

**CollPlant Holdings Ltd.**

**("The Company")**

November 24, 2014

For the attention of  
The Securities Authority  
www.isa.gov.il

For the attention of  
The Tel-Aviv Stock Exchange Ltd.  
www.tase.co.il

Dear Sir or Madam

**Re: Supplementary report to a periodic report**

In continuation of the Company's periodic report for the year 2013<sup>1</sup> ("**The annual report**"), A supplementary report is presented hereby ("**The supplementary report**" or "**The report**"), which contains clarifications and additions to Part A (Description of the entity's business) in the annual report, including by way of the presentation of tables ("**The additional details**"). The additional details, which follow, are presented in accordance with the order of the sections in the annual report. The terminology that follows shall have the meaning that is given them in the annual report, unless explicitly stated otherwise.

It is clarified that some of the data that are presented below are based on the information and the assumptions that are held by the Company at the time of the publication of this supplementary report, and in respect of some of them changes have occurred in the data, by comparison with the data that the Company held as of December 31, 2013 and at the time of the publication of the annual report.

1. **Products and services – Section 8 of Part A of the annual report – Vergenix®WD**

1.1 In connection with the Vergenix®WD product – as of the time of this report, the Company has not yet started sales of this product on a commercial scale, since the product is still in the stages of the checking of the market and the examination of the feasibility of producing it and marketing it independently, against the advantages that are inherent in granting a license for the commercialization of the product (together with and/or as part of other products), to business and/or strategic partners.<sup>2</sup>

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<sup>1</sup> The Company's periodic report for the year 2013, as published on the Magna on March 24, 2014 [Document No. 2014-01-022545] ("**The periodic report**")

<sup>2</sup> In the Company's assessment, as of the time of this report, in order to achieve profitability and economic feasibility in the market for the base products (commodities, in other word, non-premium products), the Company will need to sell very large quantities in a competitive market. Such activity is being considered together with various partners, who operate in the market for base products. However, the company sees a significant advantage in obtaining the CE Mark approval for the said product, in that the obtaining of the approval will afford it considerable experience in the licensing processes for the Company's products, and obtaining it will pave the way for the licensing approval of additional products that the Company will have, bade on human Collagen, which is produced from plants.

## **2. Products and services – Section 1- of Part A of the annual report**

- 2.1 The following table, to the best of the Company's knowledge, provides details of the products that are being developed by the Company, including, inter alia, details of the expected timings of the reaching of milestones for each such product, which is being developed and an estimate of the costs of the completion of the closest milestone for the products.

It should be clarified that the Company has not yet received the approvals that are required and has not yet started significant commercial sales of any of the new medical products that it is developing. Apart from the products in development that appear in the following table, the Company has additional products that are in more initial stages of development, and from time to time, on the basis of the business plan, the existing business opportunities and the strategic targets that have been set, it examines the continuation of the development of additional Collagen-based products.

For additional details regarding a description of the characteristics of the Company's products and their various stages of development, see Sections 13 (Competition) and 16 (Research and Development) in the annual report.

