

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

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FILER

Intra-Cellular Therapies, Inc.

CIK: [1567514](#) | IRS No.: [364742850](#) | State of Incorporation: **DE** | Fiscal Year End: **1231**
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **January 4, 2022**

Intra-Cellular Therapies, Inc.

(Exact name of registrant as specified in its charter)

Commission File Number: **001-36274**

Delaware
(State or other jurisdiction
of incorporation)

36-4742850
(IRS Employer
Identification No.)

430 East 29th Street
New York, NY 10016
(Address of principal executive offices, including zip code)

(646) 440-9333
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	ITCI	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Explanatory Note

Intra-Cellular Therapies, Inc. (the “Company”) is filing this Form 8-K to transition an exhibit previously filed with the Securities and Exchange Commission (the “SEC”) to the requirements set forth in Item 601(b) of Regulation S-K permitting registrants to omit confidential information from material contracts filed pursuant to Item 601(b)(10) without the need to submit a confidential treatment request to the SEC. The purpose of this filing is to attach and refile with the SEC a redacted version of the Supply Agreement dated as of January 4, 2017 by and between Siegfried Evionnaz SA and ITI Limited, originally filed with the Company’s Annual Report on Form 10-K on March 1, 2017 (Exhibit 10.1 hereto). This agreement was subject to an order granting confidential treatment by the SEC for certain confidential information contained therein. The order was issued on March 31, 2017 and expired on January 4, 2022. The confidential information omitted from Exhibit 10.1 is both (i) not material and (ii) is the type of information that the Company treats as private or confidential.

ITEM 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit Number	Description
10.1	Supply Agreement dated as of January 4, 2017 by and between Siegfried Evionnaz SA and ITI Limited
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

INTRA-CELLULAR THERAPIES, INC.

By: /s/ Lawrence J. Hinline

Lawrence J. Hinline
Senior Vice President of Finance, Chief
Financial Officer, Treasurer and Assistant
Secretary

Date: January 5, 2022

SUPPLY AGREEMENT

This Agreement is made as of January 4, 2017 (the Effective Date) between

Siegfried Evionnaz SA

Route du Simplon 1, 36, 1902 Evionnaz, Switzerland

(Siegfried)

and

ITI Limited

Clarendon House, 2 Church Street, PO Box HM 666, Hamilton, HM CX, Bermuda

(ITI)

Recitals

- A. ITI engages in the business of research, development and commercialization of pharmaceutical compounds and products;
- B. Siegfried has substantial expertise in process development, scale-up and manufacturing of active pharmaceutical ingredients and drug products; and
- C. ITI and Siegfried desire to enter into this Agreement to provide the terms and conditions upon which Siegfried shall manufacture Product in commercial quantities after the completion of a validation campaign.

Now, therefore, in consideration of the foregoing recitals and mutual covenants, agreements, representations, warranties and obligations expressed herein, and intending to be legally bound hereby, the Parties agree as follows:

1. Definitions

Unless elsewhere defined in this Agreement, each of the capitalized terms used in this Agreement (other than the names of the Parties and the headings of the Sections) shall have the meanings indicated below. Such meanings shall apply equally to all forms of such terms, including singular and plural forms, unless otherwise clearly indicated.

- 1.1 **Act** shall mean the United States Food, Drug and Cosmetic Act of 1938, including any amendments thereto and all rules and regulations promulgated thereunder.

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Portions of this Exhibit, indicated by the mark “[*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

- 1.2 **Affiliate** shall mean with respect to any Party any person or entity controlling, controlled by, or under common control with a Party at any time during the term of this Agreement. For purposes of this definition, the term **control** shall mean the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting stock, by contract or otherwise. In the case of a corporation, the term Control shall mean the direct or indirect ownership of at least fifty per cent (50%) of the outstanding voting stock.
- 1.3 **Agreement** shall mean this Supply Agreement including its Annexes (and appendices, if applicable), as amended from time to time according to the terms and conditions of this Agreement.
- 1.4 **API** shall mean active pharmaceutical ingredient.
- 1.5 **Applicable Laws** means, with respect to ITI, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated, and as amended from time to time, of each jurisdiction of the Territory (in which the Product is manufactured, marketed, distributed, used or sold); and with respect to Siegfried, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated, and as amended from time to time, of the jurisdiction in which it performs the Services, and cGMP Regulations.
- 1.6 **Business Day** shall mean a day (not being a Saturday or Sunday) on which banks are open for business in New York, U.S.A. and Zurich, Switzerland.
- 1.7 **cGMP Regulations** shall mean the regulations defining and regulating current Good Manufacturing Practices (GMP) as contained from time to time in the Act and related regulations, or any successor laws or regulations governing the manufacture, handling, storage and control of the Product, including without limitations, regulations promulgated by the FDA under 21 C.F.R. §§ 210, 211, EC Directive 2003/94/EC, and the World Health Organization (WHO) "Guide to good manufacturing practice (GMP) requirements, and the International Conference on Harmonization (ICH), Guidance for Industry Q7A GMP Guidance for APIs.
- 1.8 **Confidential Information** shall mean any information of whatever kind, and all tangible and intangible embodiments, and oral disclosures thereof, of any kind whatsoever, which has been or will be disclosed by one Party (**Disclosing Party**) to the other Party (**Receiving Party**) in connection with this Agreement, and which is confidential or proprietary to the Disclosing Party or an Affiliate thereof, including, without limitation, for ITI, any and all information pertaining to the Product and the Specifications, and for both Parties information which relates to the business of such Party, including without limitation business plans, strategies, operations, policies, procedures, pricing, techniques, technical and scientific information, accounts, marketing plans, financial plans and status, and personnel of either Party, that is designated or marked at the time

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of the disclosure as confidential or proprietary, or disclosed or made available under circumstances under which a reasonable person would understand the information to be confidential or proprietary, including without limitation which are obtained by Receiving Party through inspection or observation of Disclosing Party' s, or its Affiliates' , property or facilities (whether in writing, or in oral, graphic, electronic or any other form).

- 1.9 **Consigned Materials** shall mean the samples and materials, if any, that are to be provided to Siegfried by or on behalf of ITI for the Manufacture of the Product, as listed in ANNEX C.
- 1.10 **EMA** shall mean the European Medicines Agency or any successor entity.
- 1.11 **End Market Product** shall mean any pharmaceutical product containing the Product in the finished packed form for marketing, distribution and sale in the Territory.
- 1.12 **Facility** means Siegfried' s manufacturing facility located at [***] or such other manufacturing facility of Siegfried or its Affiliates as agreed between the Parties.
- 1.13 **FDA** shall mean the United States Food and Drug Administration or any successor entity.
- 1.14 **Governmental Authority** shall mean any governmental authority or authorities which are responsible for approving the conduct of clinical trials, or the manufacture, marketing, use and sale of pharmaceutical products in their respective markets of the Territory, such as the FDA and the EMA.
- 1.15 **Hidden Defects** shall mean a failure of Product to conform to the Specifications, such failure not being discoverable upon reasonable physical inspection or standard testing upon receipt of Product.
- 1.16 **Improvement** shall mean any result, data, documentation, invention, know-how, improvement, modification, adaptation, enhancement or new application to or for any part of the Product or the techniques or processes involved in its manufacture, which is conceived, derived, reduced to practice, made or developed by or for Siegfried in its performance of Services under this Agreement.
- 1.17 **Independent Improvement** shall mean an Improvement which is independent of ITI' s Confidential Information and which is not solely applicable to the Product.
- 1.18 **Intellectual Property Rights** shall mean all inventions, patent applications, patents, registered or unregistered design rights, copyrights, database rights, trademarks, trade names, know-how, trade secrets and other industrial or intellectual property rights of whatever kind.

