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

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Amendment No. 1

to

FORM 10-Q

☒ [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 1997

OR

☐ [ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM  
----- TO  
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COMMISSION FILE NUMBER: 0-23490

VIVUS, INC.  
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

94-3136179  
(I.R.S. EMPLOYER  
IDENTIFICATION NUMBER)

605 EAST FAIRCHILD DRIVE, MOUNTAIN VIEW, CA 94043  
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE)

(650) 934-5200  
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

545 MIDDLEFIELD ROAD, SUITE 200 MENLO PARK, CA 94025  
(FORMER ADDRESS)

Indicate by check mark whether the registrant (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of  
1934 during the preceding 12 months (or for such shorter period that the  
registrant was required to file such reports), and (2) has been subject to such  
filing requirements for the past 90 days. Yes ☒ [X] No ☐ [ ]

At July 31, 1997, 33,125,712 shares of common stock were outstanding.

Exhibit index on page 21.

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

VIVUS, INC.

Date: March 4, 1998

/s/ DAVID C. YNTEMA

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David C. Yntema  
Chief Financial Officer

/s/ LELAND F. WILSON

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Leland F. Wilson  
President and Chief  
Executive Officer

## MANUFACTURE AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement ("Agreement"), is entered into as of May 30, 1997 ("Effective Date") by and between Vivus, Inc., having a principal place of business at 545 Middlefield Road, Suite 200, Menlo Park, CA 94025, United States of America ("Vivus"), and Spolana Chemical Works, A.S., having a place of business at 277 11 Neratovice, Czech Republic ("Spolana").

## BACKGROUND

A. Spolana and Pharmatech, Inc., also known as Pharma Tech International, Inc. ("Pharmatech") have entered into a business arrangement pursuant to which Spolana appointed Pharmatech as Spolana's exclusive worldwide distributor of Alprostadil USP (Prostaglandin E(1)) and Pharmatech agreed to purchase certain quantities of Alprostadil USP all as described in more detail in those certain memoranda between Spolana and Pharmatech dated March 2, 1993 filed in the archives of the commercial department of the zavod kvalifikovane chemie [qualified chemistry company] and that certain agreement in the Czech language dated September 23, 1994, as amended (collectively, the "Spolana-Pharmatech Agreements").

B. Vivus, Spolana and Pharmatech entered into that certain agreement effective as of June 23, 1993 (the "Supply Agreement") pursuant to which Spolana agreed to manufacture Prostaglandins E(1) and E(2) and Pharmatech would supply quantities of Prostaglandins E(1) and E(2) so manufactured to Vivus. Therein, Vivus agreed not to purchase Prostaglandins E(1) and E(2) directly from Spolana during the term of the Supply Agreement but only from Pharmatech.

C. Thereafter, Vivus and Pharmatech have entered into a certain letter agreement dated March 17, 1997 pursuant to which Pharmatech agreed to waive or otherwise terminate its rights under the Spolana-Pharmatech Agreements and the Supply Agreement, so that Vivus may purchase Prostaglandins E(1) and E(2) directly from Spolana and Spolana may supply the same directly to Vivus.

D. Vivus desires to secure a supply of certain quantities of Alprostadil manufactured by Spolana; and Spolana desires to supply such Alprostadil directly to Vivus, and not through Pharmatech, all on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties hereto agree as follows:

ARTICLE 1.  
DEFINITIONS

1.1. "DMF" shall mean a drug master file, or its equivalent for the Product filed with a regulatory agency by or on behalf of Spolana which is adequate to comply with the applicable requirements and standards of such regulatory agency with respect to the Product.

1.2. "FDA" shall mean the United States Food and Drug Administration.

1.3. "GMP" shall mean good manufacturing practices as defined by the FDA in 21 CFR Part 211.

1.4. "MUSE System" shall mean Vivus' system for delivery of the Product to treat erectile dysfunction, as modified from time to time during the term of this Agreement.