|    | The name of the product that is being developed                                | The indication for which the product being developed in intended   | The stage of the development of the product as of the time of the report                                       | The milestones that are expected in the coming 12 months after the time of the report   | The closest milestone and the time at which it is expected to be reached <sup>3</sup> | The estimate of the cost of the completion of the closest milestone | The size of the target market (number of patients)   | The entity's estimate regarding the timing of the start of the marketing of the product under development <sup>4</sup>       | The entity's estimate regarding the market share that is expected for the product under development, on the assumption of the receipt of approval for the marketing |
|----|--|--|--|---|---|---|--|--|---|
| 1. | Product for the treatment of tendonitis<br>Collagen/PRP<br><b>Vergenix®STR</b> | The healing of inflammations in tendons, by means of the Company's collagen based implant and the concentration of platelets | The development of the product has been completed and the pre-clinical trials have been completed              | The performance and completion of clinical trials by the end of the second quarter of 2015, and the presentation of an application for CE approval by the start of the third quarter of 2015                  | The completion of the clinical trials by the start of the third quarter of 2015       | Approximately 200 thousand Dollars                                  | The size of the target market is estimated at approximately 3 million procedures a year (the financial scale is an annual amount of approximately 2 billion Dollars)                             | The Company is in the stages of checking the market and in its assessment, the sales will start in the last quarter of 2015  | The Company estimates that the market share of the product could reach 20% within a number of years from the start of the marketing of the product                  |
| 2. | Gel for the healing of wounds<br><b>Vergenix®FG</b>                            | The treatment of chronic wounds (such as diabetic ulcers, pressure wounds, trauma wounds, surgical wounds and burns)         | The development of the product has been completed and the pre-clinical trials have been completed <sup>5</sup> | The performance and the completion of clinical trials and the presentation of an application for CE approval by the start of the second quarter of 2015 and the start of sales in Europe during the year 2015 | The completion of the clinical trials during the first quarter of 2015                | Approximately 150 thousand Dollars                                  | The size of the first target market – for patients with diabetic ulcers – is estimated at approximately 300 thousand patients with an annual financial scale of 500 million Dollars <sup>6</sup> | The Company is in the stages of checking the market and in its assessment, the sales will start in the third quarter of 2015 | The Company estimates that the market share of the product could reach 50% within a number of years from the start of the marketing of the product                  |

<sup>3</sup> The Company's assessments in connection with the timings that are connected to the milestones that are expected in connection with products 1 and 2 in the above table, have been extended by comparison to the Company's assessments which were presented in the annual report, inter alia, in the light of the checks in the products that the Company conducts by means of a sub-contractor overseas, which have taken longer than is planned (and additional time was need to replace one of the parts (the syringe) in the product kit). See also footnote 10 below.

<sup>4</sup> The Company's assessments in connection with the timings that are connected to the milestones that are expected in connection with products 1 to 4 in the above table, have been extended by comparison to the Company's assessments, which were presented in the annual report. The extension of the timings is inter alia, because of the need to complete the trials for the purpose of the receipt of CE approvals for products 1 – 2. In respect of product 3, as a by-product of the entry of products 1 – 2 into the market and the Company's assessments are that the start of the commercial use of the medical products that are based on product 3 will start in 2016. In respect of product 4, the entry of an additional American company into a commitment with Pfizer and to development work jointly with the Company has led to the extension of the timetables and the update regarding the timing of the start of the marketing. See also footnote 3 above and footnote 10 below.

<sup>5</sup> As of the date of the report, the product has been checked in trials on large animals, and its superiority to a competing product that is considered to be the market leader has been proved, among the parameters that were compared were the pace of the closure of wounds and the quality of the healing.

<sup>6</sup> Royal Bank of Canada, Healthcare Conference, February 27, 2013.