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- 1.19 **Manufacture/Manufacturing/Manufactured** shall mean all activities with respect to the manufacturing and supply of the Product, including, without limitation, the purchase and incoming inspections, storage and handling of Materials, quality control testing (including in-process, release and stability testing, when applicable), and packaging, release and delivery of Products.
- 1.20 **Master Batch Record** means the document approved in writing by both Parties, and as may be amended from time to time in accordance with this Agreement and the Quality Agreement, specifying or referencing the complete set of formal instructions for the Manufacture of Product, including, but not limited to material descriptions, the formula, processing procedures, and in-process testing specifications, Specifications and packaging and shipping specifications.
- 1.21 **Materials** shall mean Raw Materials and Consigned Materials.
- 1.22 **Order** shall mean a purchase order issued by ITI in accordance with this Agreement.
- 1.23 **Order Confirmation** shall mean a confirmation issued by Siegfried that an Order posted by ITI shall be executed.
- 1.24 **Party/Parties** shall mean either ITI or Siegfried, or both, as the context may require.
- 1.25 **Product** shall mean the API as set out in ANNEX A.
- 1.26 **Quality Agreement** shall mean the signed agreement between ITI and Siegfried which defines the responsibilities of each Party (Delimitation of Pharmaceutical Responsibility) with respect to the practices to be followed to ensure Product quality and compliance under cGMP Regulations, which shall be made part of this Agreement by reference (as such Quality Agreement may be amended from time to time).
- 1.27 **Raw Materials** shall mean all raw and other materials, excluding any Consigned Materials, which are used to Manufacture the Product in accordance with the Requirements and Specifications, as applicable.
- 1.28 **Regulatory Approval** means any approval or authorizations (including supplements and amendments thereof) of any Governmental Authority in each country of the Territory.
- 1.29 **Requirements** means compliance with Applicable Laws, cGMP Regulations, the Quality Agreement and the Master Batch Records.
- 1.30 **Services** means the Manufacture of Product, and all other activities to be performed by Siegfried under this Agreement.

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- 1.31 **Specifications** shall mean the description of technical requirements the Product has to conform to, as set out in detail in ANNEX A.
- 1.32 **Territory** shall mean the United States of America (with its territories, possessions, and protectorates, such as the Commonwealth of Puerto Rico), Bermuda, the member states of the European Union and/or European Economic Area (EU/EEA), Switzerland, Japan and any other country, which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

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2. Manufacture, Purchase and Supply of Products

- 2.1 This Agreement covers the purchase, Manufacture, and supply of commercial quantities of Product after completion of a validation campaign during the term of the Agreement as set forth in Section 10 below.
- 2.2 ITI shall purchase the Product from Siegfried in accordance with the purchase requirements and all other commercial terms set forth in ANNEX B.
- 2.3 Siegfried shall Manufacture the Product in accordance with the Requirements and solely at the Facility. Siegfried may not deviate from the Requirements without ITI' s prior written consent in each instance. Siegfried shall notify ITI of any proposed changes to the Specifications and/or Master Batch Record in accordance with the Quality Agreement, and may not implement such change without ITI' s prior written consent.
- 2.4 Promptly after the Effective Date and thereafter at least [***] prior to the start of each month, ITI shall submit to Siegfried an [***] rolling forecast covering ITI' s anticipated requirements of Product during such period (each, a **Forecast**). The first twelve (12) months of each such Forecast shall be binding and [***]. ITI acknowledges that Siegfried will rely on the accuracy of ITI' s Forecasts in planning its acquisitions of Raw Materials. If at any time ITI finds that a Forecast is inaccurate, ITI shall inform Siegfried without delay and submit a modified forecast for the period in question.
- 2.5 ITI shall make all purchases hereunder by submitting Orders to Siegfried regarding ITI' s requirements of Product in accordance with Section 2.4 above. Each such Order shall be in writing and shall specify the (i) Product ordered, (ii) quantity ordered, (iii) price, (iv) delivery location(s) pursuant to ANNEX B, and (v) delivery date.
- 2.6 In accordance with Sections 2.3 and 2.5, ITI shall purchase [***] of the corresponding Forecast by respective Orders and Siegfried shall execute and fulfill such Orders which [***] of such Forecast. Orders [***] of the corresponding Forecast shall be discussed between the Parties, and Siegfried will use commercially reasonable efforts to fulfill such excess, but are only binding upon confirmation by Siegfried. ITI hereby accepts [***].
- 2.7 Within [***] from the date of the receipt of an Order from ITI, Siegfried shall confirm to ITI by way of an Order Confirmation that it will meet ITI' s quantity requirements in accordance with the delivery date(s), whereupon the Order shall be confirmed, final, and binding on the Parties. Siegfried may not reject any Order that is consistent with the terms of Sections 2 and 3.

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- 2.8 Without limiting ITI' s remedies or Siegfried' s obligations hereunder, Siegfried shall promptly notify ITI in writing of any anticipated delay or of any circumstance(s) rendering it unable to Manufacture and/or supply Product in accordance with the delivery date(s) and the estimated duration of such delay/circumstance(s) and the Parties shall discuss in good faith about the steps to be taken to overcome such delay. Siegfried will keep ITI regularly informed of the progress of such Orders.
- 2.9 The Product shall be delivered from Siegfried to ITI according to the commercial terms and at the price as set out in ANNEX B. ITI assumes all responsibilities and liability arising out of the transport, storage, handling and use of the Product after delivery by Siegfried to ITI.
- 2.10 ITI acknowledges and agrees that Siegfried will Manufacture and supply the Product in volumes to fulfil all Orders specified in Section 2.5 to the extent that such volumes in any contract year do not exceed the capacity of [***] based on the validated batch size of [***]/batch.

