvest these earnings indefinitely in the foreign subsidiary and therefore those earnings are continually redeployed in those jurisdictions.

- c. Loss (income) before taxes is comprised as follows:

	Year ended December 31,		
	2018	2017	2016
Domestic (Israel)	\$ 23,588	\$ 37,939	\$ 32,246
Foreign	(989)	(873)	(760)
	<u>\$ 22,599</u>	<u>\$ 37,066</u>	<u>\$ 31,486</u>

- d. Taxes on income for the year ended December 31, 2016 is comprised from withholding tax payments amounted to \$ 20, which were deducted from milestone payments of \$ 400 (see also Note 2j) by the German tax authorities. There were no withholding tax payments for the years ended December 31, 2018, and December 31, 2017.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 8:- INCOME TAXES (Cont.)

e. Deferred taxes:

Deferred taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company and Compugen USA, Inc.'s deferred tax assets are comprised of operating loss carryforward and other temporary differences. Significant components of the Company and Compugen USA, Inc. deferred tax assets are as follows:

	December 31,	
	2018	2017
Operating loss carryforward	\$ 57,564	\$ 54,093
Research and development	10,098	9,298
Accrued social benefits and other	1,456	874
Property and equipment	(11)	(46)
Deferred tax asset before valuation allowance	69,107	64,219
Valuation allowance	(69,107)	(64,219)
Net deferred tax asset	\$ -	\$ -

The Company and Compugen USA, Inc. have provided full valuation allowances in respect of deferred tax assets resulting from operating loss carryforward and other temporary differences. Management currently believes that since the Company has a history of losses it is more likely than not that the deferred tax regarding the operating loss carryforward and other temporary differences will not be realized in the foreseeable future.

f. Reconciliation of the theoretical tax expense (benefit) to the actual tax expense (benefit):

The main reconciling items between the statutory tax rate of the Company and the effective tax rate are the non-recognition of tax benefits from accumulated net operating loss carryforward among the Company and Compugen USA, Inc. due to the uncertainty of the realization of such tax benefits.

g. Tax assessments:

The Company has tax assessments through 2013 that are deemed to be final.

NOTE 9:- FAIR VALUE MEASUREMENTS

In accordance with ASC 820 "Fair Value Measurements and Disclosures", the Company measures its investment in foreign currency derivative contracts at fair value. Foreign currency derivative contracts are classified within Level 2 as the valuation inputs are based on quoted prices and market observable data of similar instruments.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 9:- FAIR VALUE MEASUREMENTS (Cont.)

The Company's financial assets and liabilities measured at fair value on a recurring basis, consisted of the following types of instruments as of the following dates:

Description	December 31, 2017			
	Fair value measurements			
	Fair value	Level 1	Level 2	Level 3
Foreign currency derivative contracts	17	-	17	-
Total financial assets	\$ 17	\$ -	\$ 17	\$ -

NOTE 10:- GEOGRAPHIC INFORMATION AND MAJOR CUSTOMERS

The Company's business is currently comprised of one operating segment, the research, development and commercialization of therapeutic and product candidates. The nature of the products and services provided by the Company and the type of customers for these products and services are similar. Operations in Israel and the United States include research and development, clinical operations, sales and business development. The Company follows ASC 280, "Segment Reporting." Total revenues are attributed to geographic areas based on the location of the end customer.

The following represents the total revenue for the years ended December 31, 2018, 2017 and 2016 and long-lived assets as of December 31, 2018 and 2017:

	Year ended December 31,		
	2018	2017	2016
Revenue from sales to customers:			
Europe	\$ 17,800	\$ -	\$ 712
Total revenue	\$ 17,800	\$ -	\$ 712
		December 31,	
		2018	2017
Long-lived assets:			
Israel		\$ 2,712	\$ 3,523
United States		660	1,124
Total long-lived assets		\$ 3,372	\$ 4,647
		Year ended December 31,	
	2018	2017	2016
Sales to a single customer exceeding 10%:			
Customer A	44%	-	100%
Customer B	56%	-	-

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 11: - FINANCIAL AND OTHER INCOME, NET

	Year ended December 31,		
	2018	2017	2016
Interest income	\$ 643	\$ 523	\$ 728
Bank fees and other finance expenses	(23)	(15)	(23)
Gain from sales of marketable securities	-	-	383
Foreign currency translation adjustments	60	(169)	9
Loss from sales and disposals of fixed assets	(52)	-	-
Financial and other income, net	\$ 628	\$ 339	\$ 1,097

NOTE 12: - RELATED PARTY BALANCES AND TRANSACTIONS

	December 31,	
	2018	2017
Trade payables and accrued expenses	\$ 133	\$ 78

Related parties' expenses:

	Year ended December 31,		
	2018	2017	2016
Amounts charged to:			
Research and development expenses	\$ 314	\$ 447	\$ 284

For the year ended December 31, 2018 and 2017 the Company received research and development services related with cancer studies in animal models, and breeding and maintenance of animals (mice) to support such studies. The transaction is at arm's length.