1.5. "Product" shall mean Alprostadil USP (Prostaglandin E(1)).

1.6. "Specifications" shall mean the particulars as to composition, quality and other characteristics for the Product as set forth in Exhibit A hereto, as may be amended from time to time by mutual agreement of the parties.

1.7. "USP" shall mean United States Pharmacopeia.

## ARTICLE 2. SUPPLY

2.1. Product Supply. Subject to the terms and conditions of this Agreement, Spolana shall supply to Vivus quantities of the Product ordered by Vivus from time to time during the term of this Agreement. Without limiting the foregoing, Spolana shall at all times maintain facilities to manufacture, [\*].

2.2. Forecasts. During the term of this Agreement, [\*], Vivus shall provide Spolana with a rolling written forecast of the quantities of Product estimated to be required [\*]. Notwithstanding the foregoing, Vivus' initial forecast of the quantities of Product estimated to be required [\*] is attached hereto as Exhibit B.

2.3. Orders.

2.3.1. Orders. Together with each forecast provided under Section 2.2 above (the "Current Forecast"), [\*]. Spolana shall accept such orders from Vivus, subject to the remaining terms and conditions of this Agreement, provided that Spolana [\*]. All orders placed hereunder shall be for full lots of 500 or 600 grams, or as otherwise mutually agreed.

\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2.3.2. Form of Orders. Vivus' orders shall be made pursuant to a written purchase order which is in a form mutually acceptable to the parties, and shall provide for shipment in accordance with reasonable delivery schedules as may be agreed upon from time to time by Spolana and Vivus. Spolana shall use all reasonable efforts to notify Vivus [\*] of its ability to fill any amounts of such order in excess of the quantities that Spolana is obligated to supply. No terms contained in any purchase order, order acknowledgment or similar standardized form shall be construed to amend or modify the terms of this Agreement and in the event of any conflict, this Agreement shall control unless expressly agreed in writing.

2.3.3. Minimum Orders. Vivus agrees to order at least [\*] of Product for delivery during [\*]. In addition, Vivus agrees to order [\*].

2.4 Maximum Quantities. Notwithstanding anything herein to the contrary, Spolana shall not be obligated to supply to Vivus more than [\*], provided that Spolana agrees to use all reasonable efforts to supply any quantities in excess of such amount as Vivus may order in accordance with Section 2.3 above.

2.5 Price. The price to be paid by Vivus per gram of the Product ordered by Vivus shall be [\*] by Spolana during a particular calendar year, as follows:

2.5.1. [\*];

2.5.2. [\*];

2.5.3. [\*]; and

2.5.4. [\*].

[\*].

2.6 Packaging. Products shall be shipped to Vivus in lots aliquoted to 500 or 600 grams each, packaged in containers in accordance with the United States DMF. Each such container shall be individually labeled with a description of its contents, including the manufacturer name, manufacturer lot number, quantity of Product, and date of manufacture. Each such container shall be resealable and protected from light and breakage. In addition, a separate external plastic container shall be placed outside each such container, and shall in turn be sealed within a heavy plastic bag. The shipment shall be insured and carried by a reputable air freight company reasonably acceptable to Vivus. A copy of a certificate of analysis for each such lot shall accompany such lot. A second copy of such certificate of analysis shall be separately provided to Vivus.

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2.7 Shipping Terms; Payment. [\*]. The manner of shipment shall be designated by Spolana and the airport or address shall be designated by Vivus. All payments hereunder shall be made in U.S. dollars, by direct bank transfer to an account designated in Spolana's invoice. Payment terms shall be [\*].