3. Materials

- 3.1 Siegfried shall order sufficient quantities of all Raw Materials from its selected and qualified vendors to manufacture and supply Product in accordance with ANNEX B and this Agreement. [***], where such change is agreed by the Parties in writing.
- 3.2 If ITI designates certain vendors in accordance with and if set forth in the Quality Agreement, then Siegfried shall obtain respective Raw Material(s) only from such designated vendors. [***]. In no event shall Siegfried be liable or responsible for any acts or omissions of such designated vendor, including without limitation, any delayed delivery, delivery of non-conforming Raw Material or other supply failure.
- 3.3 ITI shall supply Consigned Materials in sufficient quantities and of good quality as necessary to enable Siegfried to perform all Services, manufacture and supply Product in accordance with the Requirements, at ITI' s costs and expenses. At ITI' s option, the Consigned Materials may be delivered directly from ITI' s vendor to Siegfried at the vendor' s or ITI' s costs and expenses.
- 3.4 Consigned Materials shall be delivered to Siegfried by the delivery date or timeframe specified in the ANNEX B. In no event shall Siegfried be liable or responsible for any acts or omissions caused by third party or ITI activities under Section 3.2 and/or 3.4, including without limitation, any delayed delivery, delivery of non-conforming Consigned Materials or other supply failure.
- 3.5 Siegfried agrees that Consigned Materials shall: (i) be used solely for the purpose of Manufacture or performing other services under this Agreement; (ii) be used in compliance with all Applicable Laws; and (iii) not be transferred to any third party, except to any permitted subcontractor of Siegfried, or except as provided for under a specific Work Order.

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- 3.6 Siegfried agrees to use all reasonable and appropriate precautions in handling and storing Consigned Materials and to inform ITI promptly in writing of any adverse effects experienced by persons handling Consigned Materials.
- 3.7 ITI shall retain all right, title and interest in and to all Consigned Material delivered to Siegfried and shall insure the Consigned Materials against loss and damage. Siegfried shall only be liable for any loss of or damage to Consigned Material after delivery to Siegfried if such loss or damage was caused by Siegfried' s [***]. Following receipt of Consigned Materials, Siegfried shall inspect such items, in accordance with the procedures set forth in the Quality Agreement and/or the Master Batch Record, to verify their quantity and quality, and shall give ITI, as soon as reasonably possible, notice of any quantity or quality shortcoming. Any Consigned Materials not rejected by Siegfried within such time period shall be deemed accepted, unless they have Hidden Defects. In case the Consigned Materials are rejected by Siegfried, Siegfried shall follow ITI' s written instructions in respect of return or disposal of defective Consigned Materials, at ITI' s costs and risks. Upon delivery of any Order, Siegfried shall notify ITI of any excess Product or Consigned Materials in its possession, and unless ITI directs otherwise within [***] after receipt of such notice, Siegfried shall store all such material at its facility at an agreed rate.
- 3.8 Siegfried may subcontract its Manufacturing activities (including to any Affiliate) only upon ITI' s prior written consent. If ITI gives its consent (in its sole reasonable discretion) Siegfried will execute a subcontractor agreement with the third party subcontractor or Affiliate that contains terms at least as protective of ITI, its rights under this Agreement, and its Intellectual Property Rights as the terms in this Agreement, including, without limitation terms that, at a minimum, provide for compliance by the subcontractor with Applicable Laws, provide for ownership and allocation of Intellectual Property Rights in accordance with Section 9, and for obligations of confidentiality of information, record-keeping, access, and rights to data that are consistent with the intent and terms of this Agreement. Siegfried shall remain liable at all times for the performance of any of its obligations hereunder that it delegates to a subcontractor, and for each such subcontractor' s actions and omissions.

4. Product Inspection

- 4.1 Siegfried shall take reasonable precautions and institute procedures to ensure that the Manufacture of Product is and remains fully compliant with the Requirements.

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- 4.2 Upon receipt of the Product, ITI shall examine the Product within [***] in order to determine compliance with the Specifications. If, in ITI' s opinion, the Product delivered does not comply with the Specifications, then ITI shall notify Siegfried in writing thereof. If ITI does not notify Siegfried within [***] after receipt of the Product by ITI, then the Product is deemed accepted. ITI retains the right to reject the Product for a period of [***] after delivery in case of Hidden Defects, provided that ITI notifies Siegfried in writing within [***] of discovering the Hidden Defect. Any claims by ITI regarding Product delivered shall specify in reasonable detail the nature and basis for the claim and cite Siegfried' s relevant batch numbers or other information to enable specific identification of the Product involved. If ITI rejects any Product under this Section, then it may reject the entire batch from which such Product was derived. Siegfried shall promptly review any written claim made by ITI regarding the quality of the Product and promptly provide ITI with the results of such review. If such review and testing by Siegfried, using reasonable and documented methods in accordance with its standard operating procedures, confirms that the identified Product did not meet the Specifications, then the Parties shall proceed according to Section 12.1. ITI shall, at Siegfried' s expense, dispose or deliver the nonconforming Product to such destination as Siegfried shall direct in writing, provided that such directions are in compliance with applicable environmental laws and regulations. ITI shall not knowingly use or dispose of any Product that does not, or shall not use or dispose of any Product of which ITI claims that it does not, conform to the Specifications without Siegfried' s prior written consent. Siegfried may not make rejected Product available to any third party. ITI need not pay for any Product that it rejects until the Parties establish whether or not the rejection was proper as described in this Section 4.2 and in Section 4.3.
- 4.3 If Siegfried, using reasonable and documented methods in accordance with its standard operating procedures, does not agree with ITI that a delivered quantity of Product does not conform to the Specifications, the Parties shall have the batch in dispute tested and further analyzed by an independent testing laboratory selected by agreement between the Parties. The decision of the independent testing laboratory shall be deemed final as to any dispute over Product quality. Should the laboratory' s testing determine that the delivered Product does not conform to the Specifications, then Siegfried shall bear all costs for the independent laboratory testing, ITI shall have the right to reject such batch, Siegfried' s disposition of rejected Products shall be made in accordance with the Quality Agreement and the Parties shall proceed according to Section 12.1. However, in case of wrongful rejection of Product by ITI, then ITI shall bear the expenses of the laboratory testing and all costs incurred due to the wrongful rejection of the Product. Siegfried' s disposition of rejected Products must be made in accordance with the Quality Agreement or ITI' s instructions.
- 4.4 In the event a batch is rightfully rejected by ITI pursuant to Section 4.2 or by the independent testing laboratory pursuant to Section 4.3, upon request of ITI, Siegfried shall perform and complete an investigation with root cause analysis and corrective

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actions determined to prevent further batch rejections in accordance with the Quality Agreement, which corrective actions and sharing of costs shall be agreed to in writing by the Parties. Siegfried shall perform such investigations, root cause analysis and corrective actions reasonably diligently and expeditiously.

- 4.5 Subject to the terms of the Quality Agreement, Siegfried shall be responsible for release testing of Product, and shall release each batch to ITI as set forth in the Master Batch Record. In connection with release of a batch of Product, Siegfried shall provide to ITI promptly in response to its request [***].

