

As confidentially submitted to the Securities and Exchange Commission on January 15, 2014
This draft registration statement has not been publicly filed with the Securities and
Exchange Commission and all information herein remains strictly confidential

Registration No. 333-

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

Amendment No. 1
to
FORM F-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

MEDIWOUND LTD.

(Exact Name of Registrant as Specified in its Charter)

State of Israel (State or Other Jurisdiction of Incorporation or Organization)	2833 (Primary Standard Industrial Classification Code Number)	Not Applicable (I.R.S. Employer Identification No.)
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MediWound Ltd.
42 Hayarkon Street
Yavne 8122745, Israel
Tel: +972-8-932-4010

(Address, including zip code, and telephone number, including
area code, of Registrant's principal executive offices)

Puglisi & Associates
850 Library Avenue, Suite 204
Newark, Delaware 19711
+1 (302) 738-6680

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public:
As soon as practicable after effectiveness of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price(1)(2)	Amount of registration fee
Ordinary shares, par value NIS 0.01 per share	\$	\$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) of the Securities Act.

(2) Includes ordinary shares that the underwriters may purchase pursuant to their option to purchase additional ordinary shares, if any.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Amendment is filed solely to file the amended exhibits indicated in Item 8 of Part II. No change is made to the preliminary prospectus constituting Part I of the Registration Statement or Items 6, 7, or 9 of Part II of the Registration Statement.

Item 8. Exhibits and Financial Statement Schedules.

- (a) The Exhibit Index is hereby incorporated herein by reference.
- (b) Financial Statement Schedules.

All financial statement schedules have been omitted because either they are not required, are not applicable or the information required therein is otherwise set forth in the Registrant's consolidated financial statements and related notes thereto.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Yavne, Israel on this _____ day of _____, 2014.

MEDIWOUND LTD.

By: _____

Name: Gal Cohen

Title: *President and Chief Executive Officer*

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTED, that each director and officer of MediWound Ltd. whose signature appears below hereby appoints Gal Cohen and Sharon Malka, and each of them severally, acting alone and without the other, his true and lawful attorney-in-fact with full power of substitution or re-substitution, for such person and in such person's name, place and stead, in any and all capacities, to sign on such person's behalf, individually and in each capacity stated below, any and all amendments, including post-effective amendments to this Registration Statement, and to sign any and all additional registration statements relating to the same offering of securities of the Registration Statement that are filed pursuant to Rule 462(b) of the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated:

<u>Signature and Name</u>	<u>Title</u>	<u>Date</u>
_____ Gal Cohen	President and Chief Executive Officer (principal executive officer)	, 2014
_____ Sharon Malka	Chief Financial and Operation Officer (principal financial officer and principal accounting officer)	, 2014
_____ Ruben Krupik	Chairman of the Board of Directors	, 2014

<u>Signature and Name</u>	<u>Title</u>	<u>Date</u>
<hr/> Prof. Marian Gorecki	Director	, 2014
<hr/> Prof. Lior Rosenberg	Director	, 2014
<hr/> Meron Mann	Director	, 2014
<hr/> Ofer Gonen	Director	, 2014

SIGNATURE OF AUTHORIZED REPRESENTATIVE IN THE UNITED STATES

Pursuant to the requirements of the Securities Act of 1933, the Registrant's duly authorized representative has signed this registration statement on Form F-1 in Newark, Delaware, on _____, 2014.

By: _____

Name: Donald J. Puglisi
Title: *Managing Director*

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EXHIBIT INDEX

Exhibit No.	Description
1.1	Form of Underwriting Agreement*
3.1	Articles of Association of the Registrant**
3.2	Form of Amended and Restated Articles of Association of the Registrant, to be effective upon closing of this offering*
4.1	Specimen Share Certificate*
4.2	First Amendment to Shareholders' Rights Agreement, dated December 30, 2010, by and among Teva Pharmaceutical Industries Ltd., the Registrant and certain shareholders of the Registrant*
5.1	Opinion of Meitar Liquornik Geva Leshem Tal, Israeli counsel to the Registrant, as to the validity of the ordinary shares (including consent)*
10.1	2003 Israeli Share Option Plan**
10.2	Founders Agreement, dated January 2001, by and among Clal Biotechnology Industries Ltd., L.R. R & D Ltd., Professor Lior Rosenberg and the Registrant**
10.3	Unprotected Sub-Lease Agreement, dated July 27, 2004, as amended, by and between the Registrant and Clal Life Sciences L.P.**
10.4	Patent Purchase Agreement, dated November 24, 2010, by and between the Registrant and L.R. R & D Ltd.**
10.5	Form of indemnification agreement by and between the Registrant and each of its directors and executive officers*
10.6	Supply Agreement, dated January 11, 2001, as amended, by and between the Registrant and Challenge Bioproducts Corporation Ltd.†
21.1	List of subsidiaries of the Registrant**
23.1	Consent of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, an independent registered public accounting firm*
23.2	Consent of Meitar Liquornik Geva Leshem Tal (included in Exhibit 5.1)*
24.1	Power of Attorney (included in signature pages of Registration Statement)*

* To be filed by amendment.