|    | <b>The name of the product that is being developed</b>          | <b>The indication for which the product being developed in intended</b>  | <b>The stage of the development of the product as of the time of the report</b>   | <b>The milestones that are expected in the coming 12 months after the time of the report</b>   | <b>The closest milestone and the time at which it is expected to be reached<sup>3</sup></b>               | <b>The estimate of the cost of the completion of the closest milestone</b>                    | <b>The size of the target market (number of patients)</b>   | <b>The entity's estimate regarding the timing of the start of the marketing of the product under development<sup>4</sup></b>  | <b>The entity's estimate regarding the market share that is expected for the product under development, on the assumption of the receipt of approval for the marketing</b>   |
|----|---|--|---|--|---|---|---|---|--|
| 3. | Raw material – protein – <b>Collage®</b>                        | Raw material (a passive protein) for the production of tissue products in the human body, there is no need of a regulatory outline for this material but rather for the medical products that it is used for | Development and increasing the efficiency of the production process, in cooperation with sub-contractors  | The continuation of the development and increasing the efficiency of the production process (increasing efficiency in the production process (increasing the production capacity and lowering costs)     | An additional significant lowering of the cost of production  | Costs that are not significant to the Company   | The size of the target market – is estimated at approximately 2 million units a year with an annual financial scale of approximately 2 million Dollars <sup>7</sup>             | As of the time of the report, the product is in the stage of the development of the mass production processes and it is not being sold commercially, but rather individually to various consumers from the R&D market. In the Company's assessment, sales on a commercial scale will start in the course of the year 2016 | The product is a raw material and as such, no approval is required for its marketing. In the Company's assessment, the product's market share may reach approximately 3% of the market in a number of years                  |
| 4. | Moldable Implant for the healing of bones – <b>Vergenix®BVF</b> | The healing of bones: the completion of missing bones in limbs, the pelvis and the spinal cord (the product is not intended for weight bearing)  | This product has started development with Pfizer and as of the time of the report, the Company is continuing with the development work with an American company, which has rights to the protein that is relevant for Pfizer. The product is in the stage of pre-clinical trials <sup>8</sup> | 1. The completion of the development of the product.<br>2. The completion of the pre-clinical trials.<br>3. An additional development agreement and a commercial agreement with the development partners | The completion of the development of the product and a commercial agreement by the second quarter of 2015 | Approximately 500 thousand Dollars (all of the development expenses are borne by the partner) | The size of the target market – is estimated at approximately half a million procedures a year with an annual financial scale of approximately 1.5 million Dollars <sup>9</sup> | The Company cannot estimate the timing of the start of the sales of this project, if relevant, at this preliminary stage, and prior to the presentation of an IDE to the FDA by the American company and prior to the determination of the regulatory path  | In the Company's assessment, the product will be marketed through the strategic partner, and that the product's market share may reach dozens of percentage points within a number of years from the start of its marketing. |

<sup>7</sup> Based on global articles on subject of the Collagen and HA-based Biomaterials market, which were published in the years 2010 – 2011 by Global Industry Analysts, Inc.

<sup>8</sup> For additional details regarding the development of the product, as previously mentioned, with the American entity, see the details that have been presented within the framework of Section 27.1 of the annual report.

<sup>9</sup> Based on global articles on subject of the Collagen and HA-based Biomaterials market, which were published in the years 2010 – 2011 by Global Industry Analysts, Inc.

**Caution regarding forward looking information** – The information and the Company's assessments as aforesaid in the above table in connection with the various products and the products that are under development, the milestones that are expected in the coming year, the estimate of the cost to completion of the milestones, the size of the target market, the timings in respect of the start of the production and/or the marketing of the products that are under development and the Company's assessments regarding the share of the relevant market that is expected for it, including forecasts, timings, assessments and/or the Company's plans in connection therewith, are forward looking information, within the definition of that term in the Securities Law – 1968, which involve a high-level of uncertainty and which is based, inter alia, on third parties and on numerous factors over which the Company does not necessarily have control, and accordingly, it is possible that the completion of the development of the products that are under development, the meeting of the milestones and/or their expected cost, the timings and the timetables for their marketing, as well as the assessments in respect of the size of the relevant market, may not actually be realized and/or will not be realized in full and/or may be realized in a manner that is significantly different from the manner that was estimated or expected at the outset. Among the factors that could cause the information and the Company's assessments in respect of such information not to be realized in the desired manner, one can note, inter alia, a delay in the recruitment of patients, demands for the performance of repeat trials, a lack of success in the trials or the non-agreement of the regulatory authorities to the results of the trials, a change in and/or stiffening of the approval policies of the regulatory authorities in relation to the products that are being developed, the cancellation of significant agreements for strategic cooperations (including the non-signing of an additional development agreement or a commercialization agreement opposite a strategic partner) and/or delays in the development of the products that are being developed in accordance with them [including the need for and/or the extension of the performance of pre-clinical trials and clinical trials that may be performed by parties that are involved in the development (if relevant), inter alia, for the sake of proving clinical efficacy or a lack of success in such trials, the non-meeting of the targets in such additional trials and/or the timetables and/or in the obtaining of the financing that is required by the parties that are involved at the time and in the extent that are required for the continuation of their development (if relevant), the entry of additional competitors in the fields of the products that are being developed, and the realization of any of the risk factors that are detailed in Section 30 of the annual report. It should further be emphasized that there can be no certainty that the trials will succeed and a lack of success of the trials could require the updating of the research and development plan, the budgets and the timetables and that the Company would be exposed to additional risk, as detailed in Section 30 of the annual report, which might have a significant impact, jointly and separately, on the Company's assessments, as aforesaid.