5. Audits, Notification and Recall

- 5.1 Siegfried shall keep and maintain true, complete and accurate records, notes, accounts, reports and other records and materials with respect to all Manufacturing activities required by cGMP Regulations (“**Records**”). Records shall be maintained in accordance with Applicable Laws and shall be kept in a secure area reasonably protected from fire, theft and destruction. Siegfried shall store all Records during the term of this Agreement and for [***] thereafter, or longer if required pursuant to the Quality Agreement or in accordance with Applicable Laws.
- 5.2 ITI has the right to review and inspect Records, other than financial records, during the term of this Agreement and for [***] thereafter. During the term of this Agreement, ITI may carry out compliance and cGMP Regulation audits on the site(s) of Manufacture up to [***] during the term of this Agreement, or more frequently for cause. Access shall be granted at mutually agreed dates, during normal business hours only and upon [***] prior written notice or sooner for cause. If necessary for such audits, Siegfried may grant ITI reasonable access to Siegfried’s personnel relevant to Manufacture of the Product. ITI shall comply with all of Siegfried’s on-site policies regarding, safety, health, data protection, confidentiality and the like which Siegfried, in its sole reasonable discretion, provides to ITI in writing. From time to time throughout each calendar year this Agreement is in place, ITI may request, as a matter of oversight and direction, to send [***] who are employees of ITI to the Facility to observe the Manufacture of Product, the conditions of which shall be discussed in good faith between the Parties, and Siegfried shall use its reasonably commercial endeavors to accommodate ITI’s request. If circumstances arise that may adversely affect the quality of Product, Siegfried shall immediately notify ITI thereof in accordance with the Quality Agreement and the Parties may agree on ITI’s reasonable access to relevant Siegfried areas and records.
- 5.3 Siegfried shall permit any Governmental Authority to inspect relevant facilities, equipment and records at their request and shall resolve any issues raised by a Governmental Authority. Siegfried shall immediately notify ITI of any inquiry, audit or inspection by any Governmental Authority if such audit or inspection relates to a

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_____ Siegfried	_____ ITI

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Product, and ITI shall have the right to be present at such audit or inspection [***]. Siegfried shall promptly provide to ITI all correspondence and reports that it receives from a Governmental Authority directly relating to a Product, and shall give ITI the opportunity, if reasonably possible, to comment on any responses by Siegfried.

- 5.4 Each Party shall notify the other in writing within [***] of receipt of a complaint related to Product, or within any other timeline set forth in the Quality Agreement. Complaints related to Manufacturing issues with respect to Product will be fully and promptly investigated by Siegfried, and an investigation report will be prepared and sent to ITI within [***] of receipt of the complaint or of the notification of such complaint by ITI, or within any other timeline set forth in the Quality Agreement. ITI, and not Siegfried, will correspond with complainants on all complaints associated with Products. Siegfried shall maintain such traceability records as are sufficient and as may be necessary to permit a recall or field correction of any Product
- 5.5 In the event either Party believes it may be necessary to conduct a recall or other similar action with respect to the Product (each a **Recall**), the Parties shall consult with each other as to how best to proceed. If any Government Authority issues a directive, order or written request that any Product be Recalled, or ITI determines in its reasonable discretion that any Product should be Recalled, Siegfried will cooperate with ITI with respect to such Recall as requested by ITI, and any such cooperation will be at ITI' s expense except as provided below. If any Recall results from Siegfried' s failure to Manufacture Products in accordance with the Requirements (unless such failure arises from defects in Consigned Materials or in Raw Materials provided by vendors designated by ITI), Siegfried shall promptly, at ITI' s election and without limiting its other remedies, either: (i) refund the invoice price for such defective Product; (ii) offset the invoice price for such defective Product against other amounts due to Siegfried hereunder; or (iii) replace such Product with conforming Product without any further cost to ITI. To the extent a Recall results from negligence by Siegfried to Manufacture Product in accordance with the Requirements (unless such failure arises from defects in Consigned Materials or in Raw Materials provided by vendors designated by ITI), Siegfried shall also be responsible for the documented out-of-pocket expenses of such Recall incurred by ITI (as well as its own expenses in cooperating with ITI as required under this Agreement), as subject to Section 12.7. In all other circumstances, Recalls shall be made at ITI' s cost and expense. Under no circumstances shall either Party be prohibited hereunder from taking any action that it is required to take by Applicable Law.

6. Compensation and Terms of Payment

- 6.1 In consideration for the Manufacture and supply of the Product under the terms of this Agreement, ITI shall pay Siegfried the prices specified in, and in accordance with the payment terms set forth in ANNEX B. ITI hereby acknowledges and agrees that after the validation campaign the Parties will either confirm or adjust (on commercially reasonable terms) the price indications set forth in ANNEX B.

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_____ Siegfried	_____ ITI

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- 6.2 [***]. In case the total amount of an Order exceeds this limit, then Siegfried shall have the right to demand a reasonable prepayment on a lump-sum basis.
- 6.3 All pricing, payments, credits, allowances or other monetary adjustments under this Agreement shall be in Swiss Francs (CHF), unless otherwise agreed in writing. If provided for in ANNEX B, the Parties shall adjust the price (up or down) upon written agreement with regard to (i) documented Raw Material price increases, (ii) changes in relevant indices, (iii) exchange rate variations, and (iv) as otherwise set forth in ANNEX B, subject to this Section 6.
- 6.4 In case any undisputed invoices are not paid in accordance with such terms of payment, then ITI shall pay interest at an annual rate of [***]% on the amount of the late sum (from original due date until the late sum is paid).
- 6.5 ITI shall pay any and all taxes, duties, assessments and other charges and expenses imposed by any Governmental Authority in connection with delivery of the Product and the other services provided to ITI and payments made by ITI under this Agreement.
- 6.6 All payments made to Siegfried pursuant to this Agreement shall be (i) made by wire transfer and (ii) are non-refundable and the expiration or termination of this Agreement shall not relieve ITI of its obligation to pay any outstanding balances due.
- 6.7 Shortage of Supply: In the event of any shortage in the availability or supply of Raw Materials that Siegfried orders under section 3.1 of this Agreement and utilizes both in connection with the Manufacture of the Product and in connection with the production of other pharmaceutical products for third parties, Siegfried shall use commercially reasonable efforts to allocate equitably such Raw Materials among ITI and such third parties.

