COMPUGEN LTD
Form 20-F
February 18, 2014

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

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

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 NO. 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)

72 Pinchas Rosen Street, Tel Aviv, 6951294 Israel
(Address of principal executive offices)

_____

Dikla Czaczkes Axselbrad, Chief Financial Officer
Phone: +972-3-765-8585, Fax: +972-3-765-8555
72 Pinchas Rosen Street, Tel Aviv, 6951294 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	Name of each exchange on which registered
Ordinary shares, par value NIS 0.01 per share	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: 41,002,113 Ordinary Shares

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

o Yes x 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

o Yes x 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:

x Yes o No

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

x Yes o No

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

Large accelerated filer o Accelerated filer x Non-accelerated filer o

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

U.S. GAAP x

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

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 x 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 “may”, "assume", “expect”, “anticipate”, “could”, “project”, “estimate”, “possible”, “potential”, “believe”, and describe opinions about future events. We have based these forward-looking statements on information available to us on 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. Risk Factors”, the information about us set forth under “Item 4. Information about 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 re 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, 2013 and 2012 and for the years ended December 31, 2013, 2012 and 2011 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, 2011, 2010 and 2009 and for the years ended December 31, 2010 and 2009 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,				
	2009	2010	2011	2012	2013
	(US$ in thousands, except share and per share data)				
Consolidated Statement of Operations Data					
Revenues	$250	$1,115	$-	$242	$3,549
Total operating expenses (1)	7,879	8,769	11,979	13,583	18,083
Operating loss	(7,629)	(7,878)	(11,979)	(13,542)	(17,043)
Financial and other income (expenses), net	3,786	675	(25)	(86)	3,460
Losses before tax expenses	(3,843)	(7,203)	(12,004)	(13,628)	(13,583)
Income tax expenses	-	-	-	-	(500)
Net loss	(3,831)	(7,203)	(12,004)	(13,628)	(14,083)
Realized and unrealized gain (loss) on Investment in Evogene	3,594	2,716	(2,141)	1,103	(739)
Total comprehensive loss	(237)	(4,487)	(14,145)	(12,525)	(14,822)
Basic and diluted net loss per share	$(0.13)	$(0.22)	$(0.35)	$(0.38)	$(0.36)
Weighted average number of ordinary shares used in computing basic net loss per share	28,608,317	33,284,017	34,276,697	35,844,496	38,869,438
Weighted average number of ordinary shares used in computing diluted net loss per share	28,608,317	33,284,017	34,276,697	36,249,262	38,869,438

(1) Includes stock based compensation – see Note 9 of our 2013 consolidated financial statements.

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	As of December 31,				
	2009	2010	2011	2012	2013
	(US$ in thousands)				
Consolidated Balance Sheet Data					
Cash and cash equivalents, short-term bank deposits, marketable securities and restricted cash	$15,800	$22,508	$22,463	$19,685	$ 46,920
Receivables on account of shares and from funding arrangement	7,790	5,000	-	-	-
Investment in Evogene	3,898	6,227	4,093	5,196	4,565
Total assets	30,185	36,458	29,081	28,909	56,711
Deferred Revenues	-	-	-	-	6,772
Research and development funding arrangements and others	-	4,037	6,434	7,872	13,189
Accumulated deficit	(161,284)	(168,487)	(180,491)	(194,119)	(208,202)
Total shareholders' equity	27,398	28,285	19,581	17,672	31,888

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

B. CAPITALIZATION AND INDEBTEDNESS

Not applicable.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable.

D. RISK FACTORS

Many factors could affect our financial condition, cash flows and results of operations. We are subject to various risks including all the risks which are inherent in pharmaceutical discovery and development and those risks resulting from changing economic, political, social, industry, business and financial conditions in Israel and the major market countries. 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. 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