** Previously filed.

† Confidential treatment has been requested for portions of this document. The omitted portions of this document have been filed with the Securities and Exchange Commission.

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MediWound Ltd.

and

Challenge Bioproducts Corporation Ltd.

Supply Agreement — As amended on February 28, 2010

*** Confidential treatment has been requested for redacted portions of this exhibit. This copy omits the information subject to the confidentiality request. Omissions are designated as [***]. A complete version of this exhibit has been provided separately to the Securities and Exchange Commission.

SUPPLY AGREEMENT

This Supply Agreement (“**Agreement**”) was made and entered into as of the 11 day of January, 2001 by and between MediWound Ltd., a corporation organized and existing under the laws of Israel (hereinafter referred to as “**MediWound**”) and Challenge Bioproducts Corporation Ltd., a corporation organized and existing under the laws of the Republic of China (hereinafter referred to as “**CBC**”) and amended by the parties on February 28, 2010 (“**Amendment Effective Date**”).

WITNESSETH: THAT

Whereas MediWound and CBC have originally entered into this Agreement on the date stated above (copy of which shall be attached hereto as **Exhibit A**); and

Whereas, the parties hereto have agreed to amend and add certain terms and conditions to this Agreement as of the Amendment Effective Date, all as set forth and marked herein; and

Whereas, CBC has invented and developed methods, processes and equipment to manufacture, and produce Bromelain SP (as such term is defined below), specially processed for transformation into a Bromelain-based pharmaceutical product derived from pineapple stems, known as Debridase (the “**Product**”); and

Whereas, subject to the going into effect of a License Agreement dated September 27, 2000 between MediWound and Mark Klein (respectively, the “**Klein Agreement**” and “**Klein**”) as amended on June 19, 2007, MediWound shall have an exclusive license under patents and other intellectual property, to develop, use, manufacture, market and sell the Product for burn treatment in humans; and

Whereas, MediWound desires to utilize Bromelain SP in the development and commercialization of the Product and to subsequently purchase Bromelain SP in bulk form to make and have made Product and pharmaceutical preparations thereof; and

Whereas, CBC is willing to supply Bromelain SP to MediWound for such purpose on the terms and conditions set forth hereunder.

NOW THEREFORE IN CONSIDERATION OF THE MUTUAL PROMISES AND COVENANTS SET FORTH HEREIN IT IS HEREBY AGREED AS FOLLOWS:

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1. **Definitions**

Terms defined in this Section 1 and elsewhere, parenthetically, in this Agreement, shall have the same meaning throughout this Agreement.

- 1.1 “**Affiliate**” means any firm, person or company which controls, is controlled by or is under common control with a party to this Agreement and for the purpose of this definition the term “control” means the possession, directly or indirectly of the power to direct or cause the direction of the management and policies of such firm, person or company whether through the ownership of voting securities, by contract or otherwise or the ownership either directly or indirectly of 20% (twenty percent) or more of the voting securities of such firm, person or company.
- 1.2 “**Approval**” means the grant of all necessary governmental and regulatory approvals required for the marketing, distribution and sale of a pharmaceutical product in any particular country, by a Regulatory Authority, and approvals required for pricing and reimbursements (if appropriate).
- 1.3 “**Bromelain SP**” means material derived from pineapple stems, [having the specification as presented in exhibit 1.13] presently manufactured by CBC at the Facility by a special process and used as a raw material in the production of the Product.

- 1.4 “**Conditions Precedent**” means the cumulative conditions listed in Section 2.1.
- 1.5 “**Effective Date**” shall have the meaning ascribed to such term in Section 2.2.
- 1.6 “**Facility**” means CBC’s production facility in Tou-Liu City, Yun-Lin Hsien, Taiwan, R.O.C.
- 1.7 “**FDA**” means the Food and Drug Administration of the United States Government or any successor thereto.
- 1.8 “**Klein**” means Mr. Mark C. Klein.
- 1.9 “**LR**” means either or both of L.R. R & D Ltd. and/or Professor Lior Rosenberg.
- 1.10 “**Major Country**” means the USA, and the major European and Asian countries listed in **Exhibit 1.10** attached hereto.
- 1.11 “**MOU**” means the Memorandum of Understanding of January 18, 2000 between MediWound (as assignee of Clal Biotechnology Industries Ltd.), Klein and CBC.
- 1.12 “**Regulatory Authority**” means the FDA or similar governmental or other agency in any country having authority to grant Approval.
- 1.13 “**Specifications**” means the specifications for Bromelain SP set forth as **Exhibit 1.13** hereto, as the same may be amended with the consent of both parties hereto, it being agreed that no amendment may be made thereto or refused which would

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render Product incapable of application on humans or the use, supply or sale thereof in breach of any regulations.

- 1.14 “**Sub-Contractor**” means any firm or company whose services are retained by MediWound to transform Bromelain SP into Product and to package, label and deliver pharmaceutical preparations of the Product in finished form to MediWound and its sub-licensees. All references to “MediWound” under Sections 3.1, 5, 6 and 7.1 shall be construed as being inclusive of Sub-Contractors, unless the context dictates otherwise.
- 1.15 “**Technical Information**” means that information in use at the Facility during the term of this Agreement, relating to the manufacture of Bromelain SP meeting the Specifications, in bulk, as more comprehensively described in Section 1.15 of the TT Agreement.
- 1.16 “**TT Agreement**” means the Technology Transfer Agreement dated January 11, 2001 between the parties hereto, whereby CBC undertakes to transfer the Technical Information to MediWound.