2.8 Taxes. [\*]

ARTICLE 3.  
QUALITY

3.1. Quality. All Product supplied by Spolana shall meet (i) the current USP and European Pharmacopoeia requirements for the Product, (ii) the current Specifications, (iii) additional requirements that the parties may agree to from time to time to reflect to the manufacturing requirements of Vivus' MUSE System and (iv) the requirements of any health regulatory agency to which Vivus has submitted, or notifies Spolana it will submit or sponsor the submission of, an application for regulatory approval. In case of any official monograph or regulatory agency requirement conflicts with the current USP and European Pharmacopoeia requirements for the Product and Spolana's manufacturing and control process of Product described in the DMF, parties will consult to seek a mutually acceptable solution. All Product supplied by Spolana shall be manufactured in accordance with current GMP manufacturing and record keeping procedures and ISO 9000 regulatory requirements and record keeping procedures at Spolana's plant located at 27711 Neratovice, Czech Republic (the "Facility").

3.2. Quality Control. Prior to each shipment of Product, Spolana shall perform quality control procedures to verify that the quantity or batch of such Product to be shipped conforms fully with the Specifications. Each shipment of Product shall be accompanied by a Certificate of Analysis describing all current requirements of the Specifications, results of test performed, as well as a Batch Release Sheet certifying that the batch of Product supplied has been manufactured, controlled and released according to the Specifications, current DMFs and all relevant and current GMP requirements at the Facility stipulated under Section 3.1 above.

3.3. Rejection. Vivus shall have [\*] following its receipt of a shipment of Product to reject such Product on the grounds that all or part of the shipment fails to conform to the applicable Specifications or otherwise fails to conform to the warranties given by Spolana in Section 5.1, which rejection shall be accomplished by giving written notice to Spolana specifying the manner in which all or part of such shipment fails to meet the foregoing requirements. If rejection is based on grounds of contamination or Product not passing any physical test of Specification, Vivus' rejection notice shall be accompanied by a satisfactory sample returned to Spolana to verify such non-conformity. If Vivus rejects a shipment before the date on which payment therefor is due, it may

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withhold payment for such shipment or the rejected portion thereof. The warranties given by Spolana in Article 5 below shall survive any failure to reject by Vivus under this Section 3.3.

3.4 Returns and Settlement of Claims. Spolana shall be obliged to respond in writing to Vivus accepting or refusing a rejection notice from Vivus [\*] from the date of receipt of such rejection notice in accordance with Section 3.3 above. In case of a disagreement between the parties, the claim shall be submitted for tests and decision to an independent testing organization which meets appropriate GMP or consultant of recognized repute within the United States pharmaceutical industry mutually agreed upon by the parties (the "Laboratory"), the appointment of which shall not be unreasonably withheld or delayed by either party. The determination of such entity with respect to all or part of any shipment of Product shall be final and binding upon the parties. The fees and expenses of the Laboratory making such determination shall be paid by the party against which the determination is made (i.e., the party whose argument is rejected by the Laboratory). Products accepted by Spolana as not meeting the applicable requirements and Specifications or so decided by the Laboratory shall be returned by Vivus to Spolana. Spolana shall use its best efforts to replace the quantities of Product returned by Vivus within the shortest possible time, [\*] from the return of such quantities. The replacement of returned Product shall have priority over the supply of Product ordered for shipment, [\*] or any time after the return of the rejected quantity to Spolana. Without limiting the remedies of Vivus, if Spolana fails to replace returned Product within [\*] days from the date Product is returned to Spolana, Vivus shall have the right (i) to cancel such replacement shipment by written notice and (ii) to reclaim immediately (either through refund or setoff, at Vivus' discretion) the amounts paid pursuant to Section 2.7 above for the Product that was returned but not replaced, if such payment for such Product had already been made to Spolana.

3.5. Presence At Facility. Upon reasonable notice given by Vivus to Spolana and at reasonable frequency, Vivus shall have the right to assign a reasonable number of employees or consultants of Vivus to inspect and audit the Facility at which Product is manufactured in order to verify Spolana's compliance with the current GMP and other agreed requirements, provided, however that (a) such employees or consultants shall not unreasonably interfere with other activities being carried out at the Facility, and (b) that such employees or consultants shall observe all rules and regulations applicable to visitors and to individuals employed at the Facility. It is understood that as of the Effective Date Vivus has engaged Forum (Holdings) Limited ("Forum") pursuant to that certain agreement dated September 26, 1996 pursuant to which Forum agreed to assist Vivus in ensuring, by aiding Spolana, that Spolana meets and maintains current GMP and requirements necessary for the sale of Product throughout the world.