7. Regulatory Affairs

- 7.1 ITI shall be solely responsible for all regulatory filings for the Product and End Market Product. All information, documents and updates with regard to the Manufacture of Product which are in the possession of Siegfried and required by any Governmental Authority shall, as reasonably requested by ITI in connection with such submissions and filings, be provided by Siegfried, at ITI' s cost, to ITI or to the Governmental Authority, if requested by ITI.
- 7.2 Siegfried shall further provide ITI, at ITI' s requests, costs and expenses, with reasonable assistance in preparing or reviewing regulatory submissions or formulating responses to

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any questions and/or inquiries (i.e., deficiency letters) with respect to the above submissions. Without limiting the foregoing, Siegfried shall provide to ITI directly all information as ITI may reasonably require for purposes of applying for and maintaining Regulatory Approval, and Siegfried hereby allows ITI to provide such information to a Governmental Authority as necessary to support any application for authorization to conduct clinical trials or Regulatory Approval of a Product or in response to the requests or requirements of such Governmental Authority, provided however that ITI shall take appropriate steps to limit the disclosure of Siegfried's Confidential Information to the extent necessary to accomplish the purpose. ITI shall be responsible for preparing all submissions to Governmental Authorities with respect to the Product. Siegfried will assist ITI with all regulatory matters relating to Product, at ITI's request and expense. The parties intend and commit to cooperate to allow each party to satisfy its regulatory obligations under Applicable Laws relating to performance of this Agreement.

- 7.3 ITI shall provide, and Siegfried shall review those portions of ITI's proposed regulatory submissions relating to Siegfried's Manufacturing procedures or otherwise related to Siegfried's key obligations hereunder before the submissions are filed with relevant Governmental Authorities and ITI shall consider Siegfried's comments relating to the accuracy thereto in good faith.
- 7.4 The Parties acknowledge that the ultimate decision of whether any End Market Product will be approved for marketing and sale rests with the Governmental Authorities of the respective market in the Territory and that Siegfried shall not be liable for the failure of the Governmental Authorities to issue such approval. Accordingly, Siegfried makes no warranties or does not in any way guarantee that the Governmental Authorities approves any regulatory filing and any or all of the End Market Products for marketing and sale in any given market in the Territory for the treatment of any or all of the indications listed in any regulatory filing.

8. Confidential Information

- 8.1 Each Receiving Party agrees to retain in strict confidence any Confidential Information of the Disclosing Party (or its Affiliate), whether disclosed prior to, or after the Effective Date or the date of prior agreements and not to use any such Confidential Information for any purpose except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and not to disclose, divulge or otherwise communicate any such Confidential Information to any third party.
- 8.2 The Receiving Party may disclose Confidential Information of the Disclosing Party to the Receiving Party's (and its Affiliate's) officers, directors, employees, agents, consultants, licensees, representatives or (for Siegfried, permitted) subcontractors (each an **Entitled Person**), who, in each case, (i) need to know such information for purposes of the

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_____ Siegfried	_____ ITI

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implementation and performance by the Receiving Party of this Agreement, and (iii) are subject to confidentiality restrictions covering the Confidential Information that are at least as stringent as those contained in this Section 8. The Receiving Party is liable and responsible for such Entitled Persons' compliance with the terms of this Section 8.

- 8.3 The provisions of this Section 8 shall not apply to any Confidential Information disclosed hereunder which (a) was independently developed or known by the Receiving Party prior to its disclosure to the Receiving Party by the Disclosing Party, as evidenced by the Receiving Party's written or electronic records kept in the ordinary course of its business; or (b) was before or after the date of such disclosure in the public domain, other than through the Receiving Party's fault or breach; or (c) is lawfully disclosed to the Receiving Party by an independent, unaffiliated third party rightfully in possession of the Confidential Information and not under any confidentiality obligation towards the Disclosing Party with regard to such Confidential Information. The fact that any portion of the Confidential Information may be subject to one of the foregoing exceptions (a) through (c) shall not automatically exclude any combination of Confidential Information from protection under this Agreement unless the entirety of such Confidential Information also falls under the same exception(s). Specific information disclosed as part of the Confidential Information shall not be deemed to be in the public domain or in prior possession of the Receiving Party merely because it is included in more general information in the public domain or in the prior possession of the Receiving Party.
- 8.4 The Receiving Party may disclose the Disclosing Party's Confidential Information to the extent such Confidential Information is required to be disclosed by the Receiving Party to the officials of a Governmental Authority or to comply with Applicable Laws, to defend or prosecute litigation, or to comply with judicial orders or valid subpoenas, provided that the Receiving Party provides prior written notice of such intended disclosure to the Disclosing Party and takes reasonable and lawful actions to avoid and/or minimize the degree of such disclosure, and reasonably assists the Disclosing Party in its efforts (if any) to oppose such disclosure. The burden of proof of the foregoing exceptions shall lie with the Receiving Party.
- 8.5 Except as otherwise provided for in this Agreement, nothing herein shall be construed as giving either Party any right, title or interest in or ownership of the Confidential Information of the other Party.
- 8.6 The Parties acknowledge that any breach of this Section 8 will cause irreparable harm and damage for which monetary damages may be difficult to ascertain, or may not be an adequate remedy, and that the non-breaching Party shall be entitled to specific performance or injunctive relief to enforce this Section 8 or to prevent a breach of this Section 8, in addition to whatever remedies such Party may otherwise be entitled to at law or in equity.

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8.7 Upon termination or expiration of this Agreement, or at any other time during the term of the Agreement upon the other Party' s written request, provided that it does not prevent the Receiving Party from performing its obligations under this Agreement, each Party shall immediately deliver to the other Party (and cause any of its Entitled Persons to so deliver), at such Party' s expense, all Confidential Information of the other Party in such Party' s possession or control, including without limitation any and all copies, duplications, summaries and/or notes thereof or derived thereof, regardless of the format, and Siegfried shall return to ITI all remaining samples of Product, provided however, that both Parties may keep original documents, copies and samples as required by law or for archival purposes (all of which shall continue to be subject to the terms of this Section 8).

9. Intellectual Property

9.1 Subject to Section 9.5, and unless otherwise required by law or specified in writing, the results of the Manufacture performed pursuant to and during the term of this Agreement, including, but not limited to, any Intellectual Property Right(s) arising out of any Improvements (other than an Independent Improvement) shall be the property of ITI and all rights, title and interest therein shall be vested in ITI. Siegfried shall have no responsibility for prosecuting, maintaining and enforcing any patents or other Intellectual Property Rights that ITI obtains pursuant to this Agreement.

9.2 Siegfried shall assign and hereby irrevocably assigns to ITI all title and interest Siegfried and its Affiliates and its permitted subcontractors may have in any Intellectual Property Right(s) arising out of any Improvements (other than an Independent Improvement).

9.3 ITI shall have the sole right to file and seek protection for any Intellectual Property Right(s) arising out of any Improvements (other than an Independent Improvement). To the extent that ITI deems it reasonable to seek protection for, ITI shall bear the costs (including, but not limited to attorney' s fees) and the responsibility associated with developing, applying for, and maintaining such protection as may be granted. In the event ITI decides to file and prosecute patent applications on any Improvement (other than an Independent Improvement), Siegfried shall provide ITI with reasonable assistance to obtain and defend such patents at ITI' s costs and expenses.