2. **Conditions Precedent**

- 2.1 Conditions Precedent to the provisions of this Agreement becoming effective shall be all of the following:
- 2.1.1 Execution of a License Agreement between MediWound and LR whereby MediWound shall license certain Product-related know-how from LR; and
- 2.1.2 Execution of the TT Agreement.
- 2.2 The date upon which MediWound shall have acknowledged in writing to CBC that the Conditions Precedent have all been met shall be the “**Effective Date**”. Where the Conditions Precedent have not been met by January 31, 2001, for any reason whatsoever, then this Agreement and the MOU shall be deemed terminated as of that date with no further liability of either party, except for the obligation of confidentiality, as set forth in the MOU.

3. **Grant of Rights**

- 3.1 As from and subject to the Effective Date, and subject to the terms and conditions of this Agreement, CBC shall supply Bromelain SP to MediWound and MediWound shall acquire Bromelain SP from CBC, for transformation into the Product.
- 3.2 MediWound’s rights as per Section 3.1 will be exclusive in the sense that CBC shall not nor shall permit any Affiliate or third party to manufacture, use, supply

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or sell Bromelain SP for utilization as an ingredient of any product which directly or indirectly competes with the Product.

4. Financial Provisions

- 4.1 In consideration for CBC's undertaking to supply Bromelain SP to MediWound and other obligations of CBC pursuant to this Agreement, MediWound has paid to CBC US\$ [***] (US Dollars [***]) within 3 (three) business days of the Effective Date.
- 4.2 Payments for supply of Bromelain SP by CBC to MediWound as of the Amendment Effective Date shall be made in accordance with the following provisions:
- 4.2.1 The price of [***] Kg of an accepted batch of Bromelain SP (by MediWound pursuant to Section 6.4) shall be in accordance with the price per annual quantity table in **Exhibit 4.2** attached hereto. The price used for invoicing during the year shall be based on the quantity in the Annual Forecast. At the end of each year the parties shall recalculate the amounts to be paid pursuant to the actual quantities purchased throughout the passing year and adjust the payments accordingly (*for example: if the actual quantity purchased during the past year was higher than the Annual Forecast and such higher quantity should have been invoiced as per a lower price per Kg of Bromelain SP in accordance with price per annual quantity table in Exhibit 4.2, CBC shall recalculate the invoices for the past year as per the actual price that should have been invoiced and credit MediWound for the balance within [***] days accordingly. If the actual quantity purchased during the past year was lower than the Annual Forecast and such lower quantity should have been invoiced as per a higher price per Kg of Bromelain SP in accordance with price per annual quantity table in Exhibit 4.2, CBC shall recalculate the invoices for the past year as per the actual price that should have been invoiced and invoice MediWound for the balance within [***] days accordingly*).
- 4.2.2 CBC may increase the prices only pursuant to an increase in its cost of manufacturing of the Bromelain SP. Any such increase shall be subject to MediWound's pre-approval, and no increase shall be executed more often than once every [***] months and any changes thereto shall be in-line with current market prices for Bromelain manufacturing except that (i) there is a change of cost of manufacturing of Bromelain SP due to a change requested by regulatory agency and confirmed by MediWound; and (ii) the Taiwan official Wholesale Price Index varies over [***]% within [***] months. When such exceptional situations arise, an increase

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of price shall be considered by MediWound at CBC's written request without the limit of no more often than once every [***] months.

- 4.2.3 MediWound shall make payment for each Bromelain SP batch that was supplied by CBC on a [***] days basis as of the date of delivery of the applicable batch at MediWound, provided that MediWound has provided CBC with an Acceptance Batch Notice for such purchased batch pursuant to Section 6.4. Payment for each purchase batch shall be effected by MediWound by swift to a bank account designated by CBC, or by other requested method as agreed between the parties. MediWound shall make down payment of USD[***]/kg for the [***]% of the amount of Annual Forecast before Dec.31 of the respective year for the insurance of components and materials and maintenance of manufacture and supply capacity of the requested [***]% of the next calendar year's Annual Forecast. The down payment will be then deducted respectively as every shipment is made to MediWound and listed in CBC's Invoice to MediWound.
- 4.2.4 Payment shall be made directly to CBC for payment for each order of Bromelain SP or, at CBC's written request, to Golden Life International Co., Ltd. on CBC's behalf, for payments other than any order of Bromelain SP ("**Payee**"); *provided however*, that any such payment to the Payee shall be considered as valid payment to CBC (as if made directly to CBC) in accordance with this Agreement, and that so long as such payment is made in accordance with CBC's said request, CBC shall have no claims or demands against MediWound for non-payment or in any other respect whatsoever in this regard. CBC solely shall be responsible to ensure that payment by MediWound to the Payee pursuant to CBC's request does not violate any applicable laws and regulations. Any tax implications due to payment to the Payee in accordance with CBC's request shall be borne by CBC. For avoidance of doubt, it is clarified that the Payee shall not be considered as a third party beneficiary under this Agreement and shall not have any rights to enforce payment or any other rights of CBC under this Agreement.
- 4.2.5 Invoices shall only be issued upon delivery of the Bromelain SP batch which shall take place only after CBC's quality control department has completed its testing and authorized delivery to MediWound, and MediWound's quality control department has provided CBC with an Acceptance Sample Notice for that batch and that the batch itself can be delivered.