**3. Marketing and distribution – Section 12 of Part A of the annual report – Marketing and distribution**

3.1 In connection with the Vergenix®WD product – as of the time of this report, the Company does not see fit to promote a particular, detailed marketing strategy for this product by the Company. However, the Company does not rule out the possibility that it will enter into a commitment in the future with distributor and/or with business partners for the purpose of marketing and selling the product by them.

**4. Clinical trials – Section 16 of Part A of the annual report – Research and development**

A. In continuation to what is stated in Section 16 of Part A of the annual report, the following table summarizes the clinical trials which the Company is performing or which the Company intends to perform in the course of the coming 12 months, as of the date of this report:

| The name of the trial  | The stage of the development at which the trial is included (if relevant)   | Whether an IND or IDE has been opened in respect of the trial | The objective of the clinical trial   | The number of sites at which the trials will be conducted | The countries/geographical locations of the sited at which the trials will be conducted | The number of people that it is planned to check in the trials | The number of people to be checked who have joined the trial as of the time of the publication of the report | The nature and the status of the trial   | The timetables for the trial                                     | The estimated overall expected cost of the trial (in NIS thousands) | The cumulative cost as of the time of the start of the clinical trial and up to the time of the report (in NIS thousands) | The results of the clinical trial (interim results or final results) |
|--|---|---|---|---|---|--|--|--|--|---|---|--|
| Research with one therapeutic arm development on the Vergenix®FG product               | The end of the pre-clinical stage, the clinical trials have not yet started | Not relevant for this product                                 | Safety and the performance of the use of the product on patients with ulcers in the lower limbs                 | The trial will be conducted at three sites                | Israel  | 20   | The clinical trial is expected to start in November 2014   | Safety and the performance of the use of the product, the trial is expected to start by the end of the year 2014 | Four months (from the time of the start of the clinical trials)  | 400   | Not relevant – the clinical trials have not yet started   | Not relevant   |
| Prospective research with one therapeutic arm, development on the Vergenix®STR product | The end of the pre-clinical stage, the clinical trials have not yet started | Not relevant for this product                                 | Safety and the performance of the use of the product on patients with epicondylitis with damage to soft tissues | The trial will be conducted at three sites                | Israel  | 40   | The clinical trial is expected to start by the end of 2014   | Safety and the performance of the use of the product, the trial is expected to start by the end of the year 2014 | Eight months (from the time of the start of the clinical trials) | 600   | Not relevant – the clinical trials have not yet started   | Not relevant   |

B. In respect of the timings of the performance and the completion of the products that have been developed by the Company (the Vergenix®STR and the Vergenix®FG), the Company has updated the forecasts in respect of the start of the performance and the completion and the timings of the clinical trials that it is performing on those products, in such manner that the Company estimates, inter alia, based on the development processes for those products that the two clinical trials on the projects will occur in the year 2014, and that the timing of the completion of the clinical trials, the presentation of applications, the receipt of CE approvals and the start of the sales in Europe, will occur in the course of the year 2015.<sup>10</sup>

<sup>10</sup> The reason for the updating of the forecasts derived from the checking of the products, which the Company conducts through a sub-contractor overseas, from the extension beyond what was planned (and the need for additional time in order to replace one of the parts (the syringe) in the product kit). In the Company's best estimate, we are not talking about a delay that derives from a significant problem in the development but rather a delay that drives from a fault in a plastic comPOBent (the syringe), which was replaced accordingly. As of the time of this report, the Company estimates that the checks will end in the coming weeks and that the clinical trial will start by the end of the year 2014.