#### ARTICLE 4. REGULATORY MATTERS

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#### 4.1. Regulatory Approvals.

4.1.1. Requirements. Vivus and its marketing partners shall notify Spolana in a timely fashion about their requirements for the submission and maintenance of DMFs related to the manufacture and control of the Product adequate to comply with applicable regulatory agencies' (including without limitation the FDA's) standards with respect to the Product in the United States, Europe and Canada and other countries as is or becomes necessary for Vivus and its marketing partners to import, export and sell the MUSE System worldwide. Spolana will submit a DMF or its equivalent in any other country imposing requirements fully identical that of United States, Canada or the European Union within [\*]. In case Vivus or its marketing partner requires the submission of a DMF in a country not covered by the foregoing stipulations, Vivus will assist Spolana, directly or through others, to obtain the full details of requirements of a DMF on the manufacture and control of the Product in the country concerned. Spolana will use its best efforts to fulfill these requirements and to submit such document with content and form required in the country in question and at the time required by Vivus. Spolana shall keep Vivus and its marketing partners, as appropriate, informed about its ability or inability to submit and maintain such documentation as well as the intended or possible times of such submissions.

4.1.2 DMF Submission. Spolana shall submit DMFs in every country in English or a translation in English. An English copy of the open part of each DMF, where such open part exists, shall be provided to Vivus in parallel with the submission thereof to the applicable regulatory agency. Spolana agrees to maintain all information filed with the FDA and other regulatory bodies current and reflective of current manufacturing practices and product specifications and to update this information as required. From time to time during the term of this Agreement, Spolana shall provide letters of authorization, instruments and/or documents, and take such other actions, as Vivus may reasonably request for purposes of obtaining regulatory approvals necessary for Vivus and its marketing partners to import, export and sell Product as incorporated into the MUSE System and/or other products worldwide. Spolana agrees to notify Vivus in a timely fashion of any significant changes, deletions or modifications to any DMF or Product process or specification, and not to implement any such changes that would cause a delay in obtaining regulatory approvals to market products incorporating the Product without prior written agreement with Vivus.

4.2 Inspections. Spolana shall permit the FDA and other regulatory agencies to conduct such inspections of the Facility as the FDA or such other regulatory agencies may request, and shall cooperate with the FDA or such other regulatory agencies with respect to such inspections and any related matters. Spolana shall give Vivus prior written notice of any such inspections, and shall keep Vivus informed about the results and conclusions of each such regulatory inspection, including actions taken by Spolana to remedy conditions cited in such inspections. In addition, Spolana shall allow Vivus or its representative to assist in the preparation for and be present at such inspections.

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Spolana shall provide Vivus with copies of any written inspection reports issued by such agencies and all correspondence between Spolana and the agency involved, including, but not limited to, FDA Form 483 and all correspondence relating thereto. Vivus and its regulatory consultants, agents, marketing partners or other third parties agreed upon in advance by Spolana, under reasonable confidentiality requirements, shall have access, to quality assurance and current GMP audits of DMFs for the purposes of assessment of regulatory compliance, to the buildings, records and areas of the Facility involved in the manufacture, testing, storage and shipment of the Product.

4.3 Vivus Cooperation. Vivus agrees to keep Spolana reasonably informed as to the status of the development and applications for regulatory approvals of the MUSE System incorporating the Product supplied hereunder.

4.4 Maintenance of Approvals. Notwithstanding anything herein to the contrary, Spolana shall not undertake any modifications to Product manufacturing or testing processes, specifications or filings that could impact Vivus product approvals, regulatory product reviews, IND or any other compliance status without prior written agreement of Vivus. Spolana shall obtain and maintain all licenses, permits and registrations necessary to manufacture the Product and supply it hereunder.