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- 4.2.6 The consideration to be paid pursuant to this Agreement is final and inclusive of all taxes and/or duties, of whatsoever nature. If applicable laws require the withholding of taxes, MediWound will deduct the taxes from the related payment otherwise due to CBC, and such taxes shall be paid to the proper taxing authority. For avoidance of doubt, payments will be made only after receiving exemption from tax deduction approval from the tax authority in Israel. Delay in payment as a result of not receiving such exemption will not constitute late payment or breach hereunder.

5. Manufacture of Bromelain SP

- 5.1 Without derogating from CBC's representations and warranties herein, CBC and MediWound shall work together in order to enable the CBC facility to accomplish all required standards, related to the manufacturing, packaging and delivering of Bromelain SP in accordance with the Specifications, GACP (Good Agricultural and Collection Practice) and cGMP (Current Good Manufacturing Practice) standards, ISO 22000 and all other applicable laws and regulations. For such purpose, and without derogating from other terms herein, CBC shall permit MediWound, and/or a consultant on MediWound's behalf, to access and inspect the CBC facility and advise MediWound and/or CBC on such actions to be taken for accomplishing such compliance. Such mutual regulatory preparations shall begin no later than the finalization of MediWound's current phase III clinical trial.

CBC warrants and represents that all Bromelain SP shall be manufactured and supplied in compliance with the Specifications, quality control methods and test methods, all applicable SOP's and all applicable laws, and in accordance with GACP, cGMP, including the relevant guidelines, policies, codes, requirements, regulations, approvals and/or standards from time to time promulgated or issued by any relevant governmental and/or regulatory authority which relate to the manufacture of the Bromelain SP to be used for the production of a pharmaceutical agent as the Product.

CBC warrants further that CBC has, and will for the duration of this Agreement retain, all applicable regulatory approvals required for the carrying out of its obligations hereunder, including without limitation the manufacturing, packaging and supply of the Bromelain SP.

- 5.2 All manufacturing, packaging and labeling activities done at CBC will be performed according to the pre-approved batch records. If CBC wishes to make changes to the Specifications, the production and/or packaging batch records, the SOPs related to the Bromelain SP, or the design of the manufacturing process or any other change during production which would effect the quality of the

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Bromelain SP or of the Product and/or otherwise would effect the Bromelain SP in any way or which might effect the regulatory approvals of the Product, then CBC shall (i) notify MediWound in writing at least 6 months in advance regarding such proposed changes, and (ii) represent that such change will not adversely effect the quality of the Bromelain SP or of the Product in any way, and (iii) not make such changes without MediWound's prior written approval, and (iv) will assure that such change will not delay or in any way effect any open orders for Bromelain SP.

- 5.3 MediWound shall participate and support the upgrade of the Facility and the generation of documentation for submission to the relevant Regulatory Authorities, all as may be determined to be necessary and appropriate, by independent regulatory consultants, designated by mutual consent. Such participation and support shall be in the form of an investment made by MediWound in the CBC facility, not to exceed \$[***] (US Dollars [***]).
- 5.4 CBC undertakes to keep all records reasonably required by MediWound relating to the manufacture, quality control and testing of Bromelain SP. Such records shall include, but not be limited to, all records required by applicable laws and regulations, of the territories in which the Product is marketed and sold. MediWound (itself or through anyone on its behalf) or any relevant regulatory authority shall have the right to audit any such records and/or the relevant facilities of CBC (or any facilities of any CBC third party or subcontractor involved in the manufacture, quality control and/or supply of the Bromelain SP) with reasonable prior notice, during regular business hours, including the right to ask CBC to provide any relevant documents. CBC shall inform MediWound of any announced regulatory inspections that directly involve the Bromelain SP or the Product within 48 hours of the notification to CBC of such an inspection.
- 5.5 During the term of this Agreement, CBC shall make available to MediWound any and all information and data which it generates or which comes into its possession relating to any improvements in the manufacture and supply of the Bromelain SP. CBC shall, throughout the term of this Agreement, assist MediWound in all respects with regard to regulatory submission including but not limited to providing any information, data or documents in its possession. If any regulatory agency requests any changes to the Specifications or the manufacturing process, (including but not limited to any changes as a result of an audit performed) CBC shall (i) inform MediWound in advance and in writing of the changes needed to be made, and (ii) promptly advise MediWound as to any lead-time changes or other terms which may result therefrom, and (iii) make such changes, in coordination with MediWound as soon as possible.

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5.6 Sampling and Testing Procedures

- 5.6.1 The sampling procedures of incoming raw materials, packaging materials, in process control and released Bromelain SP shall be agreed between CBC and MediWound and conducted by CBC as per CBC's signed SOP as approved by MediWound.
- 5.6.2 MediWound and CBC will jointly agree and update from time to time as applicable the incoming raw materials, in-process and release testing methods applicable to the Bromelain SP.