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

Our business model is primarily based on receiving revenues in the form of fees, research revenues, milestone payments, royalties and other revenue sharing payments from the commercialization of drug and diagnostic products by third parties based on product candidates (i) discovered by us and then licensed to such third parties, and/or (ii) discovered pursuant to various forms of collaborations with such third parties whereby our discovery platforms or other discovery capabilities target areas of mutual interest. To date, third party arrangements have only been entered into at early validation or pre-clinical stages which have an inherent risk of high failure rate. Following establishment and validation of a sufficiently broad and integrated infrastructure of our individual predictive discovery capabilities into a “therapeutics needs (market) driven” discovery process, during 2010, a program was initiated to predict and select novel molecules in specific areas of high interest in both oncology and immunology. Therapeutic product candidates resulting from this “therapeutics needs (market) driven” effort are being validated and advanced forward in the preclinical stage prior to licensing or other collaborations (our “Pipeline Program”). To date, we have entered into only one commercial arrangement with Bayer Pharma AG ("Bayer") with respect to our Pipeline Program molecules and, other than that, we have received only minimal revenues from limited commercialization efforts with respect to molecules discovered during our infrastructure building period. We cannot be certain this business model will generate a stable or significant revenue stream. 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, 2013, we had an accumulated deficit of approximately $208 million and had incurred net losses of approximately $12.0 million in 2011, approximately $13.6 million in 2012, and approximately $14.1 million in 2013. In addition, we expect to continue to incur net losses in the future due to the costs and expenses associated with our expanding research and development activities, including significantly increasing Pipeline Program activities, our increase in activities in the United States, and the development, validation and integration of additional discovery platforms. To date, we have entered into only one commercial arrangement with respect to our Pipeline Program molecules and, other than that, we have received only minimal revenues from limited commercialization efforts with respect to molecules discovered during our infrastructure building period. We cannot be certain that we will enter into additional arrangements for our Pipeline Program candidates or other discoveries or 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 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 operations for at least the next 12 months, taking into consideration the anticipated increase in our R&D expenditures of more than 60% as compared to 2013. 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 and commercialization activities. In addition, 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.

Additional funds, including proceeds from commercialization agreements, or from other financings, may not be available to us when needed, 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 others that may require us to enter into arrangements on terms that would otherwise not be acceptable to us. Any failure to raise capital when needed would materially harm our business, financial condition and results of operations.

Our Pipeline Program will require additional resources that may not be available.

In 2010 we initiated our Pipeline Program pursuant to which we are both (i) substantially increasing the number of predicted and selected therapeutic candidates being evaluated by us, and (ii) taking certain therapeutic candidates beyond their validation stage (of either disease animal model for Fc fusion proteins or drug target expression profile for monoclonal antibody (“mAb”) targets and antibody-drug conjugate ("ADC") targets) into preclinical activities for Fc fusion proteins and to disease animal models for therapeutic mAbs against the targets, and in selected cases, possibly clinical evaluation. Assuming a similar level of success as we experienced in the past in the initial validation stages, this may result in multiple product candidates reaching more costly stages of research and development in parallel. If we are not able to secure the funding or the technologies required for these more advanced activities, we may be required to abandon, postpone, or attempt to license out certain molecules at an earlier than anticipated stage, which may result in a substantial reduction in the potential returns from the Pipeline Program, or even result in the inability to have some or all of such successful “proof of concept” therapeutic candidates further developed and commercialized.

We operate in a rapidly developing field and will be required to allocate substantial additional funds in the future to our research activities.

Our drug and diagnostic product candidate discovery capabilities rely on a proprietary infrastructure of predictive models, algorithms and other computational tools incorporating proprietary knowledge of key biological phenomena. Life science today is a rapidly changing field with substantial research being undertaken on a worldwide basis both by academia and industry. In order to maintain our competitive position in predictive discovery, we must continue to allocate resources to broadening and deepening our scientific infrastructure. Any inability to allocate such resources when needed could materially harm our future business, financial condition and results of operations.

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 collaboration and licensing activities for current and future product candidate discoveries, primarily in the form of fees, research revenues, milestone payments, royalties and other revenue sharing payments has had limited success to date. In 2013, we entered into our first collaboration with respect to our Pipeline Program activities, and have received only minimal revenues from our earlier collaborations based on discoveries made during our infrastructure building. We recognized $3.5 million in revenue in 2013, $242,000 in 2012 and no revenue in 2011. Furthermore, only in 2010 did we implement our Pipeline Program pursuant to which we are advancing certain therapeutic product candidates past disease animal model proof of concept or other validation studies and therefore we have very limited experience with respect to the financial terms that may be available for our candidates at later stages of validation and development, and financial terms for agreements by other companies, to the degree disclosed, vary greatly. Therefore, 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 and commercialization of our product candidate discoveries, or from research and development collaborations.

Risks Related to our Discovery and Development Activities

We are focusing our discovery and development activities on, mAb drug targets, mAb therapeutics, and Fc fusion proteins for uses in oncology and immunology, and have chosen novel immune checkpoint proteins as the objective for our first focused discovery program. If we fail to continue to discover and develop product candidates of industry interest in these fields, or to focus our Pipeline Program efforts on the most promising of such discoveries and candidates, our business will likely be materially harmed.