**Caution regarding forward looking information** – The information and the Company's assessments, as stated in the above table, in connection with the various products and the products that are in development, the timing of the completion and the timetables of the trials and the results thereof, the estimate of the costs in connection with the trials, the locations in which the trials will be conducted (in so far as they have not yet started), including forecasts, timetables, assessments and/or the Company's plans in connection therewith, are forward looking information, within the definition of that term in the Securities Law – 1968, which involve a high-level of uncertainty and which is based, inter alia, on third parties and on numerous factors over which the Company does not necessarily have control, and that the completion of the development of the Company's products, which are being developed, the meeting of the milestones and the expected cost thereof, the timings and the timetables for their marketing, as well as the assessments in respect of the size of the relevant markets, and therefore it is possible that in practice they may not be realized and/or they may not be realized in full and/or they may be in a manner that is significantly different from what was estimated or expected at the outset.

Among the factors that could cause the information and the Company's estimates in respect of such information not to be realized in the desired manner, one can note, inter alia, a delay in the recruitment of patients, a demand for the performance of repeat trials, a lack of success in the trials or the non-agreement of the regulatory authorities to the results of the trials, a change in and/or stiffening of the approval policies of the regulatory authorities in relation to the products that are being developed, the cancellation of significant agreements and the realization of any of the risk factors that are detailed in Section 30 of the annual report.

It should further be emphasized that there can be no certainty that the trials will succeed and a lack of success of the trials could require the updating of the research and development plan, the budgets and the timetables and that the Company would be exposed to additional risk, as detailed in Section 30 of the annual report, which might have a significant impact, jointly and separately, on the Company's assessments, as aforesaid.

## **5. Intangible assets – Section 17 of Part A of the annual report – Intangible assets**

5.1 As stated in Section 17.2 of Part A of the annual report, in accordance with the founders' agreement and the confirmation of the endorsement of rights, which is an appendix to the founders' agreement, all of the rights and the intellectual property in connection with the development of quality human Collagen from plants, which has been owned by Yissum, the Research and Development Company of the Hebrew University of Jerusalem Ltd. ("Yissum") and Professor Shosayov (the Chief Scientist and a director in the Company) were endorsed to CollPlant. In addition, it has been agreed that in the event that CollPlant's activities are discontinued in the future and/or it is dissolved, all of the rights in the patents and in the commercial secrets will revert to Yissum's ownership.



For that purpose, in accordance with the provisions of the founders' agreement, all of the intellectual property that can be registered, is supposed to be registered with 1% being owned by Yissum. Despite the aforesaid, as of the time of the report, all of the Company's patents are registered (or are expected to be registered) in CollPlant's name alone, except for a patent (which is not a patent that is connected to the Company's core activity)<sup>11</sup>, which is registered under joint ownership with Yissum, all of which is as detailed in the table of the Company's registered patents, and in the table of its applications for the registration of patents, which appears in Section 17.4.1 of the annual report.

**6. The regulatory paths – Section 24 of Part A of the annual report – Restrictions and supervision**

6.1 As of the date of this report, the Company is not holding contacts with the FDA in connection with any of the Company's products that are being developed.<sup>12</sup>

**7. Significant agreements – Section 25 of Part A of the annual report – Significant agreements**

A. In continuation of what is stated in Section 25.7 of Part A of the annual report, regarding the commitment under an agreement for the supply of Collagen with CBI ("The agreement"), the Company wishes to update that the agreement is still in force.<sup>13</sup> It should be noted that CBI has undertaken to pay royalties to the Company on future sales at a single digit rate, and that as of the date of this report, to the best of the Company's knowledge, the development of CBI's product is at the pre-clinical trial stage.

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<sup>11</sup> The intention is to a joint application for the registration of a patent, which the Company and Yissum have filed together, which is not connected to the Company's core activity in the recombinant Collagen field, but rather, which related to preparations that include Fibrillar and Polysaccharide proteins (such as Resilin), in respect of which the Company and Yissum have signed on a development agreement and the arrangement of the patent rights, as detailed in Section 17.7 of the annual report.

<sup>12</sup> For details regarding the determination that the CDRH in connection with the Vergenix®WD product and the need to receive PMA approval for that product, see Section 24.3.3(E) in Part A (Description of the entity's business) in the annual report.