- 5.6.3 CBC will test each batch of Bromelain SP for conformance with the batch Specifications, and for each batch of the Bromelain SP supplied by CBC, CBC will provide a certificate of analysis signed and dated by the responsible person at CBC, who has released the batch.
- 5.6.4 For each batch provided, CBC shall provide to MediWound a copy of the batch production and packaging execution records and shall retain such original records for one (1) year beyond the shelf-life of the Bromelain SP unless required by MediWound or under applicable laws and regulations to maintain the records for a longer period of time.
- 5.7 Quality Assurance — Investigations
- 5.7.1 Any deviation from the production process during the manufacture thereof shall be explained and documented in batch records. Any deviation that may impact on the safety/quality of the Bromelain SP or the Products and on other related issues will be investigated by CBC, and communicated to MediWound within 48 hours from the time of discovery. Following the investigation, the relevant corrective actions shall be taken and implemented.
- 5.7.2 CBC shall perform an out-of-specifications investigation in respect of batches that do not meet the batch Specifications.
- 5.7.3 Each investigation shall be reviewed by a CBC designated quality representative, and will follow the procedures recommended by regulatory agencies and as set out in relevant CBC SOP's. All completed investigation reports and other written documentation relating to all investigations shall be provided to MediWound and shall be included in the applicable released and executed batch records. Any corrective actions shall be discussed and agreed by the parties before being executed by CBC.

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- 5.8 Quality Complaints; Recall
- 5.8.1 MediWound and CBC shall notify each other immediately by an e-mail, of any information concerning the quality and/or malfunction of the Bromelain SP. The parties will investigate all complaints, and shall respond in accordance with mutually agreed SOP's. Both parties shall comply with requirements of all regulatory authorities in dealing with complaints. MediWound shall have the right to determine whether any adverse event should be reported to any applicable regulatory authority. All quality assurance and/or quality complaints shall be handled in accordance with this section above.
- 5.8.2 In the event that CBC has any reason to believe that the Bromelain SP or one or more Products should be recalled or withdrawn from distribution, CBC shall immediately notify MediWound in writing. In such event MediWound shall, at MediWound's sole discretion, determine whether to recall or withdraw the Product from the market.
- 5.8.3 If a recall of the Product is due to CBC or the Bromelain SP, then the recall shall be conducted by MediWound at CBC's expense, and CBC shall replace such Bromelain SP at no charge to MediWound or shall provide MediWound with a credit or refund of same, at MediWound's election.
- 5.9 Storage
- CBC shall store, in accordance with the applicable CBC SOP, free of charge, Bromelain SP batches at its premises in appropriate storage conditions, for up to ninety (90) days from the day of the Acceptance Sample Notice for the respective batch or longer if CBC was unable to deliver such batch to MediWound earlier following the Acceptance Sample Notice. The Bromelain SP shelf life and designated packaging shall be in accordance with CBC SOP and subject to the supportive results of a proper stability study.
- 5.10 Retention of Samples
- CBC shall retain samples of Bromelain SP stored at their original package from each batch for the duration of the Products' shelf-life and for a period of one (1) additional year thereafter, in quantities sufficient to enable the performance of two (2) CBC's full release tests in accordance with the CBC's release specifications and release methods.

6. Supply of Bromelain SP

- 6.1 MediWound undertakes to purchase, and CBC undertakes to furnish, supply and deliver Bromelain SP to MediWound, in bulk, on the terms and conditions hereinafter set forth.

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- 6.2 MediWound shall furnish CBC with a non-binding forecast of its anticipated annual requirements of Bromelaine SP by no later than November 1 of each year ("Annual Forecast"), for the next calendar year. Notwithstanding the foregoing, the first forecast for the calendar year that commenced on January 1, 2001, was furnished by MediWound to CBC by March 15, 2001. MediWound undertakes to order at least [***]% of the Annual Forecast per each year.

CBC shall maintain, at all times, manufacture and supply capacity of at least [***]% of the Annual Forecast and shall maintain, in coordination with MediWound, inventory of Bromelain SP at its premises of (i) at least [***]% of the applicable Annual Forecast; and (ii) all Bromelain SP components and materials (“the **BSP Components and Materials**”) needed for the manufacture and supply of the Bromelain SP such that CBC can guarantee continuous supply of the Bromelain SP in accordance with MediWound’s complete Annual Forecasts. In addition, the inventory of the BSP Components and Materials shall not be less than needed to manufacture [***] months stock of Bromelain SP (compared to the open purchase orders and the applicable Annual Forecast) or longer (respectively) for BSP Components and Materials having a lead time of more than [***] months. CBC shall provide MediWound with quarterly inventory and production reports for Bromelain SP and BSP Components and Materials.

Purchase orders issued by MediWound to CBC for quantities within the [***]% of the Annual Forecast shall be binding upon CBC and shall be deemed accepted upon delivery of the purchase order to CBC. Such purchase orders shall be supplied on the date specified in the applicable purchase order provided that the lead time in any purchase order shall be at least [***] days as of the purchase order’s date.