9.4 During the term of this Agreement and for a period of [***] thereafter, upon request by ITI, and at ITI' s expense, Siegfried shall promptly execute, acknowledge and deliver any papers reasonably deemed necessary by ITI to document, protect, or otherwise perfect such rights of ITI, including, without limitation, all documents necessary to obtain or perfect any protection of Intellectual Property Rights and/or to effect an assignment of ownership of the same to ITI, at ITI' s cost and expenses.

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_____ Siegfried	_____ ITI

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9.5 All rights related to any Independent Improvements shall be the sole property of Siegfried. Upon ITI's request, Siegfried shall grant and hereby grants ITI a non-exclusive, worldwide, irrevocable, royalty-free license to use Independent Improvements to the extent that, and limited to, the manufacturing, sale, commercialization or any other use of the Product is dependent upon such license.

10. Term and Termination

10.1 This Agreement shall become effective on the Effective Date and, unless earlier terminated in accordance with this Section 10, shall continue in full force and effect for five (5) years.

10.2 Either Party may terminate the Agreement immediately, [***] after becoming aware of such event, by providing written notice to the other Party upon the occurrence of any of the following events:

- (a) the liquidation or dissolution of the other Party, or the commencement of insolvency procedures or any proceeding under any bankruptcy, insolvency or moratorium law, or any other law or laws for the relief of debtors which proceeding is not dismissed within ninety (90) days, or the appointment of any receiver, trustee or assignee to take possession of the properties of the other Party; or
- (b) the cessation of all or substantially all of the other Party's business operations.

10.3 If a Party breaches a material term or condition of this Agreement, the non-breaching Party shall have the right to terminate this Agreement [***] prior written notice to the other Party unless any such breach is cured within [***]. Termination shall be in addition to all other rights and remedies available to the non-breaching Party at law or in equity.

10.4 Termination of this Agreement shall automatically terminate each outstanding Order unless ITI instructs Siegfried to fulfill such Order. Neither the expiration nor the termination of this Agreement shall relieve the Parties of their rights or obligations incurred prior to such expiration or termination. All provisions that, by their express or implied terms, are meant to survive termination of the Agreement, in particular all rights and obligations set forth in Sections 6 (Compensation and Terms of Payment), 8 (Confidential Information), 9 (Intellectual Property), 10.5, 12 (Liability and Indemnity), 13 (Miscellaneous) and 14 (Applicable Law and Dispute Resolution) shall continue irrespective of such termination.

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11. Representations and Warranties

11.1 Each Party represents and warrants to the other Party:

- (i) that such Party has the legal power, authority and right to enter into this Agreement and to perform its obligations set forth herein,
- (ii) It has and shall have throughout the term of the Agreement the required expertise, permits and approvals to perform its obligations under the Agreement.
- (iii) that this Agreement has been duly executed and delivered by such Party and constitutes the valid and binding obligation of such Party, enforceable against such Party in accordance with its terms,
- (iv) that it is not and will not become a party to any agreement, contract, arrangement or the like with any third party, which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement,
- (v) that it is not and will not be under any obligation or restriction, including, without limitation, pursuant to its charter document(s) or by-laws, which in any way limits or conflicts with its ability to fulfill any of its obligations under this Agreement, and
- (vi) that such Party nor, to its knowledge, any of its employees, affiliates or agents has been (a) debarred or (b) convicted of a crime for which a person can be debarred, under Section 335(a) or 335(b) of the Act, and such Party represents that it has never been and, to its knowledge, none of its employees, affiliates, or agents has ever been (y) threatened to be debarred under the Act or (z) indicted for a crime or otherwise engaged in conduct for which a person can be debarred under the Act; such Party shall promptly notify the other Party if it receives notification of any such debarment, conviction, threat or indictment, in which case the other Party may terminate this Agreement upon notice and without liability.

11.2 Siegfried represents and warrants that:

- (a) Each Product will conform in all respects to the Requirements at the time of its release.
- (b) Each Product, when delivered to ITI, will not be adulterated, misbranded, or otherwise prohibited from sale within the meaning of the Act or Applicable Laws.
- (c) It will procure, maintain and comply with all non-Product-specific licenses, permits, certifications and approvals required under Applicable Law for the Facility, and the portion of Facility used to Manufacture Product.
- (d) It and the Facility are registered with all applicable Regulatory Authorities pursuant to and in accordance with all Applicable Laws.

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Siegfried will provide ITI with prompt written notice of any facts or circumstances (whether occurring prior to or after the Effective Date) which cause any of the representations and warranties contained in this Section 11.2 not to be true, accurate, and complete in any material respect as of the Effective Date or as of any date during the term of this Agreement.

- 11.3 ITI warrants that (i) all quantities of Consigned Material, if any, delivered to Siegfried shall be free from defects and, if applicable, conform to the Specifications of such Consigned Material and (ii) except as set out otherwise in any particular Order, none of the processes, procedures, substances or materials, including any Consigned Material, supplied by ITI or its designee and used by Siegfried in the performance of the Services or the Manufacture of Product infringes or misappropriates or will infringe or misappropriate the Intellectual Property Rights of any third party.

ITI will provide Siegfried with prompt written notice of any facts or circumstances (whether occurring prior to or after the Effective Date) which cause any of the representations and warranties contained in this Section 11.3 not to be true, accurate, and complete in any material respect as of the Effective Date or as of any date during the term of this Agreement.

- 11.4 EXCEPT AS EXPRESSLY WARRANTED IN THIS AGREEMENT, SIEGFRIED AND ITI EXTEND NO OTHER WARRANTIES OR REPRESENTATIONS COVERING THE PRODUCT OR MATERIALS OR RELATING TO THIS AGREEMENT, EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING THE WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. EITHER PARTY'S LIABILITY UNDER THIS AGREEMENT SHALL BE STRICTLY LIMITED TO THE REMEDIES PROVIDED FOR UNDER THIS AGREEMENT.

12. Liability and Indemnity

- 12.1 If Siegfried is unable to meet the agreed time lines regarding the delivery of Product, or in case the Product is rightfully rejected by ITI in accordance with Sections 4.2 or 4.3 of this Agreement, Siegfried shall either (i) promptly deliver the delayed Product, or replace the rejected Product with Product that conforms with the Specifications as soon as possible, in each case at no additional cost to ITI (including reasonable costs of purchasing additional Consigned Materials, if necessary but only to the extent such costs are consistent with the costs usually borne by ITI for the supply of the Consigned Materials) or (ii) if delivery of conforming Product is not possible within reasonable additional time, refund to ITI within [***] all amounts theretofore paid by ITI to Siegfried

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for such late or rejected Product. Except in the case of Siegfried' s gross negligence or willful misconduct such delivery, replacement or refund shall be the only remedy available to ITI in case of late deliveries or Product not conforming to the Specifications.