<sup>13</sup> It should be clarified that in accordance with the agreement, CBI undertook to provide CollPlant with a non-binding tri-annual forecast for the supply of material(the forecast that is non-binding), and it also undertook to supply CollPlant with a binding forecast for the supply of material in relation to a period of four consecutive quarters each time, each quarter, as from a time at the end of a period of one year from the time of the agreement (the forecast that is binding). In practice, the volumes of the purchases of Collagen by CBI are set each quarter, in accordance with requisitions for the supply of Collagen, which are transferred to it by CBI.

To the best of the Company's knowledge, CBI has not yet started clinical trials (and it is still to be found, to the best of the Company's knowledge, at the pre-clinical trials stage), and accordingly, in practice, CBI is continuing to order quantities of Collagen (and the Company is continuing to supply Collagen to CBI) for development purposes, in insignificant quantities. In the Company's assessment, the rate of the supply of Collagen to CBI under the agreement will remain at this insignificant level until CBI starts the clinical trials stage and/or until it reaches a stage that is close to a commercial stage, in the period of the agreement.

- B. In continuation of what is stated in Section 25.9 of Part A of the annual report, regarding the commitment under a (non-binding) memorandum of understanding with an American investor, the Company wishes to update that with the passage of the period of validity of the memorandum of understanding in March 2014, the memorandum of understanding has expired and is not longer in force in relation to the parties.

**8. Targets and business strategy – Section 24 of Part A of the annual report – Targets and business strategy**

In continuation of what is stated in Section 28 of Part A of the annual report, the following are details of the Company's targets and milestones in the coming three years, in relation to the various products that are the subject of research and development and in relation to the progress of the main cooperations in which it is involved:

| The medical product that is being developed              | The current state   | 2015   | 2016  | 2017   |
|--|---|--|---|--|
| Vergenix®STR a product for the treatment of tendons      | The development of the product has been completed and the pre-clinical trials have been completed   | The performance and the completion of clinical trials. The presentation of an application for CE approval and the start of sales in Europe                                 | The expansion of the marketing of the product in Europe   | The marketing of the product in additional target markets in the world |
| Vergenix®FG  | The development of the product has been completed and the pre-clinical trials have been completed   | The performance and the completion of clinical trials. The presentation of an application for CE approval and the start of sales in Europe                                 | The expansion of the marketing of the product in Europe   | The marketing of the product in additional target markets in the world |
| Vergenix®BVF a moldable implant for the healing of bones | This product is being developed in cooperation with a strategic partner (the American Company) and is to be found at the stage of the pre-clinical trials | 1. The completion of the development of the product.<br>2. The completion of the pre-clinical trials.<br>3. An additional development agreement and a commercial agreement | The start of the clinical trials (subject to agreements and the terms that will be obtained with the partners to the development) | Clinical trials  |
| Collage®   | A production capacity of approximately 1,000 grams of Type 1 recombinant Collagen a year  | The lowering of costs by means of increasing efficiently and progressing with the development of the product   | The increasing of the production capacity to 2,000 grams of Type 1 recombinant Collagen a year                                    | -  |
| Vergenix®WD  | The product has CE approval for the marketing of the product in Europe  | The Company will act in accordance with the conclusions of the checking of the potential in the market and the feasibility of commercializing the product                  | -   | -  |

**Caution regarding forward looking information** – The Company's targets for coming three years, including the Company's forecasts, assessments and/or plans in relation to those future developments and timetables in connection with the realization of the developments, which are expected, as stated in the above table, are correct as of the time of this report. It is possible that these targets will not be realized and/or that they will be realized in a manner that is significantly different from what was initially expected, in whole or in part, and this is, inter alia, because of factors that are not under the Company's control, including changes in the conditions in the market and in the competitive and business environment, the results of trials that will be performed by the Company, demands by the regulatory bodies in connection with such trials as well as the realization of any of the Company's risk factors, as detailed in Section 30 of the annual report.

Yours sincerely

CollPlant Holdings Ltd.

Signed in the name of the Company by:

Yehiel Tal, Chief Executive Officer

Eran Rotem, Chief Financial Officer