Purchase orders issued by MediWound to CBC during a certain year for quantities exceeding [***]% of the applicable Annual Forecast shall be binding upon CBC, except that with respect to any amounts exceeding [***]% of the applicable Annual Forecast, CBC’s obligation to provide such exceeding quantities shall be based on best efforts and CBC shall have an extended lead time for delivery as shall be agreed upon by the parties on a case by case basis. CBC shall confirm in writing, within 5 days of its acceptance of such exceeding purchase order, and shall state the anticipated delivery date for the exceeding amounts.

Without derogating from CBC’s obligations under this Agreement, in the event that CBC is unable to supply all the Bromelain SP covered under any purchase order on the dates specified in the applicable supply plans, CBC shall promptly notify MediWound in writing in a separate notice to MediWound of such delay or noncompliance. In such event, and without prejudice to any other remedies

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available to MediWound, CBC shall use its best efforts to fully comply with the purchase order as soon as possible.

- 6.3 CBC shall be responsible to prepare the shipment of Bromelain SP in accordance with a shipment SOP. Such shipment SOP shall comply with the regulatory requirements as well as specify the documents that should accompany any shipment (i.e. pro forma invoice, value for customs, specific declaration, and specific requirement for investigational products). CBC shall provide MediWound with copies of documents and reports with respect to each shipment of Bromelain SP, for quality assurance, quality control and regulatory purposes.
- 6.4 Prior to delivery of each batch of Bromelain SP, CBC shall submit a batch sample to MediWound for inspection and approval. MediWound shall have the right, for a period of [***] days following receipt, to reject any Bromelain SP sample which:
- 6.4.1 fails to comply with MediWound’s purchase order; or
 - 6.4.2 fails to comply with the sample incoming inspection Specifications.

Within the said [***] days, MediWound shall notify CBC of either: (i) its approval and acceptance of such batch sample (“**Acceptance Sample Notice**”); or (ii) its rejection of the batch sample in which case MediWound shall detail the reason(s) for the rejection of any such Bromelain SP sample. In the event of rejection by MediWound, CBC shall deliver complying Bromelain SP sample to MediWound within [***] days of rejection, free of cost (including transportation, duty, handling and insurance costs). For clarification purposes, MediWound’s Acceptance Sample Notice in accordance with this section above shall in no event derogate from CBC’s responsibilities hereunder.

After CBC receives MediWound’s Acceptance Sample Notice, CBC shall deliver the corresponding batch to MediWound for inspection and approval. MediWound shall have the right, for a period of [***] days following receipt, to reject any Bromelain SP batch which:

- 6.4.3 fails to comply with MediWound’s purchase order; or
- 6.4.4 fails to comply with the batch incoming inspection Specifications.

Within the said [***] days, MediWound shall notify CBC of either: (i) its approval and acceptance of such batch (“**Acceptance Batch Notice**”); or (ii) its rejection of the batch in which case MediWound shall detail the reason(s) for the rejection of any such Bromelain SP batch. In the event of rejection by MediWound, at CBC’s request and expense, MediWound shall return any such Bromelain SP batch to CBC and CBC shall deliver complying Bromelain SP

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batch to MediWound within [***] days of rejection, free of cost (including transportation, duty, handling and insurance costs). For clarification purposes, MediWound’s Acceptance Batch Notice in accordance with this section above shall in no event derogate from CBC’s responsibilities hereunder.

6.5 If there is a dispute between the parties as to whether any Bromelain SP sample or batch complies with the sample or batch Specifications respectively and/or with the quality requirements set forth herein and/or under the law, then, without derogating from MediWound's remedies under this Agreement or at law, such dispute shall be resolved by mutual investigation of the parties which shall be conducted in good faith. If the parties are still unable to resolve such dispute, an independent, mutually agreed third party shall be retained as a consultant to review batch records and related documentation. Such consultant's determination in respect of the conformity of a sample or batch shall be binding upon the parties. The non-prevailing party shall bear the costs of consultant's services as well as for the production of the batch and corrective actions. If appropriate, pursuant to such investigation and/or consultant's determination, CBC shall replace the non-complying Bromelain SP within 30 (thirty) days thereafter, free of cost (including transportation, duty, handling and insurance costs).

6.6 CBC, at its own cost, shall obtain and shall cause to remain in effect, such licenses, permits, approval and consents as may be required for its performance hereunder, including, without limitation, export of Bromelain SP from the Republic of China.

7. **Liability and Indemnity**

7.1 CBC shall defend and assume responsibility for any suit, claim or other action by a third party alleging that MediWound's use of Bromelain SP infringes any patents or other rights of such third party.

7.2 MediWound shall be solely responsible for the commercialization of the Product, e.g. the completion of development, final formulation, the conduct of clinical trials (as necessary), labeling and packaging, as well as the due preparation and submission of all documentation required for the prosecution of registration and Approval of the Product in each of the countries in the Territory. MediWound shall assume all liabilities arising from the development, commercialization, use, offer for sale, sale or supply by, through or on behalf of MediWound or its Affiliates, of the Product (and related materials).