Since late 2010 we have chosen to focus our broadly applicable predictive discovery capability in the areas of oncology and immunology, including both auto-immune and inflammatory conditions, and more specifically on monoclonal antibody therapeutics and Fc fusion protein to address unmet needs in these fields. We have also chosen immune checkpoints as the objective for our first focused discovery program and more recently we have initiated our second focused program for discovery of targets for antibody-drug-conjugate (ADC) therapy. The result of our 2010 focusing decision is that we are not undertaking internal development in other areas, including those where we previously demonstrated discovery capabilities, such as diagnostic products and peptide based drugs, and intend to pursue such opportunities only in collaboration with third parties. With respect to checkpoint proteins, although there have been positive clinical results reported by others with respect to a small number of products based on certain checkpoint proteins, resulting in substantial industry, academic and medical interest, there can be no assurance that our checkpoints, which currently are the basis for the majority of candidates in our Pipeline Program, will provide similar clinical advantages or interest, that no long term adverse effects will be seen, or that a different class of molecules will not be discovered 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 Program would likely be reduced in which case our business may be harmed. Additionally, although certain of our initial candidates based on Compugen discovered checkpoint proteins are generating interest from potential partners, to date we have signed only one collaboration involving such discoveries and all such candidates are at early stages of development. There is no assurance that we will be able to consummate additional collaborations or agreements on reasonable terms, if at all. In addition, if we fail to continue to discover product candidates of industry interest in our fields of focus, or to pursue validation and development efforts in our Pipeline Program on the most promising discoveries, our business will likely be materially harmed. There are many risks associated with this decision of focusing in these areas that include, among others:

- not utilizing all of our discovery capabilities

- choosing therapeutic areas with a very high degree of competition
- choosing therapeutic areas of great complexity and with very high failure rates in product development
- failing to successfully focus our discovery infrastructure to discover novel product candidates in our chosen therapeutics areas
- having insufficient relevant knowledge in our chosen therapeutic areas to select the right unmet needs or candidates, or to properly and efficiently further them in development
- the inherent risk of high program failure rate in early stage therapeutic development.

In each case, our failure could be due to lack of experience or applying the wrong criteria, with the possible result that no selected candidates result in licensed or marketable products in these fields. If any of these risks should materialize, our business, financial condition and results of operations would be materially harmed.

Our predictive discovery capabilities remain unproven with respect to yielding marketable products. If in further development and clinical evaluation, all, or a larger percentage than typically seen in industry experience, of our product candidates fail to prove sufficiently safe and effective for regulatory approval and marketing, our business will be significantly harmed.

Our in silico (by computer) predictive approach to drug discovery remains unproven with respect to yielding marketable products, and to date, our validation efforts for our initial discoveries have been limited to in vitro testing and in vivo testing using animal disease models. These discovery capabilities, which are designed to predict and select potential product candidates in many different therapeutic and diagnostic areas of interest, rely on the modeling, by our scientists, of complex biological processes, both physiological and pathological. This modeling is partial and may prove insufficient to result in true predictions of the biological processes as they occur naturally. If in further development and clinical evaluation, all, or a larger percentage than typically seen in industry experience, of our initial product candidates fail to prove sufficiently safe and efficacious for regulatory approval and marketing, our business will be significantly harmed.

Our in silico predictive approach to drug discovery typically results in a significant number of putative discoveries of interest with each discovery program. If we or our partners fail to select the right candidates to validate and/or progress, due to either lack of experience or applying the wrong criteria, the selected candidates may never result in marketable products and our business, financial condition and results of operations will be materially harmed.

Our in silico predictive approach to drug discovery typically results in a significant number of putative discoveries of interest with each discovery program. Following each such discovery run, we assess which of such putative discoveries to move forward with initiation of validation based on various scientific and business criteria, 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 candidates to validate and/or progress, due to either lack of experience or applying the wrong criteria, the selected candidates may never result in marketable products, and our business, financial condition and results of operations may be materially harmed.

If either the predictive discovery approach in general, or our "therapeutics needs (market) driven" approach, does not prove to be successful, our business will be significantly harmed.