NOTE 13:- LOSSES PER SHARE

The following table sets forth the computation of basic and diluted losses per share:

	Year ended December 31,		
	2018	2017	2016
Numerator:			
Net loss for basic loss per share	\$ (22,599)	\$ (37,066)	\$ (31,506)
Net loss for basic loss per share	\$ (22,599)	\$ (37,066)	\$ (31,506)
Denominator:			
Weighted average number of ordinary shares used in computing basic net loss per share	55,277,428	51,179,694	50,855,908
Basic and diluted earnings per ordinary share	\$ (0.41)	\$ (0.72)	\$ (0.62)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

U.S. dollars in thousands (except share and per share data)

NOTE 14:- SUBSEQUENT EVENTS

On February 26, 2019, the Company announced a corporate restructuring to reduce costs by consolidating and streamlining R&D operations. Anticipated cost reductions are expected to extend the Company's cash runway through mid-2020 to enable the planned expansion of the ongoing Phase 1 study for COM701. In addition, the Company will maintain investment in its proprietary computational discovery platform and will continue to advance its earlier stage immuno-oncology pipeline programs, which are the Company's two long-term core value drivers.

The restructuring includes consolidation of R&D activities in one location (Israel), a 35% workforce reduction (approximately 35 employees), the majority of which is in R&D and outsourcing of certain preclinical activities to third-party service providers. The Company anticipates savings of up to \$10,000 on an annual basis.

SUBSIDIARIES

<u>Subsidiary</u>	<u>Jurisdiction</u>
Compugen USA, Inc.	Delaware

**CERTIFICATION PURSUANT TO
RULE 13a-14(a)/RULE 15d-14(a) UNDER
THE EXCHANGE ACT AND SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Dr. Anat Cohen-Dayag, certify that:

1. I have reviewed this annual report on Form 20-F of Compugen Ltd.;
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 company as of, and for, the periods presented in this report;
4. The company'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 company 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 company, 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 company'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 company'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 company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: March 21, 2019

/s/ Dr. Anat Cohen-Dayag

Title: President and Chief Executive Officer

**CERTIFICATION PURSUANT TO
RULE 13a-14(a)/RULE 15d-14(a) UNDER
THE EXCHANGE ACT AND SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002**

I, Ari Krashin, certify that:

1. I have reviewed this annual report on Form 20-F of Compugen Ltd.;
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 company as of, and for, the periods presented in this report;
4. The company'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 company 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 company, 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 company'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 company'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 company's internal control over financial reporting; and
5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: March 21, 2019

/s/ Ari Krashin

Title: Chief Financial and Operating Officer

**CERTIFICATION PURSUANT TO
RULE 13a-14(b)/RULE 15d-14(b) UNDER THE EXCHANGE ACT
AND 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 Compugen Ltd. (the "Company") on Form 20-F for the fiscal year ended December 31, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company, certify, pursuant to Rule 13a-14(b)/Rule 15d-14(b) under the Securities Exchange Act of 1934, as amended and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

1. The Report fully complies with the requirements of Sections 13(a) or 15(d), as applicable, 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.

/s/ Dr. Anat Cohen-Dayag

Title: President and Chief Executive Officer
Date: March 21, 2019

/s/ Ari Krashin

Title: Chief Financial and Operating Officer
Date: March 21, 2019

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-169239, 333-204869 and 333-223937) pertaining to the Employee's share option plans of Compugen Ltd. and Registration Statements on Form F-3 (File No. 333-213007) of our report dated March 21, 2019, with respect to the consolidated financial statements of Compugen Ltd. and the effectiveness of internal control over financial reporting of Compugen Ltd. included in this Annual Report (Form 20-F) for the year ended December 31, 2018.

March 21, 2019
Tel-Aviv, Israel

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global