7A. **Insurance**

In order to provide insurance coverage for CBC responsibilities, obligations and undertakings as set out under this Agreement and/or as required under any law with

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respect to the manufacturing of Bromelain SP, CBC undertakes, at its sole cost and expense, to take out and maintain an "All risk" insurance against loss of and destruction or damage to the Facility (including fire, theft and vandalism, etc.), third party liability insurance, product liability insurance for the Bromelain SP and employers liability insurance.

Without prejudice to the above, CBC shall maintain, or shall cause to be maintained with respect to itself and each of its Affiliates, such types and levels of insurance (including, without limitation, third party and product liability insurance), as are customary in the pharmaceutical or manufacturing industry to provide coverage for their activities contemplated hereby. Upon request of MediWound, CBC shall keep MediWound informed of the general parameters of its liability insurance program and any proposed substantive changes therein. Upon request, CBC shall furnish MediWound certification of insurance (and/or true copies of policies) showing the above coverage, signed by an authorized agent of the insurance company, certifying that liability assumed under this Agreement is fully insured without exception, and providing for at least thirty (30) days prior written notice.

7B. **Limitation of Consequential Damages**

EXCEPT FOR BREACH OF CONFIDENTIALITY OBLIGATION HEREUNDER, AND TO THE EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOSS OF USE, DATA OR LOST PROFITS, EVEN IF IT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, WHETHER UNDER THIS AGREEMENT, IN TORT OR OTHERWISE.

8. **Confidentiality**

8.1 CBC and MediWound undertake to each other to keep, and shall procure that their respective Affiliates, employees, directors, officers, consultants and contractors (including those of any Affiliate) shall keep, confidential all information received from each other during or in anticipation of this Agreement however obtained and in whatever form (the "**Confidential Information**"). For clarification purposes, any information, materials and know-how related to the Product and/or provided by MediWound in connection with this Agreement including any related intellectual property rights, shall be owned solely by MediWound and shall constitute MediWound's Confidential Information which may be used by CBC solely for the purpose of manufacturing and supply of Bromelain SP to MediWound. Confidential Information shall not include the following:

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8.1.1 information which at the time of disclosure by one party to the other is in the public domain;

- 8.1.2 information which after disclosure by one party to the other becomes part of the public domain by publication except by breach of this Agreement;
- 8.1.3 information which the receiving party can establish by competent proof was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other party; and
- 8.1.4 information received from third parties who were lawfully entitled to disclose such information.
- 8.2 Any Confidential Information received from the other party shall not be disclosed or used for any purpose other than as provided or anticipated under this Agreement.
- 8.3 The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of 5 (five) years after termination or expiry of this Agreement, provided however that any Confidential Information with respect to the Product, including without limiting, such information with respect to intellectual property rights in connection with and/or related to the Products shall remain confidential in perpetuity.
- 8.4 The provisions of this Section 8 shall in no event prevent MediWound from disclosing any Technical Information to Regulatory Authorities or other governmental agencies in support of any application for regulatory approvals of the Product or any amendments thereof or in general whenever required to disclose such information under any applicable law or regulation. MediWound shall make reasonable efforts to notify CBC of its intention and the identity of the intended recipient as soon as reasonably practicable and if possible, prior to the date of disclosure.

9. **Duration**

This Agreement shall come into force on the Effective Date and the amendments herein shall be in effect as of the Amendment Effective Date. This Agreement as amended shall continue in force until terminated in accordance with the provisions of Section 10.

10. **Termination**

- 10.1 MediWound may terminate this Agreement at any time, by 6 (six) months prior notice in writing.

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- 10.2 CBC may terminate this Agreement by no less than 24 (twenty four) months notice given in writing by CBC to MediWound, or such greater period as may be reasonable for MediWound to establish an alternative source of manufacture of Bromelain SP and/or to acquire sufficient inventory of Bromelain SP for a 24 (twenty four) months period.
- 10.3 In the event of any breach of this Agreement at any time, if the breach complained of shall not be corrected by the breaching party within 90 (ninety) days of the other party's notice, either party hereto may, at its option:
 - 10.3.1 by giving 90 (ninety) days written notice, specifying the breach complained of, terminate this Agreement, and the party asserted to be in breach shall have the right to treat the alleged breach as a dispute under Section 15; or
 - 10.3.2 regard the breach and any failure to cure as the basis for a dispute and proceed to dispute resolution under Section 15 and such legal or equitable remedy as shall be applicable.

11. **Effects of Termination**

- 11.1 Upon termination of this Agreement, the parties shall abide by and uphold any and all rights or obligations accrued or existing as of the termination date, including, without limitation with respect to outstanding orders for Bromelain SP placed hereunder.
- 11.2 Any rights or remedies of either party arising from any breach of this Agreement shall continue to be enforceable after termination of this Agreement, unless previously waived in writing.

12. **Assignment**

- 12.1 Subject to Section 12.2, neither party shall assign its rights or obligations hereunder, in whole or in part, except with the prior written consent of the other party, except to a party acquiring all of the business of the assigning party to which this Agreement relates. Prior to any such permitted assignment the party wishing to effect the transaction shall procure that the third party concerned covenants directly with the other party to this Agreement to comply with the provisions of this Agreement, which shall be binding on it as the successor and assign of such party.
- 12.2 MediWound may assign all of its rights and obligations under this Agreement or perform some or all of its obligations under this Agreement through its Affiliates and Sub-Contractors, provided that MediWound shall remain solely responsible for and be guarantor of the performance by its Affiliates and Sub-Contractors and

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procure that its Affiliates and Sub-Contractors comply fully with the provision of this Agreement in connection with such performance.