- 12.2 Siegfried shall indemnify, defend and hold ITI, its directors, officers, employees and Affiliates, harmless against losses, damages, costs and expenses (including reasonable attorneys' fees) alleged by a third party in a claim, action, demand or proceeding brought against any of the foregoing persons or entities to the extent arising out of the breach of any of Siegfried' s obligations, warranties and representations under this Agreement, except to the extent such claims, actions, demands or proceedings are caused by ITI' s negligence or willful misconduct.
- 12.3 ITI shall indemnify, defend and hold Siegfried, its directors, officers, employees and Affiliates harmless against losses, damages, costs and expenses (including reasonable attorneys' fees) alleged by a third party in a claim, action, demand or proceeding brought against any of the foregoing persons or entities to the extent arising out of (i) the breach of any of ITI' s obligations, warranties and representations under this Agreement, (ii) the death of or injury to any person or any damage to property, resulting from side effects, characteristics or defects of the Product and/or End Market Product, or (iii) the infringement of any third party' s Intellectual Property Rights based upon the manufacture, use or sale of the Product; except in each case to the extent such losses are caused by Siegfried' s negligence or willful misconduct.
- 12.4 With respect to any indemnification obligation under this Agreement, the following conditions shall be applicable:
- (a) The Party seeking to be indemnified shall notify the indemnifying Party promptly in writing of any claim which may give rise to an obligation on the part of the indemnifying Party under this Section 12; provided, however, that failure to promptly notify shall not excuse the indemnifying Party from its obligations under this Section unless such failure materially prejudices its ability to defend the claim; and
 - (b) the indemnifying Party shall be allowed to timely take the sole control of the defense of any such action and claim, including all negotiations for the settlement, or compromise of such claim or action at its sole expense; and
 - (c) the Party to be indemnified shall, at the expense of the indemnifying Party, render reasonable assistance, information, co-operation and authority to permit the indemnifying Party to defend such action; and
 - (d) no settlement or compromise shall be binding on the indemnifying Party hereto without its prior written consent.

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The indemnified Party may participate in the defense of the claim with independent counsel at its own expense.

- 12.5 During the term of this Agreement, Siegfried and ITI shall each obtain and carry in full force and effect adequate commercial, general liability insurance as common in the industry, including product liability insurance. Such insurance shall be written by a reputable insurance company and shall be endorsed to include product liability coverage. A Party shall provide another Party on request with a copy of certificates of insurance evidencing the same.
- 12.6 NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES OF THE OTHER PARTY, INCLUDING BUT NOT LIMITED TO CLAIMS BASED ON LOST PROFITS, LOSS OF TIME, LOSS OF OPPORTUNITY OR ANY OTHER ECONOMIC LOSS SUFFERED OR INCURRED AS A RESULT OF THIS AGREEMENT, WHETHER SUCH LOSS OR DAMAGE MAY BE BASED UPON PRINCIPLES OF CONTRACT, WARRANTY, NEGLIGENCE OR OTHER TORT, BREACH OF ANY STATUTORY DUTY, PRINCIPLES OF INDEMNITY OR CONTRIBUTION, OR THE FAILURE OF ANY LIMITED OR EXCLUSIVE REMEDY TO ACHIEVE ITS ESSENTIAL PURPOSE OR OTHERWISE.
- 12.7 [***].
- 12.8 SECTION 12.6 AND SECTION 12.7 SHALL NOT APPLY, FOR DAMAGES CAUSED BY A PARTY' S BREACH OF SECTION 8, DAMAGES CAUSED BY A PARTY' S WILLFUL MISCONDUCT OR GROSS NEGLIGENCE, FOR DEATH OR PERSONAL INJURY RESULTING FROM NEGLIGENCE, OR FOR FRAUD.

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13. Miscellaneous

- 13.1 No set-off. Neither Party shall be entitled to set off any of its rights or obligations under this Agreement against the rights or obligations of another Party without having first obtained the prior written consent of that other Party.
- 13.2 Force Majeure. A Party shall be excused from performing its obligations under this Agreement (other than obligations of payment) to the extent that its performance is delayed or prevented by any unforeseeable cause beyond such Party's reasonable control and not due to such Party's negligence, which may include, but is not limited to, Act of God, fire, explosion, weather, disease, war, insurrection, civil strike, riots, government action power failure or energy shortages (**Force Majeure Event**). Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement that falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability. The prevented Party shall immediately notify the other Party if, by reason of any Force Majeure Event affecting its performance of this Agreement. In the event that such Force Majeure Event prevents or delays a Party's performance for [***] or more, then the non-prevented Party may at any time after the expiration of such period, by written notice to the other Party, either (i) suspend this Agreement for as long as such Force Majeure Event continues to exist, or (ii) terminate this Agreement with immediate effect; in each case without liability for either Party.
- 13.3 Precedence of Agreement. Unless expressly agreed otherwise in writing, the terms outlined in this Agreement shall prevail over any terms and conditions outlined in any Order or Order Confirmation for Product and any general terms and conditions of a Party, and such terms and conditions are hereby expressly excluded. In case of discrepancies between this Agreement and an Annex hereto, the provisions of this Agreement shall prevail. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP Regulations, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.
- 13.4 No assignment. This Agreement is binding upon and shall inure to the benefit of the Parties hereto and their successors and permitted assigns. This Agreement and any rights or obligations hereunder may be assigned or delegated only (i) with the consent of the other Party, not to be unreasonably withheld, conditioned or delayed, or (ii) to the

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successor to all or substantially all of the business of a Party (whether by merger, consolidation, asset transfer or similar transaction) to which this Agreement relates, or (iii) to an Affiliate of such Party, or (iv) by ITI to a successor to the Product. Any other assignment or delegation by either Party without the prior written consent of the other Party is void.

- 13.5 *No waiver.* The failure by either Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute or be construed to constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. A waiver by a Party of any term or condition of this Agreement must be in writing to be effective.
- 13.6 *Independent Parties.* Nothing in this Agreement shall be deemed or construed to constitute or create between the Parties hereto a partnership, joint venture, agency, or other relationship other than as expressly set forth herein. Neither Party shall be responsible for the acts or omissions of the other Party, and neither Party shall have authority to speak for, represent or obligate the other Party in any way without prior written consent of the other Party.
- 13.7 *Entire Agreement.* This Agreement (together with the Quality Agreement) contains the full understanding of the Parties with respect to the subject matter hereof and supersedes all prior understandings and writings relating thereto. No alteration or modification of any of the provisions hereof shall be binding unless made in writing and signed by the Parties.
- 13.8 *Severability.* If any portion of this Agreement is held invalid by a court of competent jurisdiction, such portion shall be deemed to be of no force and effect and this Agreement shall be construed as if such portion had not been included herein, provided however, if the deletion of such provision materially impairs the commercial value of this Agreement to either Party, the Parties shall attempt to renegotiate such provision in good faith. The fact that any provision of this Agreement shall be prohibited or unenforceable in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction. To the extent permitted by applicable law, the Parties to this Agreement waive any provision of law that renders any provision of this Agreement prohibited or unenforceable in any respect.