Our method of discovering novel product candidates involves first selecting either on our own or with a partner company an unmet therapeutic need where we believe our predictive capabilities would be relevant, or could be modified to be relevant. In this "therapeutics needs (market) driven" approach, our goal is to harness all of our relevant capabilities in order to address the specific unmet need, rather than obtaining product candidates resulting from the development, validation or initial runs of a single discovery platform, as was the case prior to initiation of our Pipeline Program. After selection of the unmet need we wish to address, we then focus all of our relevant discovery platforms, algorithms and other computational biology capabilities to predict in silico (by computer) sequences for a typically large number of possible product candidates. Next we utilize proprietary algorithms and tools and other methodologies to select, from this large number of possibilities, those novel molecules that we believe have the highest probability of success. Selected molecules are then produced and undergo in vitro and/or in vivo validation testing. Although our initial "therapeutics needs (market) driven" approach has resulted in the discovery of a number of novel molecules in an area of significant industry interest, these molecules are in the very early stages of development. Therefore, we cannot predict whether this "therapeutics needs (market) driven" approach will continue to yield product candidates or that any of our existing discoveries or future discoveries will be suitable for final development into therapeutic products. If either the predictive discovery approach in general does not prove to be successful, or this "therapeutics needs (market) driven" approach does not lead to successful product candidates, our business will be significantly harmed.

Our focus on the Pipeline Program has resulted in a substantial increase in activities, certain of which we will undertake for the first time and may result in product candidate failures, or fewer molecules being available for commercialization.

Until recently, our in vitro and in vivo validation studies concluded with disease animal model or drug target expression profile analysis. At the completion of such activities, or earlier, we initiated our efforts to enter into collaborations for such molecules. This is at an earlier stage than is typical for licensing in the pharmaceutical industry. Pursuant to the Pipeline Program initiated in 2010, and with a more than 60% planned increase in R&D activities for 2014 in comparison to 2013, we are both advancing more molecules in parallel, and intend to advance certain molecules further towards pre-clinical activities, with the possibility of selected molecules entering clinical evaluation in the future. This decision to advance further with certain molecules is requiring us to undertake certain activities for the first time and may result in product candidate failures during such additional activities, either due to our lack of expertise or due to unsupportive findings or due to the lack of an appropriate technology. Furthermore, due to our limited resources, we must choose which Pipeline Program molecules to advance further in pre-clinical development, and in selected cases possibly clinical development in the future. This could result in fewer molecules being available for commercialization, due to our available resources being insufficient to further advance all programs. In addition, if we fail to select the right molecules to advance further, due to either lack of experience or applying the wrong criteria, the selected candidates may never result in a marketable product. 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 is limited. In order to successfully develop and commercialize therapeutic products, we must either access such expertise via collaborations or service providers or improve our internal expertise, capabilities and facilities. We may not be able to hire the scientists with the required expertise in a timely manner, if at all, and/or engage any or all of the service providers or other experts that we need in order to do so. If we 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, and as a result our business would be materially harmed.

Our establishment of our own therapeutic mAb research and development capabilities contains a number of risks.

In 2012, we announced that we had established our own therapeutic mAb development capabilities in our U.S. based, wholly owned subsidiary, Compugen USA, Inc., in order to develop mAb therapeutics against the target candidates that we discovered. The establishment of such in-house capabilities contains a number of risks, including, without limitation, the need for additional resources and funding in order to maintain such capabilities or to acquire additional technologies and the need to identify additional qualified employees and consultants in order to further advance these capabilities. Furthermore, although the scientists we have hired have prior experience with other organizations in the field of therapeutic mAb research and development, we have no experience as a company in this field and no experience in managing a site in a different geographic location. Therefore, as a result, if we are unsuccessful in any of these required undertakings, our business could be materially harmed. In addition, the chairperson of Compugen USA, Inc. has the additional position of chief executive officer of another mAb discovery and development company, which although not at present directly competitive, could present, in the future, potential conflict of interest issues.

There are risks that are inherent in the development and commercialization of therapeutic products, and if 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 biopharma companies, include, among others, the possibility that:

- our product candidates will be found to be therapeutically ineffective
- our product candidates will be found to be toxic or to have other unacceptable side effects
- our product candidates will not show added value compared to competing products
- our mAb targets will prove to be inappropriate targets for mAb therapeutics
- we or our collaborators will fail to receive required regulatory approvals
- we will not be able to generate product candidate differentiation between some of our product candidates
- we or our collaborators will fail to manufacture our product candidates in the quantity or quality needed for preclinical studies or clinical trials on a large scale and in a cost effective manner
- our early stage commercialization efforts may provoke competition by potential partners
- the commercialization of our product candidates may infringe third party intellectual property rights
- the development, marketing or sale of our product candidates will fail because of our inability or failure to protect or maintain our own intellectual property rights
- once a product is launched on the market, 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, or as a result of there being more attractive, less risky or less expensive, products available for the same use.