#### ARTICLE 5. PRODUCT WARRANTIES

5.1 Process and Product Warranties. Spolana warrants and represents that:

5.1.1 Specifications. all Product supplied to Vivus hereunder shall comply with the Specifications for the Product, shall conform with the information shown on the Certificate of Analysis and Batch Release Sheet provided for the particular shipment according to Section 3.2 hereof;

5.1.2. GMP. the Facility, and all Product supplied to Vivus hereunder meets (a) all United States regulatory requirements for commercialization of the Product, including without limitation maintenance of a current DMF with the FDA, compliance with GMP, demonstration of commercial production capability, and demonstration of acceptable stability of such Product; (b) all ISO 9000 regulatory requirements applicable to the Product; and (c) all requirements imposed other regulatory agencies with which a DMF has been filed for the Product;

5.1.3 USP. all Product supplied to Vivus hereunder shall meet all USP and European Pharmacopeia and other applicable standards and shall be fit for human use;

5.1.4 Compliance with FFDCa. none of the Product supplied to Vivus hereunder shall be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A. Section 301 et seq., as amended and in effect of the time of shipment (the "Act"), or within the meaning of any state or municipal laws applicable to the Products and containing terms with

substantially similar meanings as the meanings of adulteration or misbranding under the Act; provided, however, that this provision shall not apply to, and Spolana shall have no responsibility for, misbranding caused directly by Vivus as a result of labels or package text specified by Vivus for the Product;

5.1.5 Timing. all Product supplied to Vivus hereunder shall have been manufactured [\*];

5.1.6 Notification. Spolana will provide written notice to Vivus of any proposed alterations to the Facility or to any Product manufacturing or testing process; provided, however, that under no circumstances shall any such alteration be made without Vivus' express prior written consent, or before regulatory approval, if required for any such alteration, is received in each country in which Product is then being sold; and

5.1.7 No Encumbrance. title to all Product supplied to Vivus hereunder shall pass to Vivus as provided herein free and clear of any security interest, lien, or other encumbrance.

5.2 Disclaimer. EXCEPT AS EXPRESSLY PROVIDED IN THIS ARTICLE 5, SPOLANA MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AS TO THE PRODUCT, AND SPOLANA HEREBY EXPRESSLY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

#### ARTICLE 6. TERM AND TERMINATION

6.1 Term. The term of this Agreement shall commence on the Effective Date and continue in full force until December 31, 2001, unless terminated earlier in accordance with this Article 6.

6.2 Termination for Convenience. Either party hereto may terminate this Agreement upon [\*] prior written notice to the other party hereto; provided, however, such termination shall not become effective [\*].

6.3 Termination by Spolana. Spolana shall have the right to terminate this Agreement on [\*] prior written notice to Vivus after the beginning of any calendar year during the term of this Agreement but before [\*].

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6.4 Breach. This Agreement may be terminated by either party if the other party breaches any material term or condition of this Agreement and fails to remedy the breach within [\*] after being given written notice thereof.

6.5 Effect of Termination. In the case of notice of termination by either party under Section 6.3 or 6.4, the parties' obligations, including Spolana's obligation to supply Product ordered by Vivus, and Vivus' obligation to purchase Product included in any binding forecast pursuant to Section 2.3 shall survive. In addition, Vivus may purchase and Spolana agrees to supply quantities of Product for which Vivus has not found alternate suppliers, at Spolana's then current prices of Product.

6.6 Survival. It is understood that termination or expiration of this Agreement shall not relieve a party from any liability which, at the time of such termination or expiration, has already accrued to the other party. The provisions of Sections 3.3, 3.4, 6.5, 6.6 and 10.1, and Articles 1, 5, 7, 9 and 11 shall survive the termination of this Agreement for any reason. All other rights and obligations of the parties shall cease upon termination of this Agreement. Except as otherwise expressly provided in this Article 6, all other rights and obligations of the parties shall terminate.