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- 13.9 *Notices.* Any notice required under this Agreement shall be effective only if it is in writing and (i) delivered in person or (ii) deposited with an internationally recognized overnight courier service, or (iii) dispatched by an acknowledged e-mail (pdf), in which case such notice is to be confirmed by one of the alternate means within five (5) Business Days; in either case any notice is to be addressed to the applicable address set forth below.

if to Siegfried	Siegfried Evionnaz SA Route du Simplon 1, 36, 1902 Evionnaz, Switzerland Attention: [***] Email: [***].
with a copy to:	Siegfried AG Untere Brühlstrasse 4, 4800 Zofingen, Switzerland Legal Department Email: [***]
if to ITI:	ITI Limited Clarendon House, 2 Church Street, PO Box HM 666, Hamilton, HM CX, Bermuda Attention: Michael Halstead Email: [***]

Either Party may change its above addresses, but no such change shall have any effect until the other Party has been properly notified with written notice of the change of the address.

- 13.10 *Compliance with Laws.* Each Party shall comply with all Applicable Laws governing its performance of the terms of this Agreement, including, but not limited to, those relating to health, safety and the environment, fair labor practices, unlawful discrimination, debarment, anti-corruption and anti-bribery laws.
- 13.11 *Hardship.* If during the term of this Agreement, the performance of the Agreement should lead to unreasonable hardship for the one or the other Party, both Parties shall undertake reasonable endeavors to discuss a possible amicable resolution or possible amendment to this Agreement in light of the change in circumstances; provided, however, that neither Party shall have any obligation to amend this Agreement or to waive or modify any of its rights under this Agreement.

14. Applicable Law and Dispute Resolution

- 14.1 This Agreement shall be governed by New Jersey law without regard to its conflict of laws provisions, and the provisions of the UN-Convention regarding Contracts on the International Sale of Goods (Vienna Convention) are expressly excluded.
- 14.2 All disputes arising out of or in connection with this Agreement, including disputes on its conclusion, binding effect, amendment or termination, shall be resolved exclusively by the courts of New Jersey.

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_____ Siegfried	_____ ITI

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List of Annexes

Annex	Description	Content
A	Product, Specifications	Details and technical description of Product
B	Commercial terms	Sales prices and other commercial terms for Product
C	Materials	Description of Raw Materials and Consigned Materials

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In Witness Whereof, the Parties have executed this Agreement as of the Effective Date.

Siegfried Evionnaz SA

/s/ T. Rouillet
T. Rouillet, Quality Director

/s/ N. Chappot
N. Chappot, Head of Finance

Name / function

Name / function

Siegfried Evionnaz SA
Route du Simplon 1, 36
CH - 1902 Evionnaz

ITI Limited

/s/ Sharon Mates
Name / function Share Mates/CEO

/s/ Michael Halstead
Name / function Michael Halstead/
General Counsel

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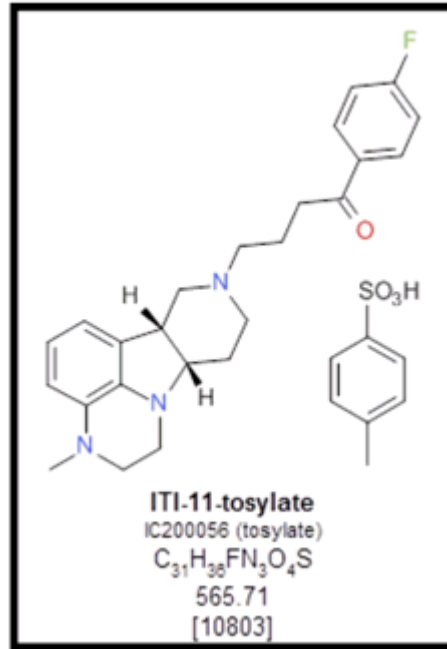
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ANNEX A

Product and Specification

Product: ITI-007



Specification: as set forth in the Quality Agreement

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ANNEX B

Commercial Terms

Scope: Post-validation of ITI-007 (Siegfried Code: ITI-11 tosylate). Manufacture will be carried out in Siegfried' s GMP facility in [***] based on the process as demonstrated in Siegfried' s 2015 campaign.

Delivery terms: FCA Siegfried Manufacturing facility in [***] (as per Incoterms 2010, made a part hereof by reference).

Payment: Undisputed Invoices are payable net without discount within [***] after the receipt of invoice.

Costs:

Post Validation Commercial Production Cost Indications

The following price indications are provided based on the production of ITI-007 using the same yield and batch size validation assumptions as described above.

The cost indications for milling are provided separately as these costs will have to be confirmed following the validation campaign.

Volume	Total (\$/kg)	Manufacturing (\$/kg)	Raws (\$/kg)
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Milling	Total (\$/kg)
[***]	[***]
[***]	[***]

NC	MH
Siegfried	ITI

Portions of this Exhibit, indicated by the mark “[*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’ s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

Future Cost Savings Opportunities

If the volumes grow to exceed [***] a complementary validation can be considered to increase the batch sizes, which would reduce the price and shorten the production lead-times. Two potential options include:

1. [***].

[***]

2. [***].

NC
Siegfried

MH
ITI

Portions of this Exhibit, indicated by the mark “[*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

ANNEX C**Materials****Raw Materials:**

Raw Materials have an overall anticipated lead-time of [***].

Consigned Materials:

The key starting material [***] (Siegfried Code: [***]) will be provided by ITI free of charge and delivered at least [***] prior to the start of the respective campaign.

NC	MH
Siegfried	ITI

Portions of this Exhibit, indicated by the mark “[*],” were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant’s application requesting confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

**Document and Entity
Information**

Jan. 04, 2022

Cover [Abstract]

<u>Amendment Flag</u>	false
<u>Entity Central Index Key</u>	0001567514
<u>Document Type</u>	8-K
<u>Document Period End Date</u>	Jan. 04, 2022
<u>Entity Registrant Name</u>	Intra-Cellular Therapies, Inc.
<u>Entity File Number</u>	001-36274
<u>Entity Incorporation State Country Code</u>	DE
<u>Entity Tax Identification Number</u>	36-4742850
<u>Entity Address, Address Line One</u>	430 East 29th Street
<u>Entity Address, City or Town</u>	New York
<u>Entity Address, State or Province</u>	NY
<u>Entity Address, Postal Zip Code</u>	10016
<u>City Area Code</u>	(646)
<u>Local Phone Number</u>	440-9333
<u>Written Communications</u>	false
<u>Soliciting Material</u>	false
<u>Pre Commencement Tender Offer</u>	false
<u>Pre Commencement Issuer Tender Offer</u>	false
<u>Security 12b Title</u>	Common Stock
<u>Trading Symbol</u>	ITCI
<u>Security Exchange Name</u>	NASDAQ
<u>Entity Emerging Growth Company</u>	false


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