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

Under the current funding agreement with Baize Investments (Israel) Ltd., we may have to share in any future economic success of certain product candidates.

Under the current funding agreement with Baize Investments (Israel) Ltd., ("Baize") Baize has the right to receive 10% of the cash consideration received by us or our affiliates from third parties, less certain pass-through amounts, with respect to certain designated product candidates through June 30, 2015. Not later than June 30, 2015 or, if later, 30 days following the receipt by Baize from Compugen of the annual report for 2014 containing a status report with respect to such designated product candidates, Baize has the right to select five of such product candidates for which it will receive such 10% of certain cash consideration received by Compugen or its affiliates as previously described through December 31, 2030. Alternatively, Baize has the right at any time prior to June 30, 2015 to cancel all of its rights to receive any cash consideration for the designated (including the selected) product candidates, in exchange for Compugen ordinary shares. Therefore, to the extent that any of the designated product candidates are successfully

licensed, developed or commercialized and Baize has not exercised its right to exchange its right to cash consideration for ordinary shares, we will need to provide Baize with 10% of the cash consideration, as described above, received by us, thus reducing the amount of net revenues we receive from such transactions.

Risks Related to Development, Clinical Trials and Government Regulation

We or our collaborators may be unable to obtain regulatory approval for any product that we or a collaborator may develop.

Any therapeutic product that we or our collaborators may attempt to develop, manufacture or market in the United States will be subject to extensive governmental regulations, including those relating to development, performance of clinical trials, manufacturing and post-approval commercialization. Preclinical testing, manufacturing and clinical trials, among other activities, will be subjected to an extensive regulatory review process before a new therapeutic product can be sold in the United States. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. The time required to obtain the approval of the U.S. Food and Drug Administration, or FDA, and other approvals for therapeutic products is unpredictable but typically requires several years.

Any therapeutic product that we or our collaborators may wish to develop, manufacture or market in countries other than the United States will also be subject to numerous regulatory requirements governing the conduct of clinical trials, manufacturing and marketing, pricing and third-party reimbursement among other things in such countries. The foreign regulatory approval process includes all of the risks and uncertainties associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in such foreign jurisdictions.

It is possible that none of the therapeutic products we or our collaborators may develop will obtain the approvals necessary for us or our collaborators to sell them either in the United States or any other country. Furthermore, approval by the FDA of a therapeutic product does not assure approval by regulatory authorities outside the United States or vice versa. Even if approval for a therapeutic product is obtained, such approval may be subject to limitations on the indicated uses or appropriate patient population that could result in a significantly reduced potential market size for the product.

If we or our collaborators fail to obtain the appropriate regulatory approvals necessary for us or our collaborators to sell our products, or if the approvals are more limited than those that we intend to seek, our business, financial condition and results of operations would be materially harmed.

It may be difficult to manufacture therapeutic products based on our technologies.

Our Pipeline Program is focused on mAbs and protein therapeutics in the fields of oncology and immunology and such therapeutic types can be difficult to manufacture. If it should prove to be difficult to manufacture any therapeutics based on our technologies in sufficient quantities 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 actions, which could affect the marketability of Compugen-discovered therapeutics 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 actions. These enforcement actions may include:

- warning letters

- recalls, product seizures or medical product safety alerts
- restrictions on, or prohibitions against, marketing such tests or products
- restrictions on importation of such tests or 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
- debarment or other exclusions from government programs.

If we or our collaborators will be 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 or product recall.

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

We use human tissue samples and conduct experiments involving animals for the purpose of development and validation of our technologies and product candidates. Our access to and use of human tissue 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 compliance with the principles of the Helsinki Declaration, the Public Health Regulations (Clinical Trials in Human Subjects) 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 failure 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 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 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 could be substantial. 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 incur substantial costs to comply with, and substantial fines or penalties if we violate any of these laws or regulations.