#### ARTICLE 7. CONFIDENTIALITY

7.1 Confidential Information. The parties may from time to time disclose to each other Confidential Information. "Confidential Information" shall mean any information disclosed by one party to the other party hereto which if disclosed in tangible form is marked "confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing party within [\*] after such disclosure. Notwithstanding the foregoing, Confidential Information shall not include any information that, in each case as demonstrated by written documentation: (i) was already known to the receiving party, other than under an obligation of confidentiality, at the time of disclosure; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement; (iv) was subsequently lawfully disclosed to the receiving party by a person other than the disclosing party; or (v) was developed by the receiving party without reference to any Confidential Information of the disclosing party.

7.2 Confidentiality. Each party hereby agrees: (i) to hold and maintain in strict confidence all Confidential Information of the other party; and (ii) not to use or disclose any

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Confidential Information of the other party except to those employees and consultants who have a need to know, as otherwise permitted by this Agreement, or as may be necessary to exercise its rights or perform its obligations under this Agreement; provided that each party to whom Confidential Information is disclosed agrees to be bound by the same terms regarding the disclosure and use of Confidential Information as set forth in this Article 7. Nothing contained in this Article 7 shall prevent either party from disclosing any Confidential Information of the other party to (a) regulatory agencies for the purpose of obtaining approval to distribute and market the Product; provided, however, that all reasonable steps are taken to maintain the confidentiality of such Confidential Information to be disclosed; (b) to accountants, lawyers or other professional advisors or in connection with a merger, acquisition or securities offering, subject in each case to the recipient entering into an agreement to protect such Confidential Information from disclosure; or (c) is required by law or regulation to be disclosed; provided, however, that the party subject to such disclosure requirement has provided written notice to the other party promptly upon receiving notice of such requirement in order to enable the other party to seek a protective order or otherwise prevent disclosure of such Confidential Information.

7.3 Return of Confidential Information. Upon termination or expiration of this Agreement, each party shall return all Confidential Information in its possession that was received from the other party.

#### ARTICLE 8. REPRESENTATIONS AND WARRANTIES

8.1 Spolana. Spolana represents and warrants that: (i) it has full power to enter into this Agreement and to grant and assign to Vivus the rights granted and assigned to Vivus hereunder; (ii) it has obtained all necessary corporate approvals to enter into and execute the Agreement; (iii) it has not entered and will not enter into any agreements with any third party that are inconsistent with this Agreement; (iv) Spolana shall fully comply with the requirements of any and all applicable federal, state, local and foreign laws, regulations, rules and orders of any governmental body having jurisdiction over the activities contemplated by this Agreement; and (v) that the provisions of this Agreement, and the rights and obligations of the parties hereunder, are enforceable under the laws of the Czech Republic.

8.2 Vivus. Vivus represents and warrants that: (i) it has full power to enter into the Agreement; (ii) it has obtained all necessary corporate approvals to enter and execute into this Agreement; (iii) it has not entered and will not enter into any agreements with any third party that are inconsistent with this Agreement; and (iv) Vivus shall fully comply with the requirements of any and all applicable federal, state, local and foreign laws, regulations, rules and orders of any governmental body having jurisdiction over the activities contemplated by this Agreement.

8.3 Disclaimer. EXCEPT AS PROVIDED IN THIS ARTICLE 8 AND ARTICLE 5 ABOVE, NEITHER PARTY MAKES ANY WARRANTIES OR CONDITIONS (EXPRESS,

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IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER  
HEREOF.