13. Miscellaneous

- 13.1 Failure or delay by either party in exercising or enforcing any right or remedy under this Agreement in whole or in part shall not be deemed a waiver thereof or prevent the subsequent exercise of that or any other rights or remedy.
- 13.2 CBC and its employees and MediWound and its employees shall at all times be considered as independent contractors of each other, and at no time or under any circumstances shall they be considered employees, representatives, partners or agents of each other.
- 13.3 This Agreement shall constitute the entire agreement and understanding of the parties relating to the subject matter of this Agreement and supersede all prior oral or written agreements, understandings or arrangements between them relating to such subject, except for the TT Agreement. The MOU shall be deemed so superseded by this Agreement only upon the Effective Date.
- 13.4 Other than as explicitly amended and marked herein, all applicable terms and conditions of the Agreement as originally executed by the parties shall remain without change and shall continue to be binding and in full force and effect. No change or addition may be made to this Agreement except in writing signed by the duly authorized representatives of both parties.
- 13.5 The provisions intended by their nature to survive the termination or expiration of this Agreement shall so survive including without limiting Sections 1, 3.2, 5.1, 5.2, 5.4, 5.8, 5.10, 7, 7A, 7B, 8, 11, 13 (as amended), 14 and 15.

Without derogating from the foregoing, it is clarified that the restriction with respect to MediWound's intellectual property and CBC's obligations under the TT Agreement as well as MediWound's exclusive rights under this Agreement (as amended) shall continue to apply and survive the termination or expiration of the Agreement.

14. Notices

- 14.1 Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid airmail, by facsimile transmission or electronic mail to the address of the receiving party as set out below unless a different address, facsimile number or e-mail address has been notified to the other in writing for this purpose.
- 14.2 MediWound's address for service of notices and other documents shall be:-

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MediWound Ltd.
42 Hayarkon St., 81227 Yavne Israel
Tel: +972 8 932 4010
Fax: +972 8 932 4011
E-Mail: [***]

- 14.3 CBC's address for service of notices and other documents shall be:-

Challenge Bioproducts Corporation, Ltd.
17 Tou-Kong 12 Rd., Tou-Liu City, Yun-Lin Hsien,
Taiwan, R.O.C., ("CBC")
Facsimile: +55-5572-045
E-Mail: [***]

15. Governing Law and Disputes

- 15.1 This Agreement is made under and subject to the provision of the substantive laws of the State of New York, without giving effect to its conflict of law rules.
- 15.2 Any disputes relating to this Agreement of whatever nature that cannot be resolved by negotiation between the parties shall be referred for final resolution to arbitration in New York City by 3 (three) Arbitrators under the Rules of the American Arbitration Association. The arbitration proceedings shall be conducted in English. The decision of the arbitrators shall be final and binding upon the parties and their legal successors. The arbitrators may at their discretion, provide for discovery by the parties not to exceed 4 (four) months from the date of notice of arbitration and the arbitrators shall notify the parties of their decision in writing within 30 (thirty) days of the completion of the final hearing. The arbitrators may at their discretion award costs and expenses in respect of the arbitration.
- 15.3 The parties submit to the exclusive jurisdiction of the courts of the State of New York.
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IN WITNESS WHEREOF, the parties, each by its duly authorized signatory, have caused this Agreement to be executed as of the date first above-mentioned.

/s/ Gal Cohen

MediWound Ltd.
By: Gal Cohen
Its: Chief Executive Officer
MediWound Ltd.

/s/ Ching-Kuan Lin

Challenge Bioproducts Corporation Ltd.
By: Ching-Kuan Lin
Its: President
Challenge Bioproducts Co., Ltd.

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List of Exhibits

Exhibit 1.13 - Current Bromelain SP Specifications

Exhibit 4.2 - Price list per annual quantity

Exhibit A - a copy of this Supply Agreement as originally signed on 11/1/2001

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Exhibit 1.13 — Current Bromelain SP Specifications

[***]

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Exhibit 4.2 — Price list per annual quantity



MediWound Ltd.
42 Hayarkon Street, Yavne, Israel
Tel: 972-8-9324010
www.mediwound.com

Supply Agreement as amended on Feb 28th 2010.

Exhibit 4.2 — Price list per annual quantity

The price of [***]Kg of released BSP below an annual ordered quantity of [***] Kg shall be USD[***]/Kg [***].

The price of [***]Kg of released BSP above an annual ordered quantity of [***] Kg shall be between USD[***]/Kg [***], as jointly agreed and set between CBC and MW, once the forecasted annual ordered quantity exceeds [***] Kg of released BSP.

Challenge Bioproducts Corporation Ltd:

Date: 2011.10.12

Signature: /s/ Ching-Kuan Lin

MediWound Ltd.

Date:

Signature: /s/ Gal Cohen
Chief Executive Officer
MediWound, Ltd.

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Exhibit A - a copy of this Supply Agreement as originally signed on 11/1/2001

[Omitted: Agreement no longer in effect]

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