Risks Related to Our Dependence on Third Parties

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

Our primary strategy for the final development and commercialization of products based on our product candidates depends on third parties to carry out and/or finance development and commercialization of such products, principally pharmaceutical, biotechnology and diagnostic companies and other healthcare related organizations. To date, we have entered into one collaboration with Bayer with respect to two molecules from our Pipeline Program and a small number of agreements covering discovery activities to be performed by us, and development and commercialization rights with respect to certain of our discovery stage product candidates. None of the product candidates subject to such agreements has advanced beyond the discovery and early pre-clinical stages and we cannot be sure that any of these agreements will result in the successful development or commercialization of any products. Further, we cannot assure you that we will succeed in identifying additional suitable parties or entering into any other additional agreements on

satisfactory terms or at all for the development and/or commercialization of our product candidates. If we are unable to identify such additional suitable parties or enter into new agreements on satisfactory terms, our business will likely be materially harmed.

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, business or other reasons

    - if our collaborators breach or terminate the agreement with us, the development and commercialization of our 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

    - our collaborators may fail to design and implement appropriate preclinical and/or clinical trials

- our collaborators may fail to manufacture our product candidates needed for either clinical trials or for commercial purposes on a sufficiently large scale 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

    - ownership of the intellectual property generated under 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 discoveries or product candidates to which they have obtained rights from us

- our collaboration partners may be acquired by, acquire, or merge with, another pharmaceutical 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.

To date we have entered into only one collaboration agreement with respect to our Pipeline Program candidates and this agreement with Bayer is subject to many risks. If such agreement is terminated by Bayer, particularly in advance of our signing additional collaboration agreements, 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 for the research, development, and commercialization of antibody-based therapeutics for cancer immunotherapy against two novel, Compugen-discovered immune checkpoint regulators – CGEN 15001T and CGEN 15022. This is our first collaboration arrangement for any of our Pipeline Program candidates.

The collaboration with Bayer is subject to all of the risks as set forth above with respect to our dependence in general on collaboration agreements with third parties. In addition, since this is our first collaboration involving our Pipeline Program candidates, and specifically covering Compugen-discovered immune checkpoint regulators, until such time as we have additional agreements, the effect of any event related to this collaboration will likely have a significantly greater effect on our business and financial condition than otherwise would be the case.

As is customary for pharmaceutical research and licensing agreements, Bayer may terminate the agreement, at any time with or without cause either in whole or only with respect to one of the two programs, and in each case also 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. If significant adverse unforeseen events occur in the Bayer collaboration or the agreement is terminated, in whole or in part, particularly in advance of 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 businesses.

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. We do not control the third parties to whom we outsource these functions, but we depend on them to undertake activities and provide results which may be significant to us. If these third parties fail to properly perform these activities, or provide us with incorrect or incomplete results 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.

We rely on the services of various third party service providers, such as contract research organizations, or CROs, contract manufacturing organizations, or CMOs, technology providers, and academia. If we fail to identify and obtain quality services from such third parties, our discovery, and validation and development capabilities may be harmed.

In carrying out discovery, validation and development activities for our product candidates, we and our partners rely on advice, services and results obtained from various third party service providers, such as CROs, CMOs, technology providers, academia and regulatory and other consultants. This includes, without limitation, production of certain biological reagents and performance of certain in vitro and in vivo validation of our discoveries and product candidates. 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 may be significantly harmed or delayed.

We have limited experience and capabilities in conducting, managing or sponsoring preclinical evaluation of therapeutic drug candidates.

During 2010, we began to focus our discovery efforts primarily in the fields of oncology and immunology, and initiated the Pipeline Program to both substantially increase the number of molecules in our validation pipeline and to increase the value of certain of our candidates by advancing selected molecules to pre-clinical studies and in selected

cases, possibly clinical evaluation. We have limited experience and capabilities in conducting, managing or sponsoring the work and efforts required beyond the proof of concept experimental validation stage towards preclinical evaluation, and by doing so we will need to rely on our consultants and third party service providers. If we fail to identify the right consultants or service providers, if the consultants or service providers fail in providing the required services or if we fail to take the necessary steps towards preclinical evaluation, for these or other reasons, our business may be harmed.

We have no experience in conducting or managing clinical trials for potential therapeutic products.

We have no experience in conducting or managing the clinical trials necessary to obtain regulatory approvals for any product, and we intend to rely on our collaborators or third parties, such as CROs, medical institutions and clinical investigators to perform these functions. Our reliance on third parties for clinical development activities reduces our control over these activities. Third-party contractors may not complete activities on schedule, or may not conduct clinical trials in accordance with regulatory requirements or our trial design. If these third parties do not successfully carry out their contractual duties or meet required performance standards or expected deadlines, we might be requir