ARTICLE 9.  
INDEMNIFICATION

9.1 Vivus. Vivus shall indemnify, defend and hold harmless Spolana, its directors, officers, employees, agents, successors and assigns from and against any liabilities, expenses or costs (including reasonable attorneys' fees) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a third party alleging physical injury or death or otherwise resulting from [\*], in each case subject to the requirements set forth in Section 9.3 below. Notwithstanding the foregoing, Vivus shall have no obligations under this Article 9 for any liabilities, expenses or costs arising out of or relating to claims covered under Section 9.2 below.

9.2 Spolana. Spolana shall indemnify, defend and hold harmless Vivus, its directors, officers, employees, agents, successors and assigns from and against all liabilities, expenses, and costs (including reasonable attorneys' fees) arising out of any claim, complaint, suit, proceeding or cause of action against any of them by a third party alleging physical injury or death or otherwise resulting from [\*], in each case subject to the requirements set forth in Section 9.3 below.

9.3. Indemnification Procedure. Any party seeking indemnification under this Article 9 (the "Indemnatee") shall (i) promptly notify the indemnifying party (the "Indemnitor") of such claim, (ii) provide the Indemnitor sole control over the defense and/or settlement thereof, and (iii) at the Indemnitor's request and expense, provide full information and reasonable assistance to Indemnitor with respect to such claims. Without limiting the foregoing, with respect to claims brought under Section 9.1 or 9.2 above the Indemnatee, at its own expense, shall have the right to participate with counsel of its own choosing in the defense and/or settlement of any such claim.

ARTICLE 10.  
INTERNATIONAL ISSUES

10.1. Language. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall not be binding on the parties hereto. All communications and notices to be made or given pursuant to this Agreement shall be in the English language.

10.2. Government Approvals. Spolana shall:

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10.2.1. at its own expense, comply with all applicable laws, and obtain all approvals and make and maintain in force all filings, registrations, reports, licenses, permits and authorizations required by national and local governments within the Czech Republic in order for Spolana to perform its obligations under this Agreement; and

10.2.2. advise Vivus of any legislation, rule, regulation or other law (including but not limited to any customs, tax, trade, intellectual property or tariff law) which is in effect or which may come into effect in the Czech Republic after the Effective Date of this Agreement and which affects the transfer of Products to Vivus under this Agreement, or which has a material effect on any provision of this Agreement.

## ARTICLE 11.

### GENERAL

11.1 Assignment. The parties agree that their rights and obligations under this Agreement may not be assigned or otherwise transferred to a third party without the prior written consent of the other party hereto. Notwithstanding the foregoing, either party may transfer or assign its rights and obligations under this Agreement to a successor to all or substantially all of its business or assets relating to this Agreement whether by sale, merger, operation of law or otherwise; provided that such assignee or transferee has agreed to be bound by the terms and conditions of this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the parties hereto, their successors and assigns.

11.2 Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the United Kingdom without reference to conflict of laws principles and excluding the 1980 U.N. Convention on Contracts for the International Sale of Goods.

11.3 Arbitration. Any dispute or claim arising out of or in connection with this Agreement or the performance, breach or termination thereof, shall be finally settled by binding arbitration in London, England under the Rules of Arbitration of the International Chamber of Commerce by three (3) arbitrators appointed in accordance with said rules. The decision and/or award rendered by the arbitrators shall be written, final and non-appealable and may be entered in any court of competent jurisdiction. The parties agree that, any provision of applicable law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against any party. The costs of any arbitration, including administrative fees and fees of the arbitrators, shall be shared equally by the parties, unless otherwise determined by the arbitrators. Each party shall bear the cost of its own attorneys' and expert fees. The arbitral proceedings and all pleadings and written evidence shall be in the English language. Any written evidence originally in a language other than English shall be submitted in English translation accompanied by the original or true copy thereof. Notwithstanding the foregoing, either party may apply to any court of competent jurisdiction for injunctive relief without breach of this arbitration provision.

11.4 Notices. Any notice or report required or permitted to be given or made under this Agreement by either party shall be in writing and delivered to the other party at its address indicated below (or to such other address as a party may specify by notice hereunder by courier or by registered or certified airmail, postage prepaid, or by facsimile; provided, however, that all facsimile notices shall be promptly confirmed, in writing, by registered or certified airmail, postage prepaid. All notices shall be effective as of the date received by the addressee.

If to Vivus: Vivus, Inc.  
545 Middlefield Road, Suite 200  
Menlo Park, CA 94025  
Attn: C.E.O. and C.F.O.

with a copy to: Wilson, Sonsini, Goodrich & Rosati  
650 Page Mill Road  
Palo Alto, California 94304-1050  
Attn: Kenneth A. Clark, Esq.

If to Spolana: Spolana a.s.  
277 11 Neratovice  
Czech Republic  
Attn: Odd. podeje KCH-OU

with a copy to: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
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11.5. Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY THIRD PARTY FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING LOST OR ANTICIPATED REVENUES OR PROFITS RELATING TO THE SAME), ARISING FROM ANY CLAIM RELATING TO THIS AGREEMENT, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EVEN IF AN AUTHORIZED REPRESENTATIVE OF SUCH PARTY IS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF SAME. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY LIMITED REMEDY, AND THE PARTIES ACKNOWLEDGE THAT THIS PARAGRAPH REPRESENTS A REASONABLE ALLOCATION OF RISK.

11.6 Force Majeure. Neither party will be liable for its failure to perform any of its obligations hereunder during any period in which such performance is delayed by acts of God, fire, war, embargo, riots, strikes or other similar cause outside the control of such party.

11.7. Confidential Terms. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party, except as required by securities or other applicable laws, to prospective investors and to such party's accountants, attorneys and other professional advisors.

11.8. Headings. Headings included herein are for convenience only, do not form a part of this Agreement and shall not be used in any way to construe or interpret this Agreement.

11.9 Non-Waiver. Any waiver of the terms and conditions hereof must be explicitly in writing. The waiver by either of the parties of any breach of any provision hereof by the other shall not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

11.10 Severability. Should any section, or portion thereof, of this Agreement be held invalid by reason of any law, statute or regulation existing now or in the future in any jurisdiction by any court of competent authority or by a legally enforceable directive of any governmental body, such section or portion thereof shall be validly reformed so as to approximate the intent of the parties as nearly as possible and, if unreformable, shall be deemed divisible and deleted with respect to such jurisdiction, but the Agreement shall not otherwise be affected.

11.11 Independent Contractors. The relationship of Vivus and Spolana established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create any other relationship between Vivus and Spolana. Neither party shall have any right, power or authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other.

11.12 Trademarks. Vivus, in its sole discretion, shall select the trademarks, trade names and trade dresses to be used in connection with the Product and all such trademarks, trade names and trade dresses shall be and become the exclusive property of Vivus. Spolana shall use said trademarks, trade names and trade dresses for the sole purpose of manufacturing the Product for supply to Vivus and at no time shall adopt any trademark, trade name or trade dress that may be confusingly similar therewith. Spolana shall acquire no rights in and to any trademarks, trade names and trade dresses selected by Vivus under this Section 11.12.

11.13 Entire Agreement. The terms and provisions contained in the Agreement, including the Exhibits hereto, constitute the entire agreement between the parties and shall supersede all previous communications, representations, agreements or understandings, either oral or written, between the parties with respect to the subject matter hereof. Notwithstanding the foregoing, neither party waives any rights it may have under the Supply Agreement. No agreement or understanding varying or extending this Agreement shall be binding upon either party hereto, unless set forth in a writing which specifically refers to the Agreement signed by duly authorized officers or



representatives of the respective parties, and the provisions hereof not specifically amended thereby shall remain in full force and effect.

11.14 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

VIVUS, INC.

SPOLANA CHEMICAL WORKS, A.S.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

## EXHIBIT A

[\*]

\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT B  
INITIAL FORECAST

MANUFACTURE and SUPPLY AGREEMENT

[\*]

\